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		PHOTE THE ATTEMPORT OF PROSPEROUS NATION!

FIRST EDITION

TECHNICAL SPECIFICATION FOR SELECTED CAPITAL MEDICAL DEVICE

ETHIOPIAN PHARMACEUTICALS SUPPLY AGENCY IN COLLABORATION WITH ETHIOPIAN MINISTRY OF HEALTH

NOVEMBER, 2019 G.C.

ACKNOWLEDEGEMENT

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In addition, EPSA and EFMOH would like to take this opportunity to appreciate partners for the technical and financial assistance in the development of the document.

FOREWARD

Medical Equipment is essential for effective prevention, diagnosis, treatment & rehabilitation of illnesses. Ethiopian health policy estates that medical equipment which is required for prevention, diagnosis, treatment and rehabilitation of diseases affecting the majority of people have to be identified and classified to respective levels of health service delivery. The achievement of health-related development goals depends upon proper manufacturing, regulation, planning, assessment, acquisition, management, and utilization of quality medical equipment. There is still huge gap in the supply of quality medical equipment. So far, there is no standard medical Equipment technical specification with respect to health facility level. The Agency has been working hard to ensure the continuous availability of quality medical equipment.

As part of its transformation, the Agency has been working on preparing a defined capital Medical Equipment technical specification that will guide its Acquisition. After series of consultative workshop involving relevant experts in each area from health facilities, RHBs, EPHI, EEFDA, development partners and the Agency, first edition of the capital medical Equipment technical specification with respect to health facility hierarchy is now ready for use. This document will serve as useful guides for the production, procurement, distribution and utilization of medical equipment in the country. Users of the capital medical Equipment are expected to consistently use the technical detail used in the document in all communications and transactions they undertake for smooth exchange of information along the supply chain.

This document will be revised every two years in line with advancements in the medical technology, in consultation with stakeholders. We would like to call upon all stakeholders to provide the necessary support for implementation of the specification and continue their support in updating technical specification by forwarding comments and suggestions to the Agency through its website (www.epsa.gov.et) or via mail (P. O. Box 21904, Addis Ababa). We also would like to take this opportunity to thank all who directly or indirectly contributed for the development of this document. We would finally like to express EFMOH's and EPSA's commitment for proper implementation of technical specification to improve appropriate availability of medical Equipment in the country and help our community to benefit from the improvement anticipated after implementation.

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ABBREVIATIONS

EPSA	Ethiopian Pharmaceutical Supply Agency
EFMOH	Ethiopian Federal Minister of Health
EFDA	Ethiopian Food and Drug Authority
UMDNS	Universal Medical Device Nomenclature System
GMDNS	Global Medical Device Nomenclature System
EPHI	Ethiopian Public Health Institute
RHB	Regional Health Bureau
HIS	Health Information System
RIS	Radiology Information System
AED	Automated External defibrillator
LAN	Local Area Network
IEC	International Electro technical committee
NFS	Network Files System
SFD	Spot Film Device
ABC	Automatic Brightness Control
AEC	Automatic Exposure Control
CAD	Computer aided detection
DQE	Detector Quantum Efficiency
DICOM	Digital Imaging and Communications in Medicine
DMPPS	DICOM Modality Performed Procedure Steps
DMWM	DICOM Modality Work list Management
PACS	Picture Archiving and Communication Systems
ADR	Automatic Dose Regulation
PPM	Parts per million
FOV	Field of View
PAT	Parallel acquisition techniques
MIP	Maximum intensity projection
MPR	Multi planar Reconstruction
DTI	Diffusion tensor imaging
MCV	Mean cell volume
MCH	Mean cell hemoglobin
MPV	Mean platelet volume
AFC	Automatic Facial Contour
EGF	Electronic Green Filter
EMSE	Electromagnetic shock waves emitter
CMC	Comprehensive Maintenance Contract

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Introduction

Since its establishment in 2007, Pharmaceutical Supply Agency (EPSA), the lead organization managing the health care supply chain of the country, has been working to ensure the availability, accessibility, and affordability of medical Equipment with appropriate quality, safety, and efficacy. To achieve these goals, EPSA has designed and implemented various innovative strategies.

One of the innovative strategies taken by the Agency in collaboration with EFMOH is defining medical Equipment list to be procured. The agency predefined capital medical Equipment list to focus on procuring, storing and distributing medical equipment that are essential for the provision of health services for majority of the population. This will improve the Agency's performance and result in better availability of this selected Equipment and reduce wastage. Health facilities will be clear on what can be supplied by the Agency on regular basis and look for options to avail products that are not supplied by the Agency.

To advance on the progress, technical working group categorized the predefined capitals medical equipment based on the Ethiopian tier system. For a health facility to deliver their service properly appropriate availability of medical Equipment is needed to be in correct standard at each level. Moreover, the Equipment must have required quality and avail in adequate quantity at all times. One of the tools for ensuring appropriateness of this medical equipment is setting a standard list based on the tier system. The Predefined list is necessary to cover different types of health facilities within the tier system. Therefore, it was determined to be important to assess types of health facilities operating at a time. Accordingly, the predefined capital medical equipment is categorized with respective health tier system; Health center, primary Hospital, General Hospital and Referral/Specialized Hospital in consideration of their service delivery.

After the categorization of capital medical Equipment in consideration with health facility hierarchy; The technical working group developed a template of technical specification for the Capital Medical Equipment based on World Health Organization medical Equipment management guides in order to tracks the necessary information required to define the Equipment clearly.

This template presented to health professional participated in consultative workshop and finally the team comes up with 12 standard features of element by incorporating comments from participant.

Generic name: Name of the medical Equipment as commonly used.

GMDN Name/Code: Name as produced and maintained by the Global Medical Equipment Nomenclature (GMDN) Agency.

Clinical Purpose/Description: A description of the essential clinical or other objective/s associated with the Equipment's utilization.

Technical Specification: The required characteristics and specific/critical functional requirements.

System Configuration Accessories, Spares, Consumables and other Components: Accessories needed (type, number, functional requirements, etc.) for full and proper functioning of the Equipment; Spare parts are likely to be needed in replacing parts of equipment; Consumables (renewable) and disposables (including single-use accessories) to be used with the medical Equipment and other components used keep the equipment utilization.

Operating Environment: Operating temperatures (+10°C to +40°C), resistance to high humidity and/or dust levels (<85%) - in accordance with local/anticipated conditions.

Utility Requirements: National standardpower requirement, water, air, gas and/or oxygen supply.

Standards & Safety Requirements: Related regulations for Equipment in relevant regulatory jurisdiction. Notably ISO Quality Management System: Risk Management System: General requirement for basic electrical safety and essential performance of IEC 60601.

Installation/Training/Commissioning: Manufacturer/supplier to perform installation, safety and operation checks before handover. Acceptance tests to be specified and local clinical and technical staff to verify proper and full functioning of Equipment. Training of users in operation and service is provided.

Warranty/ after sales service: Date of commencement, duration of warranty period, and preventive/curative maintenance support during warranty. Advanced medical Equipment need to make contract/after sales service with the Equipment manufacturer after warranty

Documentation: Operating and service manuals (language in English) including lists of important spares and accessories - with their part numbers and list of equipment and procedures required for calibration and routine maintenance. Documentation must also show recommended procedures for disposal and any probable hazards to the environment and/or community.

Packaging and labeling; Packaging of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Based on these 12 features of element template the agency organized Consultative workshops to develop the draft technical specification of capital medical equipment by Biomedical engineers and other health professionals from FMOH, EFDA, RHBs, EPHI, and Health Facility. To come up with document The Technical specification developing team referred previously floated EPSA tender, EFDA, WHO, Federal Public Procurement Directive and other international regulatory body requirement including expert opinion based on national need. The technical specification disclosed in this document is considered as a reference; professionals working on medical device can updated the technical parameters for the buyer advantage and to make competitive procedure between bidders.

Standardized Technical specifications playan important role inidentification, selection and Procurementofappropriate and costeffective medical Equipment. Standardized technical specifications for medical Equipment have a potential to define what functionality is required from the Equipment by end-user.

This document with capital medical equipment technical specification inconsideration of health facility hierarchy at national level is crucial and timely. The agency come up with this first edition of capital medical equipment technical specification based on health facility hierarchy by continuous support from stakeholders and partners. The document will be officially communicated to FMOH, RHBs, and health facilities for their reference.

The Agency will exert maximum effort to ensure the continuous availability of quality medical equipment and the technical specification will be updated every two years. The Agency will also strengthen its collaboration with all supply chain players to fully realize the goal of developed technical specification.

Base Code	Item Detail	Department	
Mrim-90	1. Generic Name: MRI 1.5 Tesla	Imaging	
	2. GMDN/UMDN Name/Code: 3. Clinical Purpose/Description:		
	MRI Machine is a medical imaging device used in radiology to form Cross Sectional image of the anatomy and physiological processes of the body.		
	4. Technical Specifications:		
	I. MAGNET & GRADIENT SYSTEM:		
	1. Magnet Type : Super conduct		
	2. Magnet Strength: 1.5 Tesla		
	3. Magnet Homogeneity mentioned in relation to 10,20,30,40,45 cm DSV (Diameter of Spherical Volume).		
	4. Automatic in homogeneity correction		
	5. Shielding Type: Active		
	6. Emergency Rundown Control at both Operator Console Room and Gantry room as well as console room Gantry Room to be provided in Gantry.		
	7. Dedicated Helium exhaust system into atmosphere		
	8. The system should be zero helium boil off technology		
	9. Magnet Bore Diameter: not less than 70 cm		
	10. Magnet bore length: 125 - 150cm		
	11. Fringe field: 1/5 Gauss line radius		
	12. Magnet Weight: 3500 Kg approximately		
	13. Emergency quenching		
	II. GRADIENT SYSTEM:		
	1. The true slew rate of 200 T/m/s at true standard configuration gradient strength 44 mT/m simultaneously should be available in each true axis (X, Y, Z) independently, for overall better duty cycle performance of the gradient. (NB: gradient strength configuration should be standard not to be with upgradable option from least gradient strength to 44mT/m)		
	2. Gradient type resonant / non-resonant :		
	3. Gradient shielding type: active		
	4. Rise Time not more than : 0.22 ms		
	5. Duty Cycle: 100% the gradient power amplifier should be water cooled.		
	6. Type of Cooling: Water		
	7. FOV : approx. 520 x 450 x 400 mm		
	8. Slice Thickness :		
	• 2D imaging minimum should be : 0.5mm or less		

Multi slice imaging: 1 – 7mm

Multi slice 2D: 0.5 mm or less

- 3 D imaging minimum should be: 0.1 mm or less
- Minimum echo spacing EPI sequence for imaging FOV should be atleast 0.7 ms or less at 256 X 256 matrix
- 9. Acquisition Matrix Minimum range:
- 10. Gradient / Acoustic noise suppression :
- 11. Echo train length in both spin echo and gradient echo should be at least 256 or more
- 13. Shall have eddy current compensation

III RF SYSTEM:

- 1. RF system type: Fully, Digital with digital transmit and digital receive
- 2. Number of independent channels in single FOV and single scan that can acquire independent image minimum: 32 or more
- 3. RF system should be compatible with parallel imaging techniques. It should be able to support time reduction with compatible coils in 2D/3D imaging in body/neuro imaging. The acceleration factor should be at least 4. Higher PAT factor will be preferred
- 4. The RF system that can support connecting maximum number of coil elements at a time specify.
- 5. Digital RF power output (kW): approx. 15 kW 25kw

IV COILS:

The system shall provide capability of doing whole body scanning from head to toe using sufficient and optimal coil elements.

- 1. The main Body coils with 18 or more channels integrated into the Gantry/magnet must be quadrature/CP for both transmission and Receiving. In addition to this coil the following coils should be available.
- 1. Phased array Body coils capable of doing chest, abdomen, pelvis, Magnetic Resonance CholangioPancreatography (MRCP), Peripheral-vascular & Angio, cardiac imaging, etc... with 32 channel or more
- 2. 16 or more channel Dedicated head coil should be compatible to parallel acquisition techniques.
- 3. Dedicated Flexible coil large
- 5. CP/quadrature/phased array Dedicated neck coil: 4 channel or more

- 6. CP/ Quadrature Dedicated ankle/foot coil: 12channel or more
- 7. CP/ Quadrature Dedicated knee coil: 12 channel or more
- 8. Dedicated Phased array Spine coil: approx. 32 channel
- 9. Dedicated Wrist array coil: 12 channel or more
- 10. Dedicated Breast Coil should be PAT compatible: 12 channel or more
- 11. Dedicated Phased Array coil for Shoulder Imaging: 12 channel or more
- 12. Endorectal coil for higher resolution imaging of prostate, colon, rectum and cervix imaging
- 13.Additional Dedicated 16 channel head coil to image the brain compatible with steriotaxy frame should be provided.
- 14. CNS imaging surface coil if the combination of head, neck and spine coil should be PAT compatible seamless CNS imaging, please quote the Head to Sacrum imaging surface coil.
- 15. Tuning of coil (automatic)
- 16. Built in RF Pre Amplifiers
- 17. Multicoil connection-it should be possible to connect atleast 2 coils simultaneously

V. PATIENT HANDLING SYSTEM:

- 1. Max. Patient Weight (kg): Not less than 180 kg.
- 2. Light localizer for patient positioning and position accuracy, at least +/-1mm or better
- 3. Physiological signals display
- 4. ECG, Pulse, Resp. Sensors for patient monitoring: points no.3 and 4 should be available in the examination room (gantry) as well as Control room through a slave monitor
- 5. Intercom for Communication with patient (Two way) for patient to call in case of Emergency
- $\hbox{6. Remote monitoring CCTV Camera with LCD/LED/TFT display to observe patient } \\$
- 7. Patient Musical System
- 8. Hand Metal Detector
- 9. Metal Detector at Gantry Room Entry
- 10. Patient Accessories:
- 11. Rack in Gantry Room for keeping coils and accessories (2 Nos)
- 12. The table should have patient auto alarm system.

- 13. The table should be fully motorized with computer controlled table movements in vertical and horizontal directions.
- 14. The table should deliver the protocols for automatic bolus chasing in peripheral angio with automatic table movement.
- 15. The table should have facility for manual traction in case of emergency.
- 16 The system should consist of detachable and dockable non magnetic trolley integrated with IV pole, arm boards, safety handrails and carrying capacity at least 180kg.

Image Transfer, archieving & Networking

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined enduser lisence PACS (Picture Archieving and Communication System).

This system should be able to provide on-line accessibility of processed image data in six OT's, ICU, CCU, and radiology conference room at trauma centre etc.

The server hardware should consist of intel multi core i7 32GB RAM, 2000GB HDD, DVD, CD RIW, 28" or more flat monitor.

Each viewing terminal should have a PC with intel core i7 latest version,32GB RAM, 500 GB HDD, CD/DVD, combo drive, 24"or more flat monitor.

VI MR WORKSTATION

One additional latest advanced post processing workstation of 19 inch LCD/TFT monitor with additional camera. It should be swappable (Interchangeable with main console with full functional capability as the main console) and should have all post processing software's and complete DICOM functionalities.

VII. COMPUTER SYSTEM:

- 1. Host Computer, Processor: intel core i7
- 3. RAM memory capacity at least : >/= 32 GB
- 4. Hard Disk Capacity Not less than 2000GB and Image Storage at least: 500,000 at 512x512 Matrix: uncompressed
- 5. DVD: Re writeable
- 1. Additionally 5000 high storage CD's or 1000 high storage DVD's to be provided.
- 9. The main console should have integrated MR compatible music system for the patient

10. Color TFT/LCD Monitor:

- High resolution flat screen monitor horizontally tilt able, forward and backward
- Screen Size(diagonal): 19 inch
- Screen matrix: 1280 x 1024

VIII IMAGE PROCESSOR:

- 1. Image Processor-RAM memory -minimum of : 32 GB
- 2. Image reconstruction time- rectangular matrix 256x256 minimum reconstruction as standard : quote your highest available reconstruction as standard
- 3. Reconstruction Matrix: Range

IX. IMAGING SPECIFICATION:

- 1. Off centre FOV:
- Lateral
- AP
- 2. Slice orientations- sagittal, Axial, coronal ,single/ double angulations Oblique etc.
- 3. Display no. of slices at the console
- 4. Display SNR of a chosen sequence at the console
- 5. Scan modes:
- · Single slice
- · 2D multiple single slice
- 2D multiple slice
- · 3D volume
- · 3D multiple stack
- Cine acquisition
- · Dynamic pre and post contrast studies
- 6. Maximum intensity projection (MIP)
- 7. Minimum Intensity Projection (Block Blood) in MRA
- 8. Multi planar Reconstruction (MPR)
- Oblique
- Orthogonal
- · Curved MPR
- 9. Pre-configured Protocols
- 10. 3D surface rendering software

11. Software for CNS imaging with surface coils to scan from head to sacrum. It should be possible to have imaging pasting/composing on the main console and workstation with the output image in DICOM format: 12 Software for peripheral angiography with surface coils from renal arteries to the lower limbs upto the feet 13. various image viewing parameter in the system 14. various image analysis parameters X. SOFTWARE SEQUENCES BASIC: A Spin Echo for 256x256 matrix: best TE and TR 1. 2. Gradient echo for 256 x 256 matrix: best TE and TR Inversion Recovery (at 256 x 256 matrix) 3. **B FAST SEQUENCES:** Fast spin Echo(at 256 x 256 matrix) 1. Turbo Factor / Echo Train length minimum: Resolution Matrix 512 x 512 2. Fast Gradient Echo(at 256 x 256 matrix) C. ULTRAFAST SEQUENCES: 1. **EPI** Type of EPI Single Shot Multi Shot EPI Factor max.: 256 **EPI Acquisition Matrix** 64 x 64 : 128 x 128 : 256 x 256 : D. These sequences should also include (but not restricted to) 1. Cardiac imaging Abdominal imaging including MRCP and noncontras angiogram NATIVE & equivalent. MR Spectroscopy **XI. Application Software:** A. MR Angio package

2D TOF 3D TOF

- MIP
- · Multi slab
- · Quantitative flow package 2D/3D steady state sequences for high resolution neuro imaging should be part of the main configuration. The real time FIESTA/Balanced FFE/true FISP should be standard. Non contrast angiography technique for renal and peripheral angio [Inhance, Native, trance etc].

B. Advance Angiography package

Phase contrast angio

- 2D PC
- 3D PC
- · MTC
- Contrast Enhanced Angio :

The system should be quoted with time resolved technique for peripheral vessels, aorta, thorax etc

The system should be quoted with 3D volume acquisition sequences/ packages for high resolution liver imaging and also steady state sequences for abdomen imaging should be quoted as standard

The system should have as standard software/technique based on the propeller techniques for motion correction for involuntary head movement of the patient

C. MR cardiac package

ECG Triggered Heart imaging

- · Advanced cardiac applications: Morphology/ wall motion: 2D/3D IR prepared sequences for myocardial evaluation: Cardiac function including EF, ED/ES volume cardiac output, wall thickening and wall thickness;
- 2D/3D steady state sequences for high resolution morphology, real time spiral imaging techniques for coronary artery imaging free breathing sequences/navigators; interactive real time sequences for on the fly change in parameters; all these cardiac related application should be quoted as standard of the main console/workstation

D. MR diffusion weighted and diffusion tensor imaging with maximum b value of 7,000s/mm2with automatic calculation of tensor trace images and ADC maps .The system should be available to perform multi direction diffusion weighted imaging and diffusion tensor imaging and the same should be possible on the main console and workstation. It should be for neuro, muscular and cardiac applications

E. 3D MRCP

- F. Functional imaging brain with EPI bold with color coding and on line calculation of Z score on the main console/workstation: optional. Also give the details about the hardware
- H. Spectroscopy the system should have the hydrogen, single voxel spectroscopy, multivoxel, multislice 2D, 3D spectroscopy, PRESS,STEAM and also the chemical shift imaging in 2d/3d. The complete processing/post-processing software including color metabolite maps should be available on the main console and it should be quoted as standard. The advanced spectroscopy post processing software should allow to process Display, manipulate, analyze and print the spectroscopy data on the main console/workstation. It should be possible to have prostrate spectroscopy in conjunction with the surface coil include any other interface, or hardware and software required for this application
- I. Fat and water excitation please the application package
- J. Single and Multi shot EPI imaging techniques.
- K. Please the motion correction algorithm/package for high-resolution motion free Diffusion weighed imaging with multishot/ segmented EPI techniques. It should be possible to have FLAIR diffusion with generation of corresponding ADC maps.
- L. Perfusion Imaging to enable large anatomy coverage of the brain and in line calculation of the resulting hemodynamic as well as physiological parameters. The perfusion analysis should have capability to calculate color display of rMTT, rCBV, rCBF, corrected CBV, permeability constant and volume leakage.

- M. BOLD(Blood Oxygen Level-Dependent) imaging: BOLD .technique with automated 3D motion correction, z- score, correlation analysis with color overlay on anatomical images. It should be possible to have Real Time Processing of BOLD imaging data on the main console for the complete reconstruction.
- N. The system should have facility for quantification of the CSF flow data on the main console and / or the workstation.
- O. The system should have the Hydrogen, Single Voxel spectroscopy, Multivoxel, multislice 2D, 3D Spectroscopy and also the Chemical shift imaging in 2D/3D. The complete processing / post processing software including color metabolite maps should be available.
- P.The system should have facility to do Head to Toe imaging without shifting the patient at one go for metastases study and without any loss of SNR.
- Q. It should be possible to have the prostate spectroscopy in conjunction with the endorectal Coils.
- R.The system should perform DTI (Diffusion tensor imaging) at least in 21 directions with possibility of processing with depiction of fractional anisotropy, mean diffusivity and other DTI metrics. Provide the fiber tracking software with overlays on various conventional images.
- S. The system quoted should have the software for Whole Body Diffusion weighted imaging.

XII . ARTIFACT REDUCTION TECHNIQUES: - details.

XIII. FAT AND FLUID SUPPRESSION TECHNIQUES: Fat suppressed technique to get fat, water, in Phase out of Phase contrast in a single acquisition essential (Dixon, ideal 3 D Dual Echo)

XIV.DOCUMENTATION:

- 1. DVD with covers-- 100 Nos
- 2. Dry view laser Imager with:
- Resolution: 14 bits/600 DPI or more
- With minimum three port
- DICOM Compatible

XV. A/C AIR CONDITION SYSTEM:

15° C to 24° C Maintenance around the Clock

Installation of Temperature & humidity meter with humidifier

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XVI. POWER REQUIREMENT:

Power input to be 220-240VAC, 50Hz / 3 Phase of appropriate rating

Resettable over current breaker shall be fitted for protection

Environmental factors:

• The unit shall be capable of operating continuously in ambient temperature of 30 deg C and relative humidity of 80%

XVII. TERMS OF INSTALLATION:

The firm shall be responsible for site evaluation and complete installation, full technical cooperation for alteration of existing building Complex etc., if needed.

Accessories

New stereotaxy frame – Leksell microsteroractic system or equivalent complete set for biopsy with all accessories; should include 2 biopsy needles, 2.1 and 2.5 mm diameter; one set of screws of all sizes, – one number

MR compatible anesthesia machine

General feature

Anestheia Machine of closed breathing circuit configuration

Suitable for Adult and pediatric

Anesthesia gas delivery system

Equipped with anesthesia vaporizer, (Sevoflorine & Isoflorine), Anesthesia ventilator

Should have independent attachments for connecting central gas supply and pin indexed cylinders Should have provision for attaching ½ cylinders of (O2 and N2O)

Monitoring system to monitor Anesthetic gases, ECG, Respiration, Pulse Ox meter, NIBP & Temperature.

Should have audio-visual oxygen Failure warning system with nitrous oxide cut off.

Trolley with upper shelf and medical utility rail

can support two 10 L an aesthetic gas bottles (O2-N20)

Flow meter

The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters

For O2: 0.1-10 L/min

For N2O: about 0.1-10 L/min

For Air : 0.1-10 L/min

Color coding

Each connection valves ,gauge, and flow meter is labeled and color-coded for the appropriate gas type

Gas supply pressure

350-500kpa (common to O2:N2O,Air)

Vaporizer

Sevoflorine & Isoflorine both calibrated. Temperature and back pressure compensated type with safety lock button

O2 flash valves

The O2 flash button can be easily pushed for O2 to the patient, flow volume approx. $45-70 \, l/min$

Safety & warning flowing device

Should have automatic cut-off valve with audible alarm when O2 pressure drops and failure below standard

Pop- off

Should prevent over-pressure with surplus gas evacuation adapter and gas open ,close ,semi close circuit selector knob

Features

A flow meter with incorporating safety mechanism

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/ with separable structure to manipulate according to the condition of surgical operation

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Complete patient monitoring capabilities :respiratory gas

Fully autoclavable and latex-free superior ventilation options

Easily adjustable and replaceable flow meter glass tube

Monitor Should provide facility

Monitoring system to monitor Anesthetic gases, ECG, EtCO2, Pulse Oximeter and airway pressure, NIBP, IBP, rectal/&skin temperature and BIS (to measure the effects of anesthetics and sedatives on the state of brain) should be present pressure transducers and necessary accessories as per requirement.

Oxygen and Nitrous oxide anesthetic agent in the inspired mixture

Oxygen situation of the blood with both adult & pediatric probes & sensors

Airway pressure monitoring should be present

Temperature monitoring with 2 probes for rectal and skin

Mounting

Mobile stand mount for the unit

Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes Individual locking front castor Brake

Color Coded Cylinder Yoke

Yokes with sliding clamping bars for easily handling .Extendable rear platform for two cylinder

Accessories

With All other complete standard accessories

Should be supplied with necessary attachments for use of the breathing circuits

Alarm system features

Low O2 concentration alarm sound with indicator light

When O2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

Ventilator

- Modes: Automatic Volumetric and Manual
- Electrically powered compressor, minute volume: 2 to 25 L/min
- Tidal volume: 20 1500 ml
- Respiratory rate: 5 to 70 cycles/min
- I/E ratio: 2/1 to 1/4
- Inspiration pressure: approx. 10 to 65 mbar
- Peak inspiratory flow: 0 to 60 L/min
- Trigger sensitivity: 1 to 10 mbar
- Front panel shows status, errors and sensors failure (low/high pressure, power failure)
- Audio-visual alert on low/high pressure, apnea, power failure
- Display of operational status, with set and measured values

- Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures
- Self diagnosis with each start-up and integrity testing of all system parameters
- With adjustable patient-circuit support arm
- Built-in rechargeable battery, autonomy approx. 45 hrs
- Automatic switch to battery in case of power failure, automatic recharge when connected to mains
- Power requirements: 220 V $\pm 10\%$, 50 Hz and rechargeable battery

Supplied with:

- 2 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)
- 2 x Adult reusable breathing circuits (tubes / balloons / valves / masks)
- 2 x Spare parts/maintenance kit (air filters, tubing, O-rings)
- 2 x Set of spare fuses

MR compatible Multipara monitor (Non Invasive Monitor) with slave monitor in console room

- 1. ECG /Resp: 10 lead ECG cable with clip -2 set per monitor.
- 2. NBP: Adult cuff -2nos per monitor and two sizes of Pediatric Cuffs one per monitor. (Complete sets)
- 3. SpO2: Adult SpO2 sensor with cable two nos per monitor and Pediatric SpO2 Sensors one no per monitor.
- 4. IBP: Include four nos per monitor of reusable pressure transducer with bracket, holder and 100nos disposable domes per monitor.
- 5. Temperature: Central temperature Probe two per monitor and Skin temperature probe one no per monitor
- 6. Airway pressure monitoring should be present

MR Compatible Pressure Injector:

Must have Independent dual Syringe powerhead.

Flow rate: 0.1-10 ml/sec

Volume: 1 ml to syringe capacity

Programmable pressure limit of 325 psi with 200 ml disposable sterile syringe

With minimum of 30 protocols

Syringe heater range 35 deg C+/- 5 deg C.

Should be provided with head mounting device and integral IV pole.

Should be supplied with at least 2000 Syringes and 2000 power injector extension cable.

Unit will be provided with display monitor to provide Pressure Monitor graph, Flow Profile, Stop Watch Feature, Scan Display, multiphase capability and protocol locking capabilities.

MR compatible oxygen cylinder (50 Liter) with oxygen regulator and humidifier

5. System Configuration Accessories, Spares, Consumables and other components:

Main unit

Main Console with 02 monitor

Additional Console (post processing workstation) with 02 monitors

DVD/CD Archieving - 02 (1 ea on all the consoles)

Patient Table

Dry view imager

Non invasive monitor

Laser color printer

Anesthesia machine

Dual head pressure injector (with 2000 syringes)

UPS with servo controlled stabilizer of one hour back up

Oxygen cylinder, 50 L---02

Hand metal detector

Stationary metal detector

Leksell stereotaxy frame with biopsy kit

RF shielding

Air conditioners (AC) with chiller

Non-magnetic dockable trolley

PACS with 06 monitors for six concurrent users with undefined end user license

DVD burning station

Standard Patient positioning acc and restraining devices--02 sets

View Boxes – slim, four in one with fluorescent tubes with shutters and variable luminescence--- 02

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, film, etc..)

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All standard accessories, parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirement:

Power input 380 +/- 10% VAC/50Hz

Resettable over current breaker shall be fitted for protection

UPS with servo controlled stabilizer of one hour back up capacity to handle complete MRI, Laser imager, work stations, color printer, anaesthesia delivery system, monitor and defibrillators.

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Mangemnt system (Or Equivalent)

9. Installation, Training and Commissioning:

- 1. The supplier must provide installation, training and commissioning of the device at health Facility
- 2. Application specialist visit at least for six weeks to orient resident technicians / Radiologists
- 3. Train one Radiology Technologist and one maintenance Engineer at the manufacturing site for three weeks (for each MRI equipment)
- 4. Train two Radiologist and two Biomedical Engineer for three weeks at a suitable centre in Ethiopia (for each MRI equipment).
- 5. Date of Commencement of warranty: After Installation, demonstration & proper functioning of equipment and handing over of the installed equipment in the specified site.

Turn key Works

PREMISES:

The interiors of the rooms (Equipment room, Console room, Patient Waiting room, Change room and Reception.) in all respects for successful installation and commissioning of the equipment to the satisfaction of the Purchaser/user department. This shall include everything required for successful commissioning but not limited to the following:

- i. **Civil Works**: Necessary Civil works like Platform, Pedestals, etc., if any, required shall be provided.
- ii. **RF shielding**: a). Radio frequency shielding protection for console and Gantry room to be provided.
- b). R.F. Shielding of room with built in medical Gas Pipe line for patient resuscitation
- c). All necessary shielding should be provided such that the filed strength/RF outside the scanning room is within

acceptable limit and have no effect on nearby equipment.

- iii. **Flooring**: Shall provide and lay Anti-static flooring of 2 mm thick, manufactured by reputed standard manufacturers. Colour as per Standard requirement.
- iv. **False Ceiling**: Shall provide and fix false ceiling of Luxalon make with necessary fixing arrangements as per manufacturers specifications. Colour as per Standard requirement.
- v. **Walls**: Walls upto ceiling shall be provided with vitrified tiles 60cm x 60cm. Colour as per Standard requirement.
- vi. **Electrical**: From the main supply point of the hospital panel board, the supplier shall supply and install the main incoming switch fuse unit, three phase electrical cable, electrical Wiring systems for light and other Electrical fittings, separate power distribution boards and lay distribution lines required for all items installed with the MRI, Console room, Patient waiting room, Change room, etc.
- vii. Plumbing: Required Plumbing work shall be provided.
- viii. **Furniture**: chair, Table, for changing room, console, radiologist's room etc.

ix. Air Conditioners

The supplier shall install AC in Gantry room, UPS room and any other adjacent rooms in order to centrally air conditioned the whole area. The temperature of the gantry room to be maintained at 20 deg C.

10. Warranty and After Sale service:

- 1. A well Experienced service and maintenance Engineer should be provided to attend the equipment with preventive schedule maintenance (Provided by the Local Agent)
- 2. Free comprehensive warranty for one years (including Labor, spare parts, accessories and liquid helium) starting from the date of commissioning.

- 3. The Cost of the extended warranty (Comprehensive Maintenance Contract) from 2nd year to 10th year inclusive of labor, spare parts, accessories and liquid helium should be separately quoted. The CMC should cover all Bidder items and local accessories.
- 4. Up time Guarantee: Minimum 95%
- 5. Upgradability: All software/system upgrade for the entire system on the existing applications must be provided whenever needs by the system free of charge throughout the basic warranty and extended warranty period. This will include any hardware or parts if the software added needs them to enhance the existing capabilities.
- 6. The machine must be fresh product

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Description	Department
Ctsc-90	1. Generic Name: CT Scan Machine - 64 Slice	Imaging
	2. GMDN/UMDN Name:	
	3. Clinical Purpose/Description:	
	CT (computed tomography), uses special x-ray equipment to obtain image data from different angles around the body and then uses computer processing of the information to show a cross-section of body tissues and organ.	
	Operational requirements	
	Multi-Slice (64 Slices) Spiral CT Scanner for High Resolution Whole Body Scanning including Cardiac, Vascular, implants or complicated fracture application. The equipment should be capable of acquiring 64 or more slices per 360 rotation. The system should be capable of doing ultra low dose imaging using model based iterative reconstruction technique.	
	4. Technical Specifications	
	Manufacturer	
	Brand	
	Model	
	COUNTRY OF Origin	
	Gantry	
	i) Aperture diameter of 70 cm or more	
	ii) Control Panel: Should have control panel on either side for easy positioning	
	iii) Positioning Lights: should have 3D laser lights for positioning.	
	iv) FOV(Field of View): should have FOV of at least 50 cms or more.	
	v) Tilt:- Remote tilt of +/- 30 Degrees or more from console.	
	X-ray Generator	
	Manufacturer	
	Brand	
	Model	
	COUNTRY OF Origin	
	i)The Generator should be of high frequency type and having adequate output to facilitate spirals of at least 100 sec duration.	
	ii)The system X-ray power should be 70kw and above.	

iii)The mA range available should be between 20 to 600 mA with increments in steps of not more than 5 mA. KV range: 80-140 KV or more X-Ray Tube Manufacturer Brand Model **Country Of Origin** 1 Tube current: 20-600mA 2 Real Time mA modulation for dose regulation.. 3 Tube Voltage:80-140 Kv or more. 4. Dual focus with Anode Heat Storage Capacity of at least 7MHU 5. Anode Temp Monitoring System. 6. Heat Dissipation rate: >/= 700KHU/minute 7. Filter and beam limiting devices: 8. Focal Spot size and number should specify. 9. X-ray tube should be Liquid cooled bearing assembly tube **Detectors** Manufacturer **Brand** Model **Country Of Origin** The data acquisition system in spiral and sequence mode should have 64 or more rows of detector electronic channels that can acquire 64 slices for complete 360 degree rotation. Detector should be Solid state (or better) of latest technology with latest scintillator material free from repeated calibration The system should have collimation for 64 slices against the thinnest possible slice of the system 64 x 0.625mm ☐ Slice thickness: 2mm to 6mm **Area of Coverage** High Resolution (0.625 mm or better) coverage along Z axis. should be 38 mm or more per rotation. Patient table 1. Minimum load bearing capacity of at least 200kg with 1 mm positioning accuracy.

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2. Table speed Horizontal: =>100 mm/sec.

3 Vertical Table travel: 40 cm

- 4 Longitudinal Scan Range: 100-1800mm or better
- 5 Facility of positioning aid for horizontal Iso centric positioning of the patient..
- 6. Carbon Fibre Table Top.
- 7. Minimum table top height should not be more than 55 cms from the floor level for easy transportation

Helical Application/Acquisition:

i)Scan length of at least 100 cm. in a single gapless Spiral/Helical Scan with a free pitch selection. Types of helicals should be mentioned.

ii)Facility to monitor contrast enhancement & automatically initiate scanning.

iii)Acquisition of Cardiac images with ECG Gating (Prospective & Retrospective Gating) the temporal resolution achieved using 1, 2 or 4 sections of consecutive cardiac cycle to reconstruct each axial image.

iv)Real time X-ray dose reduction which combines both Z axis and angular tube current modulation to adjust the dose to the size and shape of individual. It should be possible to modulate the mA with ECG signals.

V) The Reconstruction Time in Spiral scan should not be less than 15 Images / Sec

Vi) Scan Time

Complete 360 scan should be performed at 0.40 Sec. or less.

Image Resolution

high Contrast : 24 LP/cm or better for complete FOV. (the phantom used, scan time, mA, scan field, dose, slice and MTF).

Main Console:

a) It should have intel core i7 latest version with configuration of minimum 32 GB RAM and 2TG HDD or more

The System shall have all functions menu driven.

All applications like scanning, image reconstruction, filming, MPR, CT Angiography, maximum intensity projection MIP, 3D Volume rendering Technique, Virtual Endoscopy package should be possible from the console.

The image reconstruction time should be 15 images/second or more in 512 x 512 matrix.

b)There should be facility to read and write CD on main console.

Post Processing Workstation

Workstation with intel multi core latest version, 3.6 GHz processor with configuration of minimum 32 GB RAM and 700GB HDD. Satellite console should have all the features as of main console (swappable). Image Evaluation Software and following post Processing facility.

- i) Calcium scoring, cardiac LV, RV analysis, cardiac scoring & reporting, CT coronary analysis software, cardiac comprehensive report.
- ii) Software for brain perfusion and abdominal tumour perfusion studies.
- iii) Complete virtual endoscopy package.
- iv) Software for stenosis analysis.
- v) Software for Dental Planning.
- vi) Facility for direct 3D image formatting in any plane during acquisition as planned on scout images.
- vii) Osteo software or equivalent softwares for complete library of analysis templates for most Bone research
- viii) The system should consists of real time CT fluoroscopy with at least 6 to 8 frames per second with dedicated 21 inch color LCD monitor and standard accessories.

MONITORS: (for both consoles)

1 Resolution: 1280 x 1024 pixels

2. Pixel Size: <0.3 mm

- 3. Flat screen LCD Type of medical grade monitor at least 21" with fast image refresh rate should be fast and preferably instantaneous and flicker free .
- 4. Should be non interlaced and progressive display type & sturdy.

Consoles Common Feature:

- 1 The two sets of workstation should be interconnected by ISDN Lines or other communication standard (to be provided by the vendor) for two way transfer of images and reports.
- 2. Spatial alignment and visualization of two different data sets of one patient generated on different modalities or with different acquisition time..
- 3 Post Processing Software: Perfusion CT, VRT, MIP, SSD, Image Fusion, Vessel segmentation, Virtual Endoscopy software to be provided on both the workstation.
- 4. Cine display should be available ,both interactive and automatic ,and should have a minimum image refresh rates of 8-10/ sec.

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- 5. Window width and centre should be freely selectable.
- 6. Patient Registration , pre registration facility and transfer of information via DICOM should be possible.

Post processing tools

- 1. 2-D post processing: image zoom and pan; image manipulations including averaging, reversal of grey-scale values, subtraction and mirroring; image filter functions including advanced smoothing algorithm and advanced bone correction.
- 2. Real-time multi-planar reconstruction (MPR) of secondary views, with viewing perspectives in all planes including curved & orthogonal MPR.
- 3.CT angiography, MIP, MinlP, SSD, VRT and other advanced 3D applications and colour coding for different tissues..
- 4 Spatial alignment and visualisation of two different data sets of one patient generated on . different modalities or with different acquisition times.
- 5. Perfusion CT for study of brain. Liver, kidney, pancreas etc.
- 6. Volume measurements.
- 7. Fusion of morphological data obtained on CT, MR

Image Evaluation Tools:

- 1 Parallel evaluation of multiple ROI in circle, irregular and polygonal forms.
- 2. Statistical Evaluation for area/ volume, S.D, Mean value, Min/Max. value and Histograms.
- 3. Advanced cardiac packages with ECG gating for cardiac and vascular evaluation in trauma patients..
- 4. Profile cuts: horizontal, vertical and oblique views.
- 5. Distance & angle measurement, freely selectable positioning of coordinate system, grid and image annotation and labelling.
- 6. Dynamic evaluation of contrast enhancement in organs and tissues, calculation of timedensity curves, peak enhancement images and time-to-peak images.

Image Transfer, archieving & Networking

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined enduser lisence PACS (Picture Archieving and Communication System).

This system should be able to provide on-line accessibility of processed image data in six OT's, ICU, CCU, and radiology conference room at trauma centre etc.

The server hardware should consist of intel core i7 latest version, 32GB RAM, 5000GB HDD, DVD, CD RIW, 28" or more fiat monitor.

Each viewing terminal should have a PC with intel core i7 32GB RAM, 500 GB HDD, CD/DVD, combo drive, 24"or more flat monitor.

Patient communication system:

An integrated intercom and Automated Patient Instruction System (API) or other patient communication system should be provided

CONNECTIVITY AND ARCHIVAL

- 1 DICOM connectivity should be optimized for networking with other imaging systems.
- 2.DICOM converters for linking the camera with other imaging systems of the department/section should be provided, if required separately. It should have sufficient memory to store images from the CT as well as other system connected to it.
- 3. Filming parallel to other activities, including independent scanning, documentation and post-processing and configurable image text..
- 4. **Archiving:** DVD/CD writer should be provided for archival.

Option of viewing these discs on any PC without DICOM viewer should be available.

CT Scan Compatible Non Invasive Monitor

- 1. Portable and Light weight preferably <10kg
- 2. Modular with 15 inch multi colour TFT display
- 3. Monitoring parameters; ECG, respiration, NIBP, SpO2 and temperature
- 4. Digital and 6 waves / traces display
- 5. Trends up to 24 hours
- 6. 60 minutes or more battery back up
- 7. Convenient handle for carrying the same
- 8. Able to fix with bed/trolley

CT Scan Compatible Monitor Defibrillator with recorder

- 1. Biphasic, with auto and manual mode. Manual selection upto approx. $300\,\mathrm{J}$
- 2. Should be mains and battery operated, with charging indicator.
- 3. Should be able to deliver 30 shocks with fully charged battery.

- 4. Should have true 1-2-3 Color-coded operations.
- 5.to have inbuilt Internal Thermal Recorder.
- 6.Should have Automatic lead switching to see patient ECG through paddles or leads. Should measure chest impedance and should be able to compensate.
- 7. Should be provided with Adult and Pediatric external paddles.
- 8. Should have both Synchronous and Asynchronous mode.
- 9. The charging time to highest energy level should be \leq 9 seconds.
- 10.Should have external pacemaker facility.

CT Scan Compatible State of the art general anaesthesia induction system with the following

General feature

Anestheia Machine of closed breathing circuit configuration

Suitable for Adult and pediatric

Anesthesia gas delivery system

Equipped with anesthesia vaporizer, (Sevoflorine & Isoflorine), Anesthesia ventilator

Should have independent attachments for connecting central gas supply and pin indexed cylinders Should have provision for attaching ½ cylinders of (O2 and N2O)

Monitoring system to monitor Anesthetic gases, ECG, Respiration, Pulse Ox meter, NIBP & Temperature.

Should have audio-visual oxygen Failure warning system with nitrous oxide cut off.

Trolley with upper shelf and medical utility rail

can support two 10 L an aesthetic gas bottles (O2-N20)

Flow meter

The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters

For O2: 0.1-10 L/min

For N2O: about 0.1-10 L/min

For Air : 0.1-10 L/min

Color coding

Each connection valves ,gauge, and flow meter is labeled and color-coded for the appropriate gas type

Gas supply pressure

350-500kpa (common to O2:N2O,Air)

<u>Vaporizer</u>

Sevoflorine & Isoflorine both calibrated. Temperature and back pressure compensated type with safety lock button

O2 flash valves

The O2 flash button can be easily pushed for O2 to the patient, flow volume approx. 45-70 l/min

Safety & warning flowing device

Should have automatic cut-off valve with audible alarm when O2 pressure drops and failure below standard

Pop- off

Should prevent over-pressure with surplus gas evacuation adapter and gas open ,close ,semi close circuit selector knob

Features

A flow meter with incorporating safety mechanism

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/ with separable structure to manipulate according to the condition of surgical operation

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Complete patient monitoring capabilities :respiratory gas

Fully autoclavable and latex-free superior ventilation options

Easily adjustable and replaceable flow meter glass tube

Monitor Should provide facility

Monitoring system to monitor Anesthetic gases, ECG, EtCO2, Pulse Oximeter and airway pressure, NIBP, IBP, rectal/&skin temperature and BIS (to measure the effects of anesthetics and sedatives on the state of brain) should be present pressure transducers and necessary accessories as per requirement.

Oxygen and Nitrous oxide anesthetic agent in the inspired mixture

Oxygen situation of the blood with both adult & pediatric probes & sensors

Airway pressure monitoring should be present

Temperature monitoring with 2 probes for rectal and skin

Mounting

Mobile stand mount for the unit

Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes Individual locking front castor Brake

Color Coded Cylinder Yoke

Yokes with sliding clamping bars for easily handling .Extendable rear platform for two cylinder

Accessories

With All other complete standard accessories

Should be supplied with necessary attachments for use of the breathing circuits

Alarm system features

Low O2 concentration alarm sound with indicator light

When O2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

Ventilator

- Modes: Automatic Volumetric and Manual
- Electrically powered compressor, minute volume: 2 to 25 L/min
- Tidal volume: 20 1500 ml
- Respiratory rate: 5 to 70 cycles/min
- I/E ratio: 2/1 to 1/4
- Inspiration pressure: approx. 10 to 65 mbar
- Peak inspiratory flow: 0 to 60 L/min
- Trigger sensitivity: 1 to 10 mbar
- Front panel shows status, errors and sensors failure (low/high pressure, power failure)
- Audio-visual alert on low/high pressure, apnea, power failure
- Display of operational status, with set and measured values
- Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures
- Self diagnosis with each start-up and integrity testing of all system parameters
- With adjustable patient-circuit support arm
- Built-in rechargeable battery, autonomy approx. 45 hrs
- Automatic switch to battery in case of power failure, automatic recharge when connected to mains

- \bullet Power requirements: 220 V $\pm 10\%,\,50$ Hz and rechargeable battery
- Supplied with:
- 2 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)
- 2 x Adult reusable breathing circuits (tubes / balloons / valves / masks)
- 2 x Spare parts/maintenance kit (air filters, tubing, O-rings)
- 2 x Set of spare fuses

CT Scan compatible Pressure Injector with the following:

Must have Independent dual Syringe powerhead.

Flow rate: 0.1-10 ml/sec

Volume: 1 ml to syringe capacity

Programmable pressure limit of 325 psi with 200 ml disposable sterile syringe $\,$

Syringe 200 mL disposable sterile syringe with minimum of 30 protocols

Syringe heater range 35 deg C+/- 5 deg C.

Should be provided with head mounting device and integral IV pole.

Unit will be provided with display monitor to provide Pressure Monitor graph, Flow Profile, Stop Watch Feature, Scan Display, multiphase capability and protocol locking capabilities.

5. System Configuration Accessories, Spares, Consumables and other components:

Main Unit

Main Console with 02 monitor

Additional Console (post processing workstation) with 02 monitors

CT Fluoroscopy with 01 monitor

DVD/CD Archieving - 02 (1 ea on all the consoles)

Patient Table - 01

PACS with 06 monitors for six concurrent users with undefined end user license

DVD burning station

Air conditioners (AC)

Lead Glass window as per room requirement

Lead Door as per room requirement

Anesthesia Induction System with all accessories -01 set

Dual head Automatic Pressure Injector -01(with 2000 syringes and 2000 Extension cable)

Collapsible wheel chair with rubberized swivel wheels. -02

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Standard Patient positioning acc and restraining devices. -02 sets

Good quality Light weight Lead Aprons-10 No's

Gonadal shields – 2 No's

Thyroid shields – 3 No's and Lead goggles – 2 No's

View Boxes – slim, four in one with fluorescent tubes with shutters and variable luminescence-- 02

Laryngoscopes adult and Pediatric Sizes -- 01 Set

endotrachial tubes of adult and Pediatric Sizes -- 100 each

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, film, etc..)

All standard accessories, parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

Non Invasive Monitor with the following accessories - 01

- 1. ECG /Resp: 5 lead ECG cable with Clip 2 set per monitor. and 10 lead ECG cable with clip 1set per monitor.
- 2. NIBP: Adult cuff -2nos per monitor and two sizes of Pediatric Cuffs one per monitor. (Complete sets)
- 3. SpO2: Adult SpO2 sensor with cable two nos per monitor and Pediatric SpO2 Sensors one no per monitor.
- 4.IBP: Include four no's per monitor of reusable pressure transducer with bracket, holder and 100nos disposable domes per monitor.
- 5.Temperature: Central temperature Probe two per monitor and Skin temperature probe one no per monitor

Defibrillator Monitor/ Recorder with the following accessories- 01

Adult and pediatric Reusable paddle-1 each

Disposable pads - 100 each

ECG Cable- 5 lead - 1 each

ECG Electrodes - 1000 each

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Uitility Requirement:

Power input 380VAC/50Hz

Resettable over current breaker shall be fitted for protection

UPS with servo controlled stabilizer of one hour back up of suitable capacity of handle complete CT scanner, Laser imager, work stations, color printer, anaesthesia delivery system ,monitor and defibrillators.

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Mangemnt system (Or Equivalent)

System should be DICOM READY

Fire fighting and Security System with inbuilt alarm, smoke detector system, to be connected to main hospital control system.

9. Installation, Training and Commissioning:

The supplier must provide installation, training and commissioning of the device at health Facility

The supplier must provide training two radiology Technologist and two Biomedical Engineer for three weeks at installed site (for each CT Scan equipment).

The supplier must provide application specialist visit at least for four weeks to orient resident technicians/radiologists.

The supplier must provide training for one radiology Technologist and one Biomedical Engineer at the manufacturing site (for each CT Scan equipment).

Turn key Works

(c) Premises:

The interiors of the rooms (Equipment room, Console room, Patient Waiting room, Change room and Reception) in all respects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

- i. Civil Works: Necessary Civil works like Platform, Pedestals, etc., if any, required shall be provided.
- ii. X ray radiation shielding: Proper lead protection lead window as well as lead door for console, patient change room and Gantry room should be provided.
- a) lead thickness b) door frame c) Should be washable, laminate finish with color in harmony with building lead sandwich

iii. Electrical: From the main supply point of the hospital panel board, the supplier shall supply and install the main incoming switch fuse unit, three phase electrical cable, electrical Wiring systems for light and other Electrical fittings, separate power distribution boards and lay distribution lines required for all items installed with the CT, Console room, Patient waiting room, Change room, etc.

- iv. **Plumbing**: Required Plumbing work shall be provided and completed by the Bidder.
- v. Furniture: chair, Table, for changing room, console, radiologist's room etc.

vi. Air Conditioners

The supplier shall install AC in Gantry room, UPS room and any other adjacent rooms in order to centrally air conditioned the whole area. The temperature of the gantry room to be maintained at 20 deg C.

10. Warranty and After Sale service:

- 1. The supplier must be provide minimum of one years warranty for CT scanner system including Labor, X-ray tube and all parts and accessories starting from the date of commissioning.
- 2. The Cost of the extended warranty (Comprehensive Maintenance Contract) from 2nd year to 10th year inclusive of labor, spares and X Ray tube should be separately quoted. The CMC should cover all Bidder items and local accessories.
- 3. All software/system upgrade for the entire system on the existing applications must be provided whenever needs by the system free of charge throughout the basic warranty and extended warranty period. This will include any hardware or parts if the software added needs them to enhance the existing capabilities .
- 4. Up time Guarantee: Minimum 95%
- 5. A well Experienced service and maintenance Engineer (certified by the manufacturer) should be provided to attend the equipment with preventive schedule maintenance (Provided by the Local Agent)
- 6. The machine must be fresh product

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

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Addis Ababa

Base Code	Item Detail	Department
	1. Generic Name: External beam radiation therapy machine/	
Rala - 90	Teletherapy machine	Oncology
Autu - 70	2. GMDN/UMDN Code/Name:	Jicology
	3. Clinical Purpose/Description:	
	A medical Linear accelerator (LINAC) is a device most commonly used for external beam radiation treatments for patients with cancer. It delivers high-energy x-rays or electrons to the region of the patient's tumor.	
	4. Technical Specification:	
	4.1 Technological requirements	
	Linear Accelerator must be of the latest technology and should be fully computer controlled with the latest state of art digital control system.	
	RF source: Magnetron/Klystron	
	Wave Guide: Standing type along with the bending magnet, target assembly, vacuum ion pump	
	Electron Guide: - with sealed electron gun, The electron Gun can be diode device with direct or indirect heating of the cathode or other better device,	
	Upgradability:shall be upgradable to higher version	
	4.2 Photon radiation field requirements	
	Photon energy: Dual energy of 6MV and 15MV	
	Photon Beam Energy Stability: The quality index of a photon beam should not vary with time by more than $\pm 1\%$.	
	Dose Rate: -5 variable dose rates from at least 500MU/min for all photon energies.	
	Flatness: should be less than or equal to±3% along XY axis for field sizes from 10x10 to 40x40	
	Symmetry: The ratio between values measured for each pair of symmetrical points along longitudinal and transverse axis with respect to the beam axis at 10 cm depth for 0, 90, 180, and 270 gantry angles for all field sizes from 10 cm x 10 cm to 40 cm X 40 cm should not exceed ±2%.	
	Unclipped field size: 0.5X0.5 cm2 to 35X35 cm2 at 100cm SSD	

Clipped field size: 0.5X0.5 cm2 to 40 X 40 cm2 at 100 cm SSD. Clipped corners will not be acceptable for field size less than 35 X 35 cm.

Asymmetric Jaw movement: Asymmetrical collimation for both the sets of jaws shall be provided. At least one pair of jaws must be able to cross the central line by at least 10 cm to other side.

Field size accuracy: The congruence between optical and radiation fields for 5x5 sq cm and 10 cm x10 cm at 0, 90,180 and 270 gantry angles with SSD = 100 cm should be within 2 mm along X,Y axes.

Radiation field penumbra: The width between the 20% and the 80% isodose lines measured for 10 X 10 sq cm at depth of 10 cm at 100 cm SSD should not be more than 8 mm.

4.3 Electron beam requirements

Electron energy: -4 electron energies between 6 and 15 MeV

Dose Rate for electron Energy: - The dose rate at the isocenter shall not be less than 600MU/Minute for each electron energy.

Focal spot size: should be 3 mm or better

Field size for electrons: 4-5 Applicator sizes with from 6X6cm2 to 20X20cm2. a method to obtain irregular field shapes shall be provided.

Flatness: For electron beam intensity relative to the central axis over the central 80% of the field size at 10X10 to 20X20 cm at 10cm depth

4.4 Dose Monitoring

MU chamber features:

Dual ionization chamber system with independently monitored high voltage supply; interlocks to detect dose rate differences between the two channels; a high dose rate interlock to prevent an excess dose rate; an independent backup timer.

4.5 Gantry and treatment heads

Gantry mount: motorized with isocentric design

Gantry rotation range: ±190°

SID (source isocentre distance):100 cm

Isocentre height above floor level: ≤ 135 cm

Isocentre clearance (with devices inserted):≥ 30 cm

Isocentre maximum sphere in diameter:≤ 2.0 mm

Hand-held control of parameters inside the treatment room

Collimator jaw position indication: mechanical or electrical with mechanical backup;

Collimator rotation: at least $\pm 100^{\circ}$ with motorized rotation;

Optical distance indication range: SAD \pm 20 cm, with mechanical backup

Secondary collimation for blocks: A transparent shadow tray to support blocks up to 20 kg. To allow treatment at any angle with blocks, it shall be possible to fix the blocking tray to the collimator without use of hand tools. A standard set of blocks shall be supplied. It shall be possible to use blocks and wedges simultaneously.

Physical wedges: Nominal wedge angles of 15, 30, 45 and 60° must be available. An extended set of wedge angles (achievable as a single beam) would be preferred. The wedged field size should be at least $20 \text{ cm (w)} \times 30 \text{ cm}$. (Coverage of the full field size in the unwedged direction is preferred.) Insertion of wedges must not restrict the use of secondary collimation. The maximum field size covered by the wedge must be interlocked to the machine. Wedges shall be fixed for rotation of collimator and gantry. It shall be possible to use blocks and wedges simultaneously.

Dynamic wedge:created by jaw movements should be available

4.6 Multileaf Collimators (MLC)

MLC flexibility: the Multileaf Collimator must be used in conjunction with the primary collimators.

Number of leaves: at least 80 (40 pairs).

MLC driving mechanism: independent drive for each leave

Leaf width:< 10 mm at isocenter

Over center travel of leaves: ≥10 cm

Field length for each pair of leaves: =40 cm

Penumbra for fields defined by MLC: < 7 mm for 10X10 field

Average transmission through Leaves: <0.375%

4.7 Treatment Couch

Couch mount:Isocentric

Couch top material: Homogeneous carbon fiber, indexed for immobilization device

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Couch degrees of freedom: longitudinal, lateral, vertical, roll, pitch and rotation

Power means for emergency couch movements: Electrical backup and mechanical in case of electrical power failure

Control: Local and/or Remote

Minimum height from floor: 65-70 cms

Table top dimensions: Width=50cm, Length =200cm

Lift capacity: ≥ 250 Kg

Angular rotation limits: $\pm 180^{\circ}$.

Isocentric rotation limits: ±90°.

Lateral motion range of a patient on the couch: ± 20 cm

Angular rotation limits of the table top: $\pm 180^{\circ}$.

Vertical movement: motorized, with a minimum height of ≤ 80 cm but not less than 40 cm below the isocentre, and at least up to 3 cm above the isocentre.

Longitudinal range: ≥ 70 cm.

Table top sag: ≤ 5 mm with a patient of 80 kg

Couch movement accuracy: \pm 1mm with 0.1 cm resolution in digital display must be in room and in control console area.

4.8 Control console and treatment room display

Main control Console: computerized controlled console must be provided outside the treatment room.

Control console displays: The control console must have digital displays of gantry rotation, collimator rotation, collimator jaw setting (symmetric & asymmetric) treatment couch motions (lateral, vertical, longitudinal and turn table rotation about isocentre) and accessories attached to the machine

Treatment room monitors:should display important parameters and accessories attached to the machine.

4.9 Supported treatment techniques

Supported treatment fields:Isocentric and fixed SSD fields, photons, electrons, coplanar and non-coplanar fields, asymmetrical collimators with field central axis over-travel, irregular fields shaped with molded blocks, irregular fields shaped with MLCs, Coplanar and planar fields, wedged fields with physical wedges, fields with dynamic wedges, IMRT fields, VMAT fields.

5. System Configuration accessories, spares Consumables and other components

5.1 Beam modifiers:

Physical wedges:

Regular Blocks:

5.2 Mold room accessories

Block Cutter: Hot wire foam cutter

Cerrobend boiler:

Hood: Lamina flow hood for sucking harmful gas out of the mold room when the cerrobend is melting

Perspex glass: Perspex glass trays to support molded cerrobend blocks

5.3 Immobilization devices and accessories:

Breast board/ wing board: At least 4

Combifix with kneefix and feetfix: At least 4

Belly board: At least 2

Prone cushion: At least 2

vac-lok cushions: At least 10

Short head and neck thermoplastic mask(Reinforced style): At least 100

Long head, neck and shoulder thermoplastic mask (Reinforced style): At least 100

Water bath: Wide enough to accommodate the long thermoplastic masks

Vaccum compressor: At least 1

5.4 Patient positioning devices and accessories

Lasers:3 treatment room lasers

Tattooing device: At least 1 with at least 1000 sterile needles

5.5 Dosimetry devices

Farmer type ionization chambers with plastic walls: At least 2, 0.6 ccvolume approximately, with Co-60, 6MV and 15MV energy buildup cap, a 10 m long cable and a 10 m long extension cable with connectors calibrated at a standards laboratory. The chamber model must be included in IAEA dosimetry publications.

Farmer type ionization chambers with graphite walls: At least 2, 0.6 cc volume approximately, with Co-60, 6MV and 15MV energy buildup cap, a 10 m long cable and a 10 m long extension cable with connectors calibrated at a standards laboratory. The chamber model must be included in IAEA dosimetry publications.

Cylindrical ionization chamber: At least 2, 0.1–0.3 ccvolumeapproximately, with a 10 m long cable (maximum electrode diameter: 1 mm)

Check source: A radioactive source for checking the stability of the cylindrical ionization chamber

Plane-parallel ionization chamber: At least 2, for electrons (minimum width of guard ring: 4 mm). The chamber model must be included in IAEA dosimetry publications

Specification for wide Bore CT- simulator

Wide Bore CT Scan: - The wide bore CT scanner is designed to increase quality and service to patients. This technology is a multi-slice computed topography scanner with specialized features. It enables us to prepare and plan treatment with three-dimensional software.

Multi function wide bore CT scanner for radiotherapy simulation , placement of treatment fields and marking of radiation field ports on patient's skin is required

Flat Table

Carbon fiber tabletop construction flat table with indexing facilities

For all kinds of immobilization patient positioning system along entire length of the overlay used in radiotherapy ,identical to that of LINAC in the department

Easily locks and unlock from the CT Table, providing easy transition between therapy and diagnostic procedure

The CT -simulator should have at least three computer controlled moving lasers for marking the field reference points, consists of a single overhead moving laser to project sagittal plane, two moving lasers to project the axial plane this should eliminate couch movement.

The CT scanner should also have conventional in-built lasers for positioning the patient along with all positional device (Laser alignment Lights)

The Detailed Specification of (CT) Planning for Radiation Therapy

- $1.\ Ct$ scanner Whole body spiral , Multi slice (Minimum 32 slices per rotation or more)
- 1.1 Gantry:- Apertures of at least 80 cm, the design should be meet the most demanding radiotherapy procedures like Breast simulation with patient on 15 Degree Breast Board Angle.

Scan filed of view of at least 50 cm or more

Extended field of view of minimum 70 cms for radiotherapy planning should be available.

The Gantry must have built in laser positioning Lights with internal and external scan planes positioning accuracy of +-1 mm or better

1.2 Couch

The couch top material must be fiber with minimum dimension of 235cm X40cm horizontal moving range of 170cm or more

The speed of horizontal movement must be variable with maximum speed 100mm/second, better than table top must be ± 0.25 table longitudinal accuracy with scan able range 150 cm or more.

Maximum load, 180 kg or more

Couch must meet the following vertical movement ranges:-55 to 95 cm when outside the gantry

Within the Gantry it must have a moving range 20cm

The minimum height outside the gantry must be 52 cm +-1 cm

It must able to take maximum weight of 180 kg or more without any change in stated performance specification (like the positioning accuracy)

The couch top must be carbon Fiber flat bed type. Indexed couch top machine the Linac to facilitate accurate treatment delivery with ease and convenience

X-Ray system:

The Generator should be of high frequency type and having adequate power rating output at least 50 kw or more.

The KVP should be in the range of 80kV to 140 Kv or better

The mA range must be from 10 to 500 or better with step size of 5mA or better

Heat Dissipation rate of at least 800KHU /minute or better,

X-Ray tube should be have dual focal spot.

Detectors:

The detector system should be a high performance, low noise high data density ,active response data acquisition system.

The detector should be solid state or latest technology

It should be free from repeated calibration

There should be Multiple rows of detectors for taking a minimum of 32 slice at a time

Scan parameters:

Slice thickness should be at least sub-millimeter.

Kv: 80-140 kV

mA: 10-500 mA increment of 5 mA or better

Retrospective reconstruction should be possible on raw data files with change in parameters such as FOV

The slice thickness should be users selectable starting from 1mm or less.

Scan time for full 360 degree rotation should be 0.5 sec. or less.

Scan field view should be 50 cm or more

Intra-Plan Delay of 5 sec. or less should be possible

Retrospective reconstruction should be possible on raw data files with change in parameter such as FOV.

Starting with a cold tube, the maximum helical scan distance using a 1mm imaged slice thickness and a pitch of 1.5 should be 1500 mm or more.

The following scanning modes should be possible: - Scanogram, Axial and spiral

The scanogram length should be more than 1500 mm long and the width must be at least 500 mm.

It must be possible to obtain the scanogram from AP or PA or left to right or right to left directions

The accuracy of slice prescription from the scanogram should be $\pm\,0.5\text{mm}$ or better

The accuracy of distance measurements in the scanogram (taken at isocenter distance) must be better than $\pm\,0.5$ mm or better than twice the pixel dimension

Reference scan should be possible on an arbitrary slice with the proposed treatment volume.

High contrast spatial resolution: It should be at least 15 lp/cm maximum at 0% MTF.

Low contrast detect ability: 5mm or less @ 0.3% using 20cm CATPHAN on 10 mm slice thickness.

The CT number accuracy must be better than \pm 4 HU for water and \pm 10 HU for air.

Necessary phantoms to check the spatial resolution of the scanner should be provided. A

special phantom to check the electron density - HU relationship for the different body tissues must be provided.

Image Quality:

The reconstruction matrix must be 512 x 512 or higher. The reconstruction time should be as low as possible.

Simultaneous scanning and reconstruction should be possible.

It should be possible to do:

- 1. Simultaneous scanning & routine analysis.
- 2. Simultaneous scanning & archiving and / or hard copying and
- 3. Simultaneous scanning and transfer to second console / workstation.

ii) The system must have automatic mA control software that automatically adjusts mA for patient size, adjust mA along the z-axis, modulates mA during rotation.

Spiral Parameter.

- i) Different selection of pitch should be possible, from 0.5 to 3 in 0.1 increments. Indicate the pitch available. Mention the single run coverage and the table scans able range. Inter Scan Delay in different group of spiral should not be more than 5 sec.
- ii) Intra-plan delay of 5 sec or more should be possible
- iii) Retrospective reconstruction should be possible on raw data files with change in parameters such as FOV
- iv) The following scanning modes should be possible: Scanogram, Axial, Spiral, Cine and biopsy mode
- v) Pilot scan: The pilot scan field size should be more than 1500 mm long. The reconstruction time for pilot scan should be 3sec for a 512 matrix and 5sec for a matrix of larger size
- vi) Reference scan should be possible on an arbitrary slice within the proposed treatment volume
- vii) The table speed to the scan in terms of Z-axis coverage.

COMPUTER SYSTEM OF CT SCANNER:

- i) State-of-the-Art, high end main computer system must be provided. The system must have two processors (parallel), RAM size must be at least 4 GB or better.
- ii) There must be two monitors in the console and they must be 19" LED monitors. One of these will be used for acquisition and the other will be used for review and processing.
- iii) The hard disk capacity of the main computer system must be at least 275 GB or more.

In the hard disk meant for image storage, the number of uncompressed 512 x 512 images that can be stored should be at least 250,000 or more.

The maximum possible hard disk capacity must be provided.

For archiving, DVD writer should be provided for providing copies of individual studies.

The archiving system should provide back up for imaging needs of an average radiology facility for 2 years.

All necessary hard ware and consumables (DVD / DAT cartridges) to be specified and provided. Printer with color laser connected with UPS to be provided.

iv) The CT-Simulator system should be fully DICOM complaint. The DICOM should support the following:

Dicom 3.0 Print service class as a user.

Dicom 3.0 Storage class as a user.

Dicom 3.0 Storage class as a provider.

Dicom 3.0 Send / Receive

Dicom 3.0 Query / Retrieve service class as a user.

Dicom 3.0 Query / Retrieve service class as a provider.

Dicom compliance statement should be provided.

A bi-directional speaker communication must be provided between the operator and the patient.

2B. Computer System for Moving Laser System:

The laser system provided must be 4 moving lasers for marking the isocenter without moving the table top.

Following the isocenter localization in the CT simulator workstation, the isocenter coordinate will be sent directly to the computer system that is controlling the movements of the lasers.

This computer in turn should drive all the lasers, so that without Complete quality assurance tool (as stated above) must be provided. moving the table top, the lasers point to the isocenter.

The control computer system must be Windows XP based system with Pentium 4 processor or higher.

2C. Connectivity:

i) The entire CT Simulation system must be interconnected (all the workstations, laser systems, printers etc.) and must be integrated into the department's any treatment planning systems for smooth transferring of images and DICOM-RT structures including the system to be purchased soon in this year.

The system should be networked with all radiotherapy treatment planning system in the department and necessary software support shall be provided for all existing external beam radiotherapy and Brachytherapy planning.

- ii) Complete import export options and archival facility with third party systems shall be provided.
- iii) Softwares required: Perfusion CT, Lung CT, Bone CT, Virtual endoscopy and CT angiography.
- 3. Essential accessories to be included with the unit:

Sets of patient positioning accessories namely head holder, positioning kit, mattresses (for diagnostic procedures) must be provided.

3A. UPS: On line UPS with MF batteries with rack for the backup of the entire system (i.e. for the complete system including Gantry, computer system, anesthesia delivery system, monitor and defibrillators) for at least thirty minutes.

Broadband connectivity in console, power panel in the electrical room including power cable approx. 100 RM (as per requirement) from the Transformer to the electrical room of the equipment.

- 3B. LASER Camera: Dry laser camera to be provided
- 3C. Lead Glass: 100 cm X 150 cm or more with lead equivalent to meet the AERB"s radiation safety requirements.
- 3D. Pressure Injector: CT compatible pressure injector with remote console 100 disposable syringes.
- 3E. Dose computation & display: The system should display CTDLw (CTDI1 00), DLP
- 3F. Quality assurance accessories and phantom: All QA tools (CATPHAN, Laser Alignment, Diagnostic QA tools etc) of international standard must be provided.
- 3G. 4D Gated Phantom shall be provided.
- 3H. Remote diagnostic monitoring: Remote diagnostics tool and software should be included along with internet connection for on-line remote diagnosis. All such running costs will be at suppliers account for the duration of warranty and CMC.

3 I. Reputed brand supporting furniture, air conditioners for the machine room, control console and for the additional workstations must be provided along with the unit.

CT SIMULATION WORK STATION:

GENERAL:

The workstation should have advanced CT simulation tools for radiation therapy treatment planning with dose calculation engine including workstation that can control the laser marking system.

Any CT-simulation workstation that cannot control the laser marking system is not acceptable and liable to be rejected.

The supplier should give a completed description about the laser marking system offered and how the CT-Simulation software integrates with it and TPS

All necessary calibration / quality assurance phantom / check device should also be provided,.

The workstation should be able to provide complete volume definition and geometric beam placement for radiotherapy.

It should have complete compatibility and error-free networking with the CT scanner computer and TPS.

The CT Simulator technology should backup the existing Brachytherapy system in the institute pertaining TPS and IMRT Interstitial applications.

The CT-Simulation should generate digitally reconstructed radiographs (DRRs) in a true volumetric environment.

It should be possible to overlay the beams on any DRRs or on any slice (obtained and reconstructed).

It should be possible to load over 250 CT images per patient for reconstruction and simulation.

HARDWARE:

a. Hardware specification should be mentioned clearly the system should be running on a high-end workstation platform of reputed brand like "Sun micro system / H.P. Workstation/Del/Silicon Graphics with at least 4 GB RAM or more.

Minimum 128 bits processor with minimum of 275GB hard disk or more.

- b. Networking with TPS All the software with licenses required should be included.
- c. Laser Printer should be provided.
- d. It should be possible to take printouts on this printer from any of the CT Simulation workstation.

Software:

- i) Complete software doing all the functions of CT simulator as per requirement and should have following features :
- ii) Software should be Unix / Window / Silicon graphics based system.
- iii) The software should have a volume accelerator for high speed 3D rendering at full spatial resolution.
- iv) On the monitor screen it should be possible to view at least 36 images or more.
- v) The standard screen layout should consist of one main view port and three Sub-view ports for frequent usage of other images, quick manipulation of Images, or for displaying reference views, while the main view port is used for high resolution display.
- vi) Image manipulation such as changing window width and window level, hot keys activated automated study archive, deletion, screen layout changes, disk space display, archiving, and graphic overlays such as annotation.
- vii)It should be possible to simulate all kinds of teletherapy machines in the simulation workstations. It should conform to IEC and other international standard norms and support cobalt therapy, linear accelerator of all types, and other user defined linear accelerator and compatible with multileaf collimator of all the suppliers.
- viii) It should be possible to visualize interactive reference views in axial, coronal, sagittal, isocenter image planes and in any oblique directions with overlay of beams on DRRs.
- ix) DRR must provide fully divergent beam's eye view of 512x512 matrix.
- x) The DRR/BEV and Room Eye View image should display the machine diagram to allow real-time checking of machine and patient geometry.

xi) Facility for multi modality fusion to accept the data from other DICOM compatible and DICOM supporting modalities such as MRI/CT/SPECT/PET should be able to fuse them.

Respiratory Gating software: The machine should have both prospective and retrospective respiratory gating module.

CONTOURING:

- i) Volume definition should be possible using volume segmentation using threshold. Free hand contour tracing, contour editing. 3D anisotropic margins etc and any other advanced tools.
- ii) System must be able to contour in axial, sagittal, coronal and oblique projections.
- iii) It should be possible to do manual, semi-automated, fully automated contouring/segmentation in the images by defining volume of interest.
- iv) Time taken for automated contouring with a single mouse operation for 50slices should be provided
- v) The software should have facility for automated uniform or non-uniform margins.

For example it should be possible to expand the clinical target volume (CTV) on all three dimensions by same magnitude or by different magnitude to define the planning target volume. (PTV).

Any software without this automated uniform/non-uniform feature will be considered as inadequate.

- vi) It should be possible to copy one organ to another with margin, and margins on a single slice, a range of slices or all slices
- vii) It should also be possible to interactively edit the contours with user"s choice of segments to reject or accept.
- viii) Interpolate algorithm should be available to provide interactive, shape based interpolation after contouring only in selected slices. The algorithm should automatically interpolate the closely fitting contour in other slices.
- ix) Interpolated contour may be edited; accepted or rejected.
- x) Tracking of source to skin distance should be possible.
- xi) Contouring and editing and extraction of wall should be possible.

ISOCENTER MANAGEMENT:

- i) The software should support separate isocenters for multiple target volumes or general regions.
- ii) Marked and final isocenters should be reported and displayed in the localization package for easy confirmation of a physical simulation session.
- iii) Hardcopy of the isocenter coordinates should be possible for record of the simulation session.
- iv) Isocenter positioning should be automatic.
- v) No limit on number of isocenters per target

3-D VIEW AND VOLUME RENDERING CAPABILITIES:

- a) Post processing features like volume rendering, real-time multi-axial volume reconstruction, 3-D surface rendering. Color wash 3D should be available.
- b) It should allow completed 3D volume to be defined including complex 3D volumes, user selectable multi-image views, beams eye view, room eye and DRR.
- c) DICOM Radiotherapy plans and data structure with import/export of data should be possible.

The DICOM compliance statement should be provided.

d) Accuracy of locating any point in 3-D should be 0.1 mm or less.

BEAM PLACEMENT & DEFINITION:

- A. If should support extensive beam shapers (shielding blocks etc) and beam definition methods.
- B. Manual or automatic beam placement tool.
- C. Tools for real time checking of machine geometry.
- D. Beam shaping should be possible in multiple ways like automatic shielding block, definition conforming to selected volume, definitions aperture or shielding manual free hand definition, automatic collimator jaw or multileaf position definition.
- E. It should be possible to define this asymmetric collimator feature, where both the Xand Y-axis of jaws are asymmetric, in the CT simulation software.

Similarly the software should allow multi-leaf-collimator placement up to 40 pairs or more.

Any software that cannot handle 40 pairs of MLC leaves is not acceptable.

DRR FEATURES:-

- A. Interactive DRR calculation mode must be available.
- B. Automatic window width/level selection for DRR.
- C. DRR should be interactively updated when the isocenter position is modified.
- D. Should be possible to highlight or suppress different density region in the DRR.
- E. Printing of DRR images should be possible. DRR should be user defined.
- F. Marco function to save a series of frequently used steps should be available.
- G. DRR image enhancement tools to improve DRR image quality.
- H. Reconstruction of DRRs should be real-time or in sub-seconds.
- I. Direct printing of DRR on laser film should be possible.
- J. Real time display of DRR as beam parameters changes.

DEPTH CONTROL:

- A. System should support depth control mode creating a DRR from slab of 3-Dmode, perpendicular to beam axis.
- B. DRR must be calculated over a user-defined thickness.
- C. Depth control in oblique projections must be possible.
- D. Should be possible to merge two DRR image on the same beam.
- E. Cross-hair display on DRR to provide scale information.

DATA IMPORT / EXPORT:

- A. System should be able to export image, volume and plan data in DICOM 3.0 standard along with all Radiotherapy specific data and private objects, DICOM RT plans and data sets.
- B. System should be able to export DICOM RT data to the linear accelerator of any supplier.
- C. CT simulator system should be fully integrated with the existing TPS.

The supplier should inspect and will be responsible for complete integration.

D. All import and export licenses should be provided.

MEASUREMENT PACKAGE:

- A. The software should provide the density value (in Hounsfield unit) of a particular point on an image. It should compute distance along straight lines and curved lines, angles between the lines, and radius of curvature for curves.
- B. For a specified region of interest, ROI, the area, minimum and maximum voxel values, mean and standard distribution and a density histogram should be available.
- C. The software should be able to calculate the volume of a displayed 3-D object.

Additional Workstations: Two additional workstations for contouring and plan evaluation shall be provided by supplier.

Power Supply:

Should work on three phase 380V/50 Hz

Online UPS of suitable rating should be supplied for the complete system including Gantry, computer system, anesthesia delivery system, monitor and defibrillators with at least 30minutes back up

Reset-table over-current breaker shall be fitted for protection

6. Operating Environment;

Room Planning and designing and construction. Space requirements to be spelt out in advance

Electrical Requirements to be specified and substation to be made.

All AERB Clearances and Environmental clearances to be arranged with local authorities.

Institute will provide all the documentations.

Cooling water temperature, flow and pressure monitoring to be installed.

Air Conditioning and monitoring of Temperature; Relative Humidity and Air changes to be installed.

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

Shall meet IEC- 60601- 1- 2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC; EMC- directive.

7. Utility Requirements:

Three phase 380V / 50Hz Power

UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up for whole Linear Accelerator Systems (including associated TPS, server etc.)

Resettable over current breaker shall be fitted for protection as required

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Machine shall be typed approved by A.E.R.B.

The unit shall meet all the radiation safety standards & Quality Assurance of its mechanical, electrical and electronic provisions set by regulatory bodies (AERB).

System shall have all safety interlocks as per AERB guideline.

Company shall provide certificate of trouble free operation of machine for five years from existing five users.

It shall be brand new machine. Supporting documents to be furnished.

Company should provide the certificate of life of machine.

Company should provide the list and cost of spares for five years after warranty period.

Company should give the undertaking for supply of spares till machine life.

Company should provide the list of 3rd party supply with manufacturer name, address and warranty period.

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The Linear accelerator Systems Including consumable, software, treatment planning systems and dosimetric Equipment shall have warranty/guarantee of 24 months + extended warranty of another 36 months + 60 months of CMC from the date of commissioning approval, certificate against manufacturing defects of materials and workmanship.

Software up- gradation with all added features should be provided free of cost for warranty period.

Company should be responsible for commissioning and handing over the machine to institute/ health facility in fully running (proper working) condition.

Company should make availability of spares for ten years.

Networking and configuration with existing & procured equipment should be done by suppliers at their own cost. No extra payment will be made to supplier for this work.

The company should be responsible for installation, commissioning, maintenance and down time of the machine, software, accessories and networking which will help directly and indirectly in proper functioning of the machine.

Company should provide the installation & commissioning.

Chiller room responsibility (installation, maintenance, off time etc.) should be of company.

Chiller room architectural drawing and other details should be provided by company.

B. Other details:

Construction and electrifications of complete linear accelerator room & associated facility as per AERB norms will be sole responsibility of supplier.

Associated facility includes: T.P.S. room (5X5m2), Patient waiting area (10X10m2), Patient review room (5X5m2), UPS, chiller and Air handling room. Supplier must visit the site/department for inspection of area, construction and scope for any modification

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

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11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Diam-90	1. Generic Name: Dialysis Machine	Dialysis Unit
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description:	
	A process of purifying the blood of a person whose kidneys are not working normally. Achieves removal of waste products such as potassium, urea and free water from the blood when the kidneys are in a state of kidney failure.	
	4. Technical Specification:	1
	Touch screen/button control with digital display	1
	Should have inbuilt battery for 30 min	
	Facility to show trends curve of all parameter	1
	Automatic self test facility	
	Extracorporeal circuit	=
	Arterial pressure range: -280 mmHg to + 400 mmHg or wider range, Accuracy: ±10mmHg	_
	Venous pressure range: 60 mmHg to + 380 mmHg or wider range, Accuracy: ±10mmHg	
	Trans membrane pressure: -60mmHg to +400 mmHg or wider range, Accuracy: ±10 mmHg	
	Blood pump: Peristaltic pump	
	Blood flow range: 50 to 500 ml/min in 8mm size tube, Accuracy: ±10%	
	Air bubble detector: Ultrasound method, monitor the entire operating phase	
	Alarm Indicator: Traffic light to indicate the status such as bypass, air leak, blood leak, dialysis temperature, etc	
	Dialysis Fluid system	
	Dialysis fluid flow range: 300 - 800ml/min, selectable	
	Dialysis fluid temperature: 35°C to 39°C, Accuracy: ±0.2%	
	Blood leak detector: Optical detector, color specific	
	Ultra filtration rate: 0 to 4.00 L / hr (higher range is acceptable), Accuracy: \pm 3%	
	Dialysis fluid filter system: Endotoxin filter	
	Disinfection and Cleaning program: Rinse, Hot cleaning and Hot disinfection cycles are required.	
	Use recommended chemicals at a temperature of min 84°C.	
	Blood pressure monitor facility	
	Supplied with endotoxin filter	
	Indicating Real time Kt/V measurement	7
	System shall have Heparin Module	1
	Dialysis chair	7

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Multi positioning electro hydraulic operation with stable base

Chair height adjustment

Chair back fully reclines to the horizontal position

Chair foot area rises to the Trendelenburg position

Hand held control unit for easy adjustment of chair/recliner two large adjustable arm rests

Large stable vein puncture platform also promotes patient comfort

Cleanable and sanitized

Stainless steel frame

Premium medical grade treated vinyl upholstery

Replaceable clear protective cover foot areas

Securely balanced in all operational position

Both side armrest extension

Arm set fold to allow side entry of the patient

Arm extensions must provide visibility of elbow region, be large enough to securely support when puncture be refracted in case of patient collapse.

Minimal bending for vein puncture

Rapid and Easy adjustment from sitting to relining supine and Trendelenburg position

Easy repositioning and lock to secure safety in operation

Provision for railing

Carrying capacity: 180kg

Seat dimension: 200 x 60 x 60-90 cm (L x W x H)

Trendelenburg position: 12⁰

CPR support

Headrest

Cushioned seat

Cushioned arm rest

Reclined base to floor

Leg support

Water Treatment system

Designed for maximum saving of raw water, with high efficiency

Raw water storage tank that can support 30 dialysis machines

At least 20 x 60 inch Multimedia Filters with automatic control head

At least 20 x 60 inch Water softener, single or duplex with automatic head

Product storage tank that can support 30 dialysis machines

At least 20 x 60 inch Carbon filters with automatic control head

Complete pressure reading, flow, temperature monitoring

Visual and Audible alarms: Conductivity, water quality

Visual and Audible displays of operations status at location and at Nurse Station

Ultraviolet Disinfection

All pretreatment modules programmable backwash and regeneration facility

Compact in sleek cabinet, housing membrane, and high pump and bypass mechanism.

Reverse Osmosis

Double pass or double stage

Produce water 2 times higher than required

Film tech Membranes with housing

With Multi stage vertical pump with back up Distribution system

Stainless Head Pump with back up pump

Motorized ball valve for automatic recirculation system

Made of high medical grade material

Primary loop with minimal number of joints

Disinfection of membrane and distribution loop

Heat resistant for hot disinfection

Smooth interior

Drain piping with air gap

Fully automated control system

Automatic activation of backup system

Output water quality match AAMI (Association for Advancement of Medical Instrumentation) standards for hemodialysis

5. System Configuration Accessories, Spares and Consumables

Venous blood Clamp

Blood tubing compatible for the machines

Dialyzer poly sulphone steam/gamma ray sterilized different sizes

Fistula needle different sizes

Acid concentrate

Bicarbonate cartridge /powder/

Hemodialysis catheter temporary and permanent different size

Semi-automatic renal biopsy needle

Plasma filter gamma ray sterilized

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning should be included.

6. Operating Environment;

Operating Temperature: +10°C to +40°C

Relative Humidity: <85%

7. Utility Requirements:

Power Supply: 110-220VAC, Frequency: 50/60Hz

Electromagnetic compatibility: EN 60601-1-2: (IEC 601-1-2)

UPS with stabilizer for 1hr backup

Inlet water pressure: 1.5 - 6 bar $\overline{\text{max}}$

Water temperature range: 5°C to 30°C

Concentrate supplies: Canister / Cartridge / Bags

Document: Capital Medical Device Technical Specification

Version 1: November, 2019 G.C.

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation/Training/Commissioning:

The supplier must provide Installation, technical and end user training on site.

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Xfcd-90	1. Generic Name: C-arm fluoroscopy x-ray machine, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	It used for cardiac, orthopedics, vascular, trauma, spine and general surgery procedures.	
	4. Technical Specification:	
	Fully counterbalanced C-arm with compact flat detector.	
	Integrated operator control panel with 12" color LCD/TFT monitor for positioning the system.	
	Hand switch and/or foot switch control.	
	Radiation indicator.	
	system lock for x-ray control	
	C-arm mobile stand	
	Orbital movement:125° (-35° to +90°)	
	Angulations: ±190°	
	Horizontal movement: 20 cm (7.9") or more	
	Swivel range: ±12°	
	Vertical Travel: 40 cm (15.7") or more	
	Source to Image Distance (SID): 86 cm (33.8")	
	Immersion depth: 63.5 cm (25")	
	Lateral movement: steering wheel	
	Integrated laser for radiation free positioning of C-arm	
	Automatic Exposure Control (AEC)	
	X-ray generator	
	High-frequency generator with power output 15kW or more	
	kV range: 40 kV to 120 KVp, with KVp accuracy of ±10%	
	mA range: 5mA to 100mA	
	Radiography parameters	
	kV range: 40 kV to 120 kVp	
	mA: 5 mA to 100 mA	
	mAs: max. 300 per exposure	
	Exposure Time: For patient exposure ≤1s and For tube capacity up to 5 s	
	Fluoroscopy Parameters	
	Continues fluoroscopy mode	
	kV range: 40 kV to 120 kVp	
	mA range: up to 12mA	
	Pulsed fluoroscopy mode	

kV range: 40 kV to 120 kVp

mA range: up to 30mA

Continues with road map and Pulsed with real time subtraction facility for Digital Subtraction Angiography (DSA) should be provided as standard

X-ray tube

Dual focus rotating anode

Small focus: 0.3mm Large focus: 0.6mm

Tube voltage: 40-120Kvp

Anode heat capacity: 300KHU

Anode cooling rate: 60KHU/min.

Flat Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector size: 26 cm x 26 cm or more.

Pixel size: 155 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero Line pairs or more.

at least three user selectable input fields

Integrated laser localizer

Active matrix size: 1.5k x 1.5k or more.

5.2 Mobile View Work Station

Compact and light weight design with mobile castors for easy maneuverability

Monitors height should be adjust for the convenient of surgeons position: up to $20\ \mathrm{cm}$

Monitors rotate 170° for optimized viewing angle in horizontal and vertical direction

An injection trigger for contrast media

Connectivity:

Digital video output: 2 DVI connectors enables image display on external monitors

Video input: displays external video signals like ultrasound images on the right monitor.

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.

Storage of 30,000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM

System should be ready DICOM interface and have networking capability

DICOM print

DICOM store -enables image transfer to DICOM compliant workstations for off-line processing of images, store images/runs on CD-R to PACS system and to PC

Document: Capital Medical Device Technical Specification

Version 1: November, 2019 G.C.

DICOM Modality Work list Management (DMWM) for communications with HIS/RIS system

DICOM Modality Performed Procedure Steps (DMPPS)

Monitor:

Two 19" high brightness LCD/TFT color monitors for live image display, Last Image Hold and stored memory display.

Resolution: 1280 x 1024 pixels

Touch screen system control and with external keyboard should be supplied

Anti-glare

Image acquisition and image processing

The digital workstation should be based on the latest high speed processors of at least 64 bit.

Patient data management; Electronic record with name, date, anatomy, etc.

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold

Video invert

Annotation (text, trace ,arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc..

5. System Configuration Accessories, Spares, Consumables and other components:

C-arm Fluoroscopy unit with x-ray generator, x-ray tube ----1

Flat panel detector---1

Mobile view workstation with two monitors---1

All software packages for cardiac, trauma, vascular, orthopedics, spine, general and other procedures should be provided as standard

A CD-R/W based long term archiving with envelope----1000

External key board----1

UPS for mobile view workstation and C-arm----1

Whole body lead aprons with 0.5 mm, 0.35 mm, 0.25 mm lead thickness (or equivalent) ----2 of each

Thyroid guard--3

Gonad shield with small, medium, large size---2 of each

Eye Goggle---3

Lead Glove—3 pair

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media)

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards & Safety Requirements:

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

The machine should be fresh product

The machine should compliant with IAEA safety standards

9. Installation/Training/Commissioning

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty/ After sales service:

The supplier must be provided minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Xrrd 90	1. Generic Name: X Ray - Radiography, Digital with fluoroscopy	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	-
	Digital Radiography Machine used for imaging of internal structures of the body	
	4. Technical Specifications:]
	A fully digital radiography system capable of detector exposure in vertical, horizontal and oblique positions to perform general radiography Completely integrated (integrated Generator and Image Acquisition) and auto quality control features incorporated	
	System should have Automatic Exposure Control (AEC)	
	Automatic brightness control (ABC) function	
	System must have a method of measuring and recording patient absorbed dose (Dose Area measurement system)	
	System should have Anatomical programming radiography (APR)	
	System should have over load protection feature	_
	System should have switch on x ray indicator	_
	Generator:	
	Generator should be of high frequency inverter technology for constant output and lowest radiation doses.	
	KV range: $40 - 150$ KVp, with KVp accuracy of $\pm 10\%$	
	Protection level against electric shocks: type B	_
	mA range: 10 to 1000 mA (with 16 values of high voltage current adjustment)	_
	Power: 65 - 85KW	<u> </u>
	mAS maximum: 600 per exposure	
	The X-ray exposure time (radiography time) should be automatically adjusted	-
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	
	Digital Fluoroscopy:	_
	Real-time optimization techniques to maintain constant brightness at the lowest allowable dose to the patient.	
	Continues with road map and Pulsed with real time subtraction facility for	
	Digital Subtraction Angiography (DSA) should be provided as standard	4
	Direct digital imaging system for fluoroscopy	4
	Last image hold facility during fluoroscopy The standard continuous fluoroscopia operating mode from single image.	4
	The standard continuous fluoroscopic operating mode from single image display to serial exposures with varying frame rates up to 15 fps	
	Foot switch for fluoroscopy and acquisition.	1
	Having independent fluoro KVP and mA selector	

Continuous fluoroscopy mode

mA range: up to 12mA

kV range: 40 kV to 120 kVp

Pulsed fluoroscopy mode

kV range: 40 kV to 120 kVp

mA range: up to 30mA

X-Ray tube and collimator:

X ray tube should be floor mounted for fluoroscopy and ceiling mounted for radiography purpose

Floor mounted, with longitudinal movement not less than 140cm and lateral movement not less than 24cm

Tube rotation vertical and horizontal angle: 270° (+180°/-90°)

X-ray tube anode heat monitoring with thermal switch control

Multi leaf collimator having halogen/bright light source with auto shut provision for the light

High speed rotating anode compatible with the generator

Over loading protection feature

Dual focus rotating anode with spot sizes less than 1.3mm

Anode heat capacity: 300KHU or more

Auto-tracking with detectors and collision protection sensors

All movements electromagnetic brakes with fully counter balanced mechanism

Provision for auto positioning, auto synchronization and auto centering with vertical Bucky and table

Adjustable multi leaf collimation system

Automatic shut-off timer to preserve the collimator field lamp.

Has a rectangular light field with cross hair markings and lamp/timer feature

With cross hair centering and pre-indication of field sizes at certain source to image distance (SID)

Radiographic Table:

Integrated Bucky unit for flat panel detector

Grid ratio: 10/1

Film to Focal Distance (FFD): 100cm

Balanced at counter weight

Table movement: 4 ways with breaks

The table must have easy access from both sides (for patient transfer purposes and cross table imaging)

The table Bucky must include automatic exposure control

The table must have foot activated locks for hands free position

The table should be mounted on high quality fiber wheels with brakes

Horizontal table with carbon fiber table top of minimum 210cmx80cm

The tabletop move in the lateral direction and the imaging system move in the longitudinal direction.

The table tilts from the upright vertical position (+90°) to the horizontal

position (0°) to the head-down-tilt position (-15°)

Allowable patient weight: Min. 200kg

Facility for tracking with X-Ray tube.

Provision for collision protection.

Flat panel Detector System:

Separate detector for table and Bucky

Flat panel wireless detector solid state technology or latest with cesium iodide scintillator

Detector size: 43 cm x 43 cm or more

The detector should be movable to the entire length of the table

Pixel size: 148 um or less.

Facility of tracking with X-Ray tube

Detector Quantum Efficiency (D.Q.E) 65% or more @ Zero Line pairs

Active matrix size: Aprox. 2.8k x 2.8k

Minimum image depth of 16 bit

The machine a detector storage compartment

Vertical Bucky Stand

Grid ratio: 10/1

Film to Focal Distance: 140cm

Balanced at counter weight

The unit should be provided with vertical Bucky having tilting facility across +90 degrees

A detector capable to take digital images in horizontal, vertical and oblique positions

Provision to do chest radiography without grid

Control Console

With technique selector and digital display for KV, mAs and/or mA and exposure time

Auto Bucky Selection switch

Auto tube focal spot selection switch

Audiovisual indication of the x-ray exposure

Provided with hand switch for control of radiographic exposure.

Tube readiness for exposure

Self diagnostic Programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc..

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6

Document: Capital Medical Device Technical Specification

GHz processor, 32GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Image acquisition and image processing workstation:

A separate workstation for image positioning and patient demographic data

The digital workstation should be based on the latest high speed processors of at least 64 bit.

The processing station must have 8 GB RAM, Intel multi core latest generation, at least 1TB, HDD and 19 inch or higher medical grade high definition color display TFT/LED touch screen monitor with external keyboard and all necessary software package

The machine an integrated workstation with a color display TFT touch screen monitor.

Real-time image processing: Digital Compensation Filter and Super Noise Reduction Filter

The server provide full amount of post processing features viz. geometric corrections, window level algorithms, annotation like markers, predefined text, drawing lines and geometrical shapes, multi-scale image processing, measuring distance and angles, shuttering, histograms, zoom, grey scale reversal, edge enhancement, noise reduction, indication of gray scale saturation level, latitude reduction.

The post processing features should also include contrast and brightness adjustment, storage of image with a memory of at least 200,000 images.

The machine should be fully network ready and it should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless connectivity

Read and Write in CD/DVD for data Storage and review

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, spares and consumables

X-ray generator -----1

X-ray tube one for floor mounted and one for ceiling mount

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Bucky stand ----1

Radiographic table---- 1

Flat panel detector----2 (One for the Bucky stand and one for the radiographic table)

UPS with stabilizer for complete system---1

Image acquisition Workstation ---- One main and one additional fully networked workstation with high resolution

Archiving System (PACS) with four monitors ----1

CD-R/W based long term archiving with envelope-----10,000

Exposure switch----2

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Lead glass of 2mm lead thickness (or equivalent) with frame -----1

Lead Glove----3

Lead door as per room requirement

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, etc...)

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}$ C to $+40^{\circ}$ C

Relative Humidity: <85%

7. Utility Requirements:

Suitable Power input to be 380VAC, 50Hz

Suitable UPS with stabilizer for 30 minutes backup

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General electrical safety Requirements

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation, Training and Commissioning

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training.

Turnkey works

The Supplier is responsible to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include but not limited to the following:

a). Radiation safety:

Proper X-Ray shielding lead lined door of 2mm thickness (or equivalent) should provided for the main equipment.

Proper lead glass window of 2mm lead thickness (or equivalent)

Red Warning Light 220V Above Exposure Room Door

b). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (grounding should be included)

Three phase breaker with size as per manufacturer recommendation

c). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

d). Network:

Network Outlet provided on the control and 4 doctors room and connected and working

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Xrad -90	1. Generic Name: X Ray - Radiography, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Digital Radiography Machine used for imaging of internal structures of the	
	body made by electromagnetic radiation passing through the body.	
	4. Technical Specifications:	
	A fully digital radiography system capable of detector exposure in vertical, horizontal and oblique positions to perform general radiography	
	Completely integrated (integrated Generator and Image Acquisition) and auto quality control features incorporated	
	Read and Write in CD/DVD for data Storage and review	
	System should have Automatic Exposure Control (AEC)	
	System must have a method of measuring and recording patient absorbed dose (Dose Area measurement system)	
	System should have Anatomical programming radiography (APR)	
	System should have over load protection feature	
	System should have switch on x ray indicator	
	Generator	-
	Latest high frequency inverter technology for constant output and lowest radiation doses.	
	KVp: 40 – 150, with 1KV increment, and KVp accuracy of ±10%	
	Protection level against electric shocks: type B	
	mA range: 10 to 1000 mA (with 16 values of high voltage current adjustment)	
	Power: 65-85KW	•
	mAS maximum: 600 per exposure	
	The X-ray exposure time (radiography time) should be automatically adjusted	•
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	
	Over load protection feature	
	X-Ray tube and collimator	
	Floor mounted, with longitudinal not less than 210cm and lateral movement not less than 24cm	
	Dual Focal spot sizes of 1.3mm sq. or less	1
	Tube stand vertical movement is 120 to 180cm	1
	Tube rotation angle: ≥ ± 120°	1
	X-ray tube anode heat monitoring with thermal switch control	1
	High speed rotating anode and dual focus tube compatible with the generator	1
	Over loading protection feature	1
	High speed rotating anode dual focus tube compatible with the generator	1

Anode heat capacity: 300KHU or more.

Housing Material: built in material resistant to blows and falls

Multi leaf collimator having halogen/bright light source with auto shut provision for the light

Adjustable multi leaf collimation system with SID laser localizer

Automatic shut-off timer to preserve the collimator field lamp.

Has a rectangular light field with cross hair markings and lamp/timer feature

With cross hair centering and pre-indication of field sizes at certain source to image distance (SID)

Radiographic table:

Integrated Bucky unit for flat panel detector

Grid rate: 10/1

Film to Focal distance (FFD): 100cm

Balanced at counter weight

Table movement: 4 ways with breaks

The table must have easy access from both sides (for patient transfer purposes and cross table imaging)

The table must have foot activated locks for hands free position

The table should be mounted on high quality fiber wheels with brakes

Horizontal table with carbon fiber table top of minimum 210cmx80cm

The tabletop move in the lateral direction and the imaging system move in the longitudinal direction.

Allowable patient weight: Min. 200kg

Flat panel detector

Flat panel wireless detector solid state technology or latest with cesium iodide scintillator

Separate detector for table and Bucky

Detector size: 43 cm x 43 cm or more

The detector should be movable to the entire length of the table

Pixel size: 148 um or less

Facility for tracking with X-Ray tube

Detector Quantum Efficiency (D.Q.E) 65% or more @ Zero Line pairs

Active matrix size: approx. 2.8k x 2.8k

Minimum image depth of 16 bit

The machine a detector storage compartment

Vertical Bucky Stand

Grid ratio: 10/1

Film to Focal distance (FFD): 140cm

Balanced at counter weight

The unit should be provided with vertical Bucky having tilting facility across +90 degrees

Control Console:

With technique selector and digital display for KV, mAs and/or mA and

exposure time

switch on indicators

Auto Bucky Selection switch

Auto tube focal spot selection switch

Audiovisual indication of the x-ray exposure

Provided with hand switch for control of radiographic exposure.

Tube readiness for exposure

Self diagnostic Programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc..

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6 GHz processor, 32GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Image acquisition and image processing workstation:

A separate workstation for image positioning and patient demographic data

The digital workstation should be based on the latest high speed processors of at least 64 bit.

The processing station must have 8 GB RAM, Intel core i7 latest generation, at least 1TB, HDD and 21 inch or higher medical grade high definition color display TFT/LED touch screen monitor with external keyboard and all necessary software package

The machine an integrated workstation with a color display TFT touch screen monitor.

Real-time image processing: Digital Compensation Filter and Super Noise Reduction Filter

The server provide full amount of post processing features viz. geometric corrections, window level algorithms, annotation like markers, predefined text, drawing lines and geometrical shapes, multi-scale image processing, measuring distance and angles, shuttering, histograms, zoom, grey scale reversal, edge enhancement, noise reduction, indication of gray scale saturation level, latitude reduction.

The post processing features should also include contrast and brightness adjustment, storage of image with a memory of at least 200,000 images.

The machine should be fully network ready and it should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless connectivity

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, spares and consumables

X-ray unit with x-ray generator, x-ray tube -----1

Bucky stand ----1

Radiographic table---- 1

Flat panel detector----2 (One for the Bucky stand and one for the radiographic table)

UPS with stabilizer with 30 minutes backup---1

Image acquisition Workstation ---- One main and one additional fully networked workstation with high resolution

Archiving System (PACS) with four monitors----1

CD-R/W based long term archiving with envelope-----10,000

Exposure switch----2

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Lead glass with frame -----1

Lead door as per room requirement

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (if any)

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}$ C to $+40^{\circ}$ C

Relative Humidity: <85%

7. Utility Requirements:

Suitable Power input to be 380VAC, 50Hz

8. Standards & Safety Requirements:

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation, Training and Commissioning

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training.

Turnkey works

The Supplier is responsible to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include but not limited to the following:

a). Radiation safety:

Proper X-Ray shielding lead lined door of 2mm thickness (or equivalent) should provided for the main equipment.

Proper lead glass window of 2mm lead thickness (or equivalent)

Red Warning Light 220V Above Exposure Room Door

b). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (grounding should be included)

Three phase breaker with size as per manufacturer recommendation

c). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

d). Network:

Network Outlet provided on the control and 4 doctors room and connected and working

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.
Name and Model of the product
PO Box 25-11-276-32-66
Tel: +251-11-276-32-66
Fax: +251-11-275-25-56
Addis Ababa

Base Code	Item Detail	Department
Xrmd-91	1. Generic Name: X ray - Mobile, Digital	Imaging
	2. GMDN/UMDN Name/ Code:	
	3. Clinical Purpose/Description	
	Clinical Purpose/Description: A compact, light weight device used in emergency, trauma and ICU departments as well as operating theaters for conventional radiography	
	4. Technical Specification:	
	Mobile stand	
	Compact and light weight design with mobile castors for easy maneuverability	
	Fully counterbalanced with compact flat detector	
	Backup battery with continues operating time of 2hrs/100 exposures	
	Dose area measurement system	
	Automatic exposure control	
	KV, mA increase & decrease	
	Effective braking system for parking, transport and emergency.	
	Articulated arm for maximum positioning flexibility in any patient position.	
	Emergency stop button	
	Standby and exposure release switch	
	Ready and X-Ray on switch with Indicators	
	All cables shall be concealed in the arm system	
	Storage facility for flat panel detector and other supplies	
	Digital display of kV, mAS and/or mA and time	
	X-ray generator:	
	High Frequency generator without put power 25Kw	
	kV range: 40-125Kvp	
	mA: 20 mA to 320 mA	
	mAs: max. 280 per exposure	
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	
	Self diagnostic programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc	
	X-ray tube and collimator:	
	Output should match the output of the generator	
	Dual focus rotating anode with spot size less than 1.3mm	
	Tube focal spot selection Switch	
	Total filtration: minimum 2 mm Al	
	Tube voltage: 40-125Kvp	

Anode heat capacity: 300KHU

Anode cooling rate: 40KHU/min.

Tube horizontal movement: 45 cm or more

Tube vertical movement: 100 cm or more

Adjustable multi leaf collimator with SID laser localizer

Collimator lamp on switch

Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector active size: 35cm x 43cm or more.

Pixel size: 148 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero LP/mm or more.

With at least two user selectable input fields

Active matrix size: 2.8k x 2.3k

Image acquisition and image processing:

Shall have integrated 17" high brightness LCD/TFT color button/touch screen monitor.

The digital workstation should be based on the latest high speed processors of at least 32 bit.

Patient data management- Electronic record with name, date, anatomy, etc..

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold

Annotation (text, trace, arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc..

Connectivity:

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.

Storage of 3000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM:

System should be ready DICOM interface and have networking capability

DICOM print

DICOM store enables image transfer to DICOM compliant workstations for off-line processing of images, store images/runs on CD-R to PACS system and to PC

DICOM Modality for communications with HIS/RIS system

DICOM Modality Performed Procedure Steps (DMPPS)

5. System Configuration Accessories, Spares, Consumables and other components:

Main unit with x-ray generator, x-ray tube----1

Flat panel detector----1

All software packages shall be provided as standard

A CD-R/W based long term archiving with envelope----10,000

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ---- 2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}$ C to $+40^{\circ}$ C

Relative Humidity: <85%

7. Utility Requirements:

Power input: 220V/ 50Hz

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device

The supplier must provide sufficient technical and end user training on site.

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including Labor, X-ray tube, detectors and spare parts and accessories from the date of installation as well as after sale services.

The supplier must provide extended warranty from 3rd year to 5th year inclusive of labor, spare parts, accessories, detector and X Ray tube.

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency

(EPSA)
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Base Code	Item Detail	Department
Ultec-90	1. Generic Name: Electrotherapy modalities (TENS, Ultrasound &	Physiotherapy
	Combination therapy)	
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	- TENS: A medical device use electric current to stimulate the nerve for	
	therapeutic purpose and to reduce acute and chronic musculoskeletal	
	pain.	
	- Ultrasound therapy: The use of high frequency vibration sound wave	
	that can breakup stony deposits or tissues, accelerate the effect of drugs in targeted area and assist in the measurement of the elastic properties of	
	tissue.	
	4. Technical Specification:	-
	Adjustable digital timer, auto shut off buzzer	1
	The unit should be user friendly and ergonomically designed	-
	The unit Shall have LED color screen to display all parameters	-
	The unit Shall have contact treatment control	_
	The unit should be portable/ mobile on trolley, operated by mains power	-
	supply	
	The unit Shall have on/off switch	-
	Ultrasound therapy:	-
	The use of high frequency vibration sound wave that can breakup stony	<u>-</u> -
	deposits or tissues, accelerate the effect of drugs in trageted area and	
	assist in the measurement of the elastic properties of tissue.	
	Ultrasound modes: pulsed and continues	
	Ultrasound frequency: 1 and 3 MHz	
	Pulse frequency: approx. 10Hz to 100 Hz	
	Intensity: 1 – 3 w/cm ²	
	Duty cycle: 5, 10, 20, 50, and 80%	
	two water proof treatment head	
	Number of connections: one	-
	TENS	<u>-</u>
	TENS is a medical device use electric current to stimulate the nerve for	-
	therapeutic purpose and to reduce acute and chronic musculoskeletal	
	pain.	
	Shall have four independent current channels.]
	Shall have approx. 50 treatment suggestions	1
	Shall have approx. 60 current forms per channels.	-
	Combination therapy:	-
	Adjustable intensity per channel	-
	J J T T J X T T T T T T T T T T T T T T	

Comprises of TENS and ultrasound therapy which used for nerve stimulation, pain relief and to treat tendon and ligaments.

Shall have dual treatment suggestions

5. System Configuration Accessories, Spares, Consumables and other components :

Power cable

Trolley for mounting purpose

Ultrasound multi frequency treatment head with holder---02

Ultrasound gel 450ml---20

Velcro straps (small and large size)---10m of each

Rubber electrodes (Different size of rectangle, Different size of butter fly, Different size of long strips, Different size of round)-- 300 of each

Moist pads -- 300 of each

Patient cables, plugs

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment:

Operating Temperature: +10°C to +30°C

Relative Humidity: <85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility /NA/

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each

package

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Addis Ababa

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Base Code	Item Detail	Department
Xrmd-90	1. Generic Name: X ray - Mammography, Digital	Imaging
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description:	
	Digital Mammography machine is used as screening tool to detect and diagnosis early breast cancer in experiencing no symptoms with facility for stereotactic biopsy and 3D tomosynthesis.	
	4. Technical Specification:	
	Full Digital Mammography System consisting of exposure stand with attached swivel system, separate console with radiation shield, automatic exposure control and mammography X-Ray Tube which allows fast, low-dose, high-quality imaging of the breast and Upgradable system with latest technology available in future.	
	Full Digital Mammography System consisting of exposure stand with attached swivel system, separate console with radiation shield, automatic exposure control and mammography X-Ray Tube which allows fast, low-dose, high-quality imaging of the breast and Upgradable system with latest technology available in future.	
	System should have Automatic Exposure Control (AEC)	
	Should be able to upgrade with contrast enhanced mammography techniques.	
	System should be upgradable with latest technology available in future.	
	Gantry assembly:	
	Isocentric system	
	Collimator: Fully Automated adjustment for different paddles, sizes and magnification	
	Movement: Motorized vertical and rotating movement	
	Arm locking system: Electromechanical brakes or equivalent	
	Arm moving system: Motorized	
	Control buttons for vertical and rotational movement on both sides of C-arm	
	Focal spot to image detector distance (SID): >65cm	
	Patient face shield for 2D imaging	
	Breast Compression: Manual and automated breast compression	
	Max. force for automated: ≥150N and ≤200N Emergency release	
	Automatic decompression after exposure Digital numerical both sides indicator: for C-arm rotation angle and compression force	
	Memorizable MLO angle: C-arm shall be able to stop automatically at contra lateral angle	

Scatter rejection: Antiscatter grid (or equivalent technology)

Magnification views: at least one magnification view, magnification ratio shall be provided

Antiscatter grid removal: Automatic, motorized for magnification views

Shifting paddle: should be available

Maximum compression thickness:15 cm or more.

The compression extremely smooth and there be automatic decompression at the end of each exposure.

Safety mechanism for compression with respect to power failure.

Large paddle, Regular sliding paddle, Round spot and square spot compression paddles and Special paddles

Highly effective computer aided detection (CAD) digital mammography solution for early detection of cancer.

Latest advanced technology for identification of micro classification and suspicious lesions

X-Ray Generator:

The X-ray generator be high frequency with the following parameters:

Power output : ≥7kw

KV range: at least 25-35 kV in steps of 1 kV

mAS range max.: 5-500 mAS

Exposure time: for Patient exposure; 25ms-700ms and for tube capacity; up to 4.5s

Maximum mA: 180mA

X-Ray tube unit:

Dual focus rotating anode tube with the following parameters:

Nominal focal spot size: large and small: 0.3mm and 0.1mm

Anode heat storage: 200 KHU or more

Anode material: Tungsten

Flat Panel Detector:

Flat panel wireless detector solid state technology or latest with CsI Scintillator

Detector size: 24 x 26cm or more with two image formats

pixel size: 85 um or less

Detector Quantum Efficiency (D.Q.E): 65% @ Zero Line pairs or more

Image matrix size in pixels: approx 2.8 Kx 3K or more

Machine with detector storage compartment

Stereo tactic biopsy system

Fully compatible with Full Field Digital detector

Facility to do stereotactic biopsy automated on the entire three axis.

Facility for needle core biopsy, Fine needle aspiration and wire localization.

Compatible to use with vacuum assisted biopsy.

Transparent lead radiation shield, face shield, remote service modem, quality control tool kit

ACR phantom, phantom for calibration of AEC, phantom for calibration of image detector.

The system should have capability of 3D Tomosynthesis and vacuum assisted

biopsy system.

Facility to place the Patient for stereotactic biopsy on a couch for patient comfort.-(supine, lateral or prone position).

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Acquisition Workstation/Operator console:

A separate workstation for image positioning and patient demographic data is required.

Both detector and generator controls integrated in the same console

Dose index shall be displayed for each exposure and recorded

Computer system: System of latest technology (processor generation/type/speed, RAM, HDD, Storage systems, etc...)

Storage capacity: for 5000 patients

High Contrast 3Kx 3K 21inch TFT/LCD medical grade monitor be provided with workstation.

Double hand switch for the exposure and double foot switch for breast compression/arm movements shall be available

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

The following image processing should available on the workstation:

Freely selectable screen layout

Windowing, Contrast and Brightness setting/adjustment

Magnification, panning and zooming

Image inversion (black/white and possibly color)

Contrast enhancement (with table)

Display of histogram

Before /after comparison

Filter

Annotation:

Left/right marking

Text additions

Lines

Rectangles and circles

Measurements:

Distance

Angle

Density

Biopsy:

Stereo tactic biopsy system which is fully compatible with FFDM (Fully Field Digital Mammography).

A high resolution image of 20 1p/mm possible with the stereo tactic biopsy system.

5. System Configuration Accessories

Mainframe System----01

X-Ray tube Unit & tube----01

Flat Panel Detector---01

Image acquisition Workstation---01

Stereotactic Biopsy System----01

Archiving System (PACS) with four monitors---01

All software packages should be supplied

A CD-R/W based long term archiving with envelope----10,000

Compression paddle: Standard, High edge, Small, Medium, and Spot

Mammography Lead guard with frame----01

UPS with stabilizer for one hour backup----01

Patient comfort couch for stereotactic biopsy in supine, lateral or prone position---01

Phantoms and meters for the quality control and calibration of the various components (mammography, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be

Document: Capital Medical Device Technical Specification

included in the offer.

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General electrical safety Requirements

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

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Addis Ababa

Document: Capital Medical Device Technical Specification Version 1: November, 2019 G.C. **Ethiopian Pharmaceutical Supply Agency**

Base Code	Item Detail	Departmen
Hema-91	1. Generic Name: Analyzer - Hematology, 5 Differential	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Automated differential blood count: Automated hematology instruments using	
	multiple parameters and methods (such as fluorescence, flow cytometry and	
	impedance) are used to count and identify the 5 major white blood cell types in	
	blood (so-called 5-part differential count): neutrophils, lymphocytes, monocytes, eosinophils and basophils.	
	4. Technical Specification:	
	Measuring parameter:-A minimum of WBC, RBC, HGB, HCT, MCHC, MCH, MCV, PLT, RDW-SD, RDW-CV, MPV, PDW, P-LCR, PCT NEUT%, MONO%, EO%, BASO%, LYMPH%, IG%, NEUT#, MONO, RET%, RET#, IRF, LFR, MFR, HFR, RET-He WBC-BF, RBC-BF, PMN%, PMN#, MN%,	
	MN#, TC-BF#, NRBC #, NRBC %. Technology :-Fluorescence Flow Cytometry, Impedance, photometry and	
	smear technology	
	Throughput:-A minimum of 100 test per hour for CBC + 5 diff. and 50 slide smears per hour. Modular system	
	Sample volume: 110µl of whole blood in open & closed mode	
	Quality control 3 levelsand calibrator should be supplied	
	Fault statistics: RBC and WBC clogging of measurement (normal use)	
	Calibration: - Automatic (by calibrator) with 1-, 2-, or 3 measurement, or factorial (manual) calibration of WBC, HGB, PLT, MCV, RDW, MPV, PDW.	
	Automatic sampler with minimum of 50 samples	
	STAT option and Sample type:- Whole blood and other body fluids	
	Capacity to measure body fluids like CSF	
	Data capacity: 100 000 results with all scatter-grams & histograms	
	Quality control : 3 levels, average, + (-) range SD and CV for all measured and calculated parameters, Levey Jennings Chart, Separate QC database	
	Peripheral ports: USB interface (4), Support for host computer, Support for external printers, Support for hand-held barcode reader	
	Display: LCD screen	
	Indication of self-test failures and assistance messages	
	Sample ID, date and time are reported with test results	
	Supplied complete with dedicated data analysis and data management software	
	Results are reported on external inkjet printer	
	Casing, corrosion proof material such as plastic or epoxy coated steel	
	Data back-up method: USB mass storage device	

Software upgrades method: Via USB port

5. System Configuration Accessories, Spares, Consumables and other components:

UPS and stabilizer as one unit, with maintenance free batteries for minimum 30 minute back-up

Supplied with external printer with local market available cartilage

continues supply of reagents controls and calibrators

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Addis Ababa

		T
Base Code	Item Detail	Department
Meto-90	1. Generic Name: Microscope - Operating, Ophthalmic	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Operating microscope which is primarily used for ophthalmology and	
	ophthalmic eye surgery.	
	4. Technical Specification:	
	Full motorization of the controls and the zoom magnification.	
	Handling and versatility in ophthalmic surgery	
	Head: Zoom optical head	
	Magnification: 5x – 32x continuous zoom(electronic/hand controlled)	
	Magnification of assistance microscope: 6x, 10x, 16x	
	Eye pieces: 10x paired wide field, dioptric setting + 5D to - 5D	
	Variable working distance from 200 mm to 500 mm through motorized multi focal lens.	
	Adjustable range for Pupil Distance: 50mm to 75mm	
	Light source: LED illumination]
	Illumination: Coaxial through the lens with fiber optic cable]
	Illumination type: 6 + 0 deg. coaxial illumination, 2+6 deg. Oblique illumination	
	Coaxial illumination: ≥60,000 Lx	
	Oblique illumination: ≥60,000 Lx	
	Inclinable binocular tube, inclinable over range of minimum 0- 180Deg.	
	Arm: counter balanced pantographic arm with 3200 rotation	
	Stand: Mobile floor stand on four castor wheels for easy handling and absolute stability	
	Ergonomic handles with buttons for motorized control of focus and zoom both hand & foot.	
	Graphic display LCD with background illumination	
	Camera should be independent of microscope.	
	Essential Accessories: o Stereoscopic co observation attachment for second observer with tilt able eyepieces, minimum 0-160 Deg.	
	Integrated Beam Splitter	
	3-Chip CCD HD (high definition) output camera with c-mount for connecting with the microscope & recording on a hard drive on mini DV disks.	
	Digital video recording facility with appropriate video editing software.]
	Accessories: Diploscope (face to face attachment)	1
	Function footswitch: 12 up to 14	1
	Digital still camera for attachment with microscope System	

5. System Configuration Accessories, Spares, Consumables and other components:

Supplied with extra LED spare x2

Appropriate Eye piece a pair of 6x, 10x, 16x

Power cord x1

Fiber optic cable x1&Power board x1

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base Code	Item Detail	Department
Uran-90	1. Generic Name: Analyzer - Urine	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: Qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen	
	4. Technical Specification:	
	Tests to include: color, turbidity, creatinine, ascorbic acid, bilirubin, glucose, hemoglobin, ketones, nitrites, pH, protein, urobilinogen, specific gravity, blood, red cells, white cells, casts, crystals, sperm, and microorganisms. Internal memory capacity for>2,000 samples.	
	Quality control routines to be user friendly with results recorded internally	
	Bar code reader facility required for automated registering of samples Support calibration.	
	LCD display for testing parameters visualization.	
	Micro pipes maximum accepted volume not less than 1.5 ml. /automated and manual mode	_
	Capability to use reagents of most common brands without exclusive use of reagents produced by a single supplier for at least 85% of all possible equipment tests and analysis and reagents available ,and for placement closed system otherwise open system	
	5. System Configuration Accessories, Spares, Consumables and other components:	-
	Complete spare is need	
	All necessary reagents for at least 5,000 samples testing	
	Complete set of calibration / test samples for all tests (50 sets if not reusable)	_
	UPS and stabilizer with one unit	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code		Department
	Item Detail	
Ccan-91	1. Generic Name: Analyzer - Clinical Chemistry, Fully Automated	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: Chemistry Analyzer is required for the detection and quantification of blood chemistry and other body fluids.	
	4. Technical Specification:	-
	The Operational Requirements: should be with programmable memory	
	The Processing mode: - patient by patient , Test by test and STAT mode	
	Operating Mode: End point, Kinetic, initial rate, monochromatic, bichromatic, turbid metric, serum blank (differential), fixed time, optics and wavelength range.	
	System: open system-able to work with reagents and supplies from other manufacturers	
	Automatic Wavelength selection by multi-position filter wheel – selection from wavelength of $340-800$ nm.	
	Throughput: more than or equal to 200 tests/hr under speed optimized conditions	
	Assay: End point, rate assay, fixed point assay	
	Calibration: Linear, non-linear, with possibility of two and multi point calibration; multi point calibration for kinetic and fixed type modes.	
	Light Source: long life halogen or equivalent lamp.	-
	Resolution: 0.0001 Abs	1
	Temperature control: cuvette heating (electrical) in caruousel and reading path: 37 0C	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1- main unit	1

Document: Capital Medical Device Technical Specification Version 1: November, 2019 G.C.

Page 99 ISBN No: 2- Graphic printer- for printout of parameters, results, calibration curves,

kinetic and statistics, facility to store data in PC through connecting data

cable and related software must be provided along with quotation.

3- Desktop PC (microprocessor with speed not less than 3.00 GHz, 512MB

RAM, 80 GB HDD, 105 keys Board, scroll mouse,

multimedia kit, 56 kbps modem 32 MB AGP Card, 52xCD CD-RW Drive,

with 17" TFT Digital Color Monitor) with compatible Operating system

must be provided along with quotation

4-Complete Start up kits consumables (reagents, kits, controls...),

accessories, and spares required for installation and standardization of the

System to be provided.

5- Reusable: cuvette block for 4 tests Each

Reagent bottles

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

~ -		
Base Code	Item Detail	Department
Mibl-90	1. Generic Name: Microscope - Binocular, LED	Laboratory
	•	,
	2. GMDN/UMDN Code/Name:	-
	3. Clinical Purpose/Description: To magnify and study specimens and small objects by transmitted visible light	
	4. Technical Specification:	
	Microscope frame with revolving, 30 degree inclined binocular tube 360 degree	
	rotatable head illuminator LED light source with white light intensity control and	
	LED light life more than 10,000 Hrs.	
	Fixed graduated mechanical stage approx. 200 x 150 mm, travelling approx. 80 x	
	50 mm	
	Double slide holder	
	Coarse focusing: approx. 3 mm per rotation	
	Fine focusing: approx. 0.3 mm per rotation	
	Range of magnification: 40 to 1000x	
	Reverse angle quadruple revolving nose-piece, with distinct click-stop, with	
	rubber	
	grip for easy handling	
	Objectives, full plan achromatic: 10x (0.25 NA), 20x (0.4 NA), 40x (0.65 NA), 100x	
	(1.25 NA, oil) and 100X oil immersion	
	Condenser: Abbe with iris diaphragm aperture, 1.25 NA	
	Eyepieces: Focusable pair, 10x (FN 20), with inter-pupillary distance- and dioptre	
	Adjustment	
	Retractable eye guards	
	Filter: blue	
	All optics anti-fungus treated	
	Brightness control: 0 to 100 % (linear)	
	Detachable plano-concave mirror unit with adjustable convex and concave mirror	
	on alternate side	
	5. System Configuration Accessories, Spares, Consumables and other	
	components: 1 x Pair eye shades	
	•	
	1 x Pair of tube caps	-
	1 x Oil, immersion	-
	1 x Lens cleaning kit consisting of lens cleaning tissue, 100 ml cleaning solution,	-
	dust blower	
	2 x Fuse	
	1 x Power cord	
	dust cove and storage box	

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

		T
Base Code	Item Detail	Department
Refb 90	1. Generic Name: Refrigerator- Blood Bank, 300L/500L/700L	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Upright refrigerator for storing whole blood or red blood cell packs in a blood bank.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant	
	Storage capacity: 300L/500L/700L	
	Easily adjustable ≥ 3 shelves	
	Fan-cooled for even distribution of air in the cabinet.	
	Roll out drawers easily height adjustable.	
	Material, internal: Drawer made of stainless steel.	
	Material, external: stainless steel or epoxy coated steel.	
	Insulation material: polyurethane, CFC-free]
	Lockable door, glass	
	Electronic temperature control: 2°C to 6°C.	
	Accuracy, whatever the load: +/- 1 °C	
	Hold-over time: min. 6hrs (full load at 4 °C (+/- 1 C) takes at least 6 hrs to reach 10°C, at ambient 32°C)	
	Cooling-down time: max 8 hrs (full load at 37 °C (+/- 1 °C) takes max 8 hrs for all packs to reach 6°C)	
	External digital display with actual interior temperature, minimal graduation+/-0.1 C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures, sensor fail	
	Battery back-up for audio and visual alarm system, and temperature recording device fit with remote alarm connection and interface	
	Fitted with integrated castors	
	Minimum compressor starting voltage: 22 % below nominal voltage	
	Supplied with automatic voltage regulator:	
	Microprocessor controlled spike and surge protection, and protectionagainst disturbances	
	Accepted input range: -30%-20% to +20 %]
	Response time: <15 ms	
	Multiple LED bar-graphs display: connected/disconnected status,	
	Electronic fuse disconnects and reconnects automatically	
	KVA rating matches power consumption of the refrigerator	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	<u> </u>

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

The supplier should provide all necessary spare parts at least for 2 years

6. Operating Environment;

Operating Temperature:+10 °C to + 30 °C/43 °C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of 2 years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Addis Ababa

Base Code	Item Detail	Department
Frep-90	1. Generic Name: Freezer - Plasma, 300L/500L/700L	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Blood plasma freezers are used for plasma storage.	
	4. Technical Specification:	
	Hold over time during: power cut: Greater or equal to 6Hr	
	Ice pack freezing capacity: At least 30 Kg/24 hour	
	Features: Temperature range: down to -40 C. Hot zone appliance	
	compression type	
	Refrigerant CFC free	
	Automatic defrost.	
	Fan-cooled for even distribution of air in the cabinet	
	Easily adjustable shelves	
	Easily adjustable ≥ 3 drawers	
	Lockable door, solid	
	Electronic temperature control: up to -50°C	
	Accuracy, whatever the load: +/- 1 °C	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal	
	graduation 0.1 °C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature	
	recording device Fitted with integrated castors	
	Minimum compressor starting voltage: 22 % below nominal voltage	
	Supplied with automatic voltage regulator:	
	Microprocessor controlled spike and surge protection, and protection	
	against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status,	
	voltage fluctuation And load as % of nominal current	
	Electronic fuse disconnects and reconnects automatically	_
	KVA rating matches power consumption of the freezer	
	Power requirements: 220V / 50/60 Hz	
	Accepted input range: -20 % to +20 %	
	Response time: <15 ms	
	5. System Configuration Accessories, Spares, Consumables and	
	other components:	_
	Spare parts to be included for each freezer	

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10°C to 30°C

 $Relative \ humidity: < 85\%$

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Addis Ababa

Anbg -90	1. Generic Name: Analyzer - Blood Gas 2. GMDN/UMDN Code/Name: 3. Clinical Purpose/ Description: Blood gas analyzers are used to measure blood gases, electrolytes, Ph values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	Department Laboratory
	3. Clinical Purpose/ Description: Blood gas analyzers are used to measure blood gases, electrolytes, Ph values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	3. Clinical Purpose/ Description: Blood gas analyzers are used to measure blood gases, electrolytes, Ph values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	Blood gas analyzers are used to measure blood gases, electrolytes, Ph values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	biochemical parameters of the blood 4. Technical Specification:	
	-	
	Compact design, light weight	
	Fully automatic, upgradeable, fast electrolyte analyzer	
	Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric	
	Pressure, Na+, K+, Ca++, Cl-, Bood urea and Sr Creatanine & Blood	
	sugar. All these parameters should be measured simultaneously	
	Calculated parameters should include BE, BE ecf, HCO3, Lactate,	
	Anion Gap, SaO2 etc	
	Sample volume: <100ul.	
	Result should be available: < 45 sec	
	Maintenance free electrodes with individual electrodes ON/OFF facility	
	Fully automatic liquid calibration of all parameters at user-defined	
	intervals without the use of Gas calibrated reagents, external gases, tanks or regulators	
	Continuous reagent level monitoring with graphic display.	
	Storage of data of 1000 procedures	
	Rinse procedures and reference measurements performed with each	
	sample	
	Automatic zero calibration within each cycle	
	Patient results, calibration, maintenance schedule and quality control	
	data are displayed on well-illuminated, adequate size LCD color touch	
	screen display.	
	Noise level: <60dB	
	pH Analyte	
	Measuring Range: 6.8 - 7.8pH	
	PO2 Analyte	
	Measuring Range: 0 - 760mm Hg	
	pCO2 Analyte	
	Measuring Range: 5-100 mm Hg	
	Na+ Analyte	
	Measuring Range: 100-180mmol/L	
	K+ Analyte	

Measuring Range: 1-10mmol/l

Ca++ Analyte

Measuring Range: 0.25-5.00mmol/l;

Hct Analyte

Measuring Range: 15-70%

tHb Analyte

Measuring Range: 3.0 -23g/dL;

Heat disbursed through a exhaust fan

Easy and safe transport stable when tabletop mounted.

Different report lay-outs are selectable

Data print out on built in graphic printer.

Built in auto quality control facility

Automatic result processing, test ordering and transmission to Hospital Information System

Automatic data archiving and customizable layout.

Data backup with read/write CD-ROM drive

USB ports for easy connection of e.g. flash drives, keyboards, etc.

5. System Configuration Accessories, spares, Consumables and other consumables:

Blood Gas Analyzer -01

Reagents for one year 20 samples/day or as per requirement should be provided along with the machine.

Electrodes for all the parameters specified -01 set

Quality control tools/reagents for one year 20 samples a day-01 set or as per requirement.

Two sets of spare/replaceable fuses, reagents and capillary tubes sufficient for 100 tests;

Cartridges-combination of various tests;

External source of gas (if applicable);

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the

Document: Capital Medical Device Technical Specification

device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

- ~ -		
Base Code	Item Detail	Department
Anac-90	1. Generic Name: Analyzer – Coagulation	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Used to measure a coagulation pathway speed, as well as thrombin and	
	thromboplastin (TPL) levels in as low as a few minutes.	
	4. Technical Specification:	
	Complete with all its accessories	
	Fully automated, open random access, 4 detector channel Blood	
	Coagulation Analyzer having clotting, chromogenic and immunological assay channels.	
	Clotting detection methods by recording change of viscosity and/or change of light transmit ability and permitting both chromogenic and immunogenic assays	
	Coagulometric tests such as PT, aPTT, fibrinogen, single factors FII-FXII (analyser depending)D-Dimer, derived fibrinogen	
	Measuring principle: turbo densitometric; opto-mechanical with automatic zero adjustment and magnetic stir bar for homogenizing of the test suspension and increased sensitivity.	
	Provision for simultaneous random analysis for at least 15 parameters such as PT, APTT, Fibrinogen, Protein S, Protein C, APC resistance, ProC, Antithrombin III, Heparin, Plasminogen Activator inhibitor, D-Dimer Plus, von Willebrand Antigen, Lupus Anticoagulant, and coagulation factors VIII & IX	
	Pre-programmed and user definable methods	
	Flexibility: test parameters can be modified	
	Built-in Quality control	
	Sensitivity: PT> 10 % of norm	
	Test through put: PT, >100 tests/Hr aPTT 60/h,+/- 20 tests/h	
	Cuvette volume: min 150ul, max. 300ul (test suspension)	
	Calibration: manual input of calibration points, method dependent	
	Software: loaded in memory	
	Programmed method: PT, in sec, %, Ratio ,INR (combinations) aPTT ,in sec , and Ratio Fibrinogen, in sec, mg/dl, thrombin T in sec D-Dimer	
	PT/Fib(derived Fibrinogen) internal factor, in external factor, in %	
	Light source: LED, light emitting diode or equivalent	
	Display: 2 lines with 20 characters each, liquid crystal display	
	Incubation block: controlled at $37^{\circ}c \pm 0.3^{\circ}c$	
	Measuring channels: 4	
	Light protection caps: for yellow tips	
	Cuvette positions: 16	

Disposables:cuvette, paper for thermal printer; tips

Measuring timer: max. Approx 420 sec

Voltage: $220 \pm 10 \% \text{ V}$, 50 Hz, power state.

Printer; Internal thermal printer, 26 characters/ line, memory = 10 k Byte

Detection: photo-optical(405nm)

a intra assay reproducibility

System time: real time clock for time and date

5. System Configuration Accessories, spares, Consumables and other consumables:

UPS, Voltage stabilizer - 01

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65
Tel: +251-11-276-32-65
Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Detail	Departmen
Mcil-90	1. Generic Name: Microscope - Inverted	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	An inverted microscope is a microscope with its light source and condenser	
	on the top above the stage pointing down, and the objectives and turret are	
	below the stage pointing up.	
	For analysis of cell tissue culture and CPE in culture vessels, micro test and microfiltration plates using bright field and phase contract with transmitted light	
	4. Technical Specification:	-
	A 4x, A Ph 10x (phase contrast) and SPL pH Ox (phase contrast) with large working distance.	
	Objectives for bright field and phase contrast with 40xmagnification.	7
	Height adjustable 30W high light density halogen lamps	1
	Illumination unit swivels for contrast adjustment	1
	Large specimen surface (max 220 mm)	
	5. System Configuration Accessories, spares, Consumables and other consumables:	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment:	
	Operating Temperature: +10°C to +43°C	
	Relative Humidity: <85%	
	7. Utility Requirement:	
	Power: 220V / 50Hz	1
	Compatible UPS with maintenance free battery and Resettable over current breaker (voltage regulator)	
	Resettable over-current mains fuse to be incorporated	
	Electrical protection by resettable over-current breakers or replaceable fuses	
	fitted in both live and neutral lines	4
	8. Standards & safety Requirements:	4
	Shall meet IEC-60601-1-2:2001(Or Equivalent) General Requirements of	
	Safety for Electromagnetic Compatibility Should comply with quality system. Medical device applicable to	4
	Should comply with quality system- Medical device applicable to manufacturers and service providers that perform their own design activities	
	Should comply with electrical safety requirements for electrical equipment	-
	for measurement control and laboratory use	
	9. Installation/Training Commissioning:	1
	The supplier must be provide installation, and commissioning of the device	1

The supplier must be provide technical and end user training for two weeks on site.

10. Warranty/After sale Service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of installation.

After basic warranty the supplier must be provide Five years maintenance contract period with price break down along.

11. Documentation:

User, technical and maintenance manual must be supplied in English and devices/machines

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively

Additional packing and labeling requirements should bear in each package

Federal Democratic Republic of Ethiopia Pharmaceuticals Fund and Supply Agency (EPSA)

Tender and Purchase Order No.

UMDNS Name and Model of the product

P.O. Box 25-11-276 32 65

TEL: 251-11-276-32-65

FAX: 251-11-275-25-55

Base Code	Item Detail	Departmen
Inst-90	1. Generic Name: Inspissator -TB Culture Preparatory	Laboratory
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Used for preparation batches of uniform TB culture medium in clinical research laboratory	
	4. Technical Specification:	
	Ergonomically designed with a digital display which is easily read from a distance.	
	The unit consists of tank, vessel/tray and outer case which are made of stainless steel	
	digital temperature control	
	Incubation temperature: 80°C	
	Temperature uniformity: ±0.9°C	
	Inspissations time: 47 minutes	
	a facility to maintain constant liquid level and temperature	
	capacity of 150 test tubes or 160 universal containers	
	5. System Configuration Accessories, Spares, Consumables and other componenets :	
	Insect resistant blanket and quilt replacement for Inspissator	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	1

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Addis Ababa

Base Code	Item Detail	Department
Mira-90	1.Generic Name: Microtome - Rotary, Fully Automated	Laboratory
	2.GMDN/UMDN Code/ Name:	
	3.Clinical Purpose/Description:]
	Fully motorized heavy duty automated microtome: Rotary microtome are	
	precision instruments designed to cut uniformly thin sections of a variety of	
	materials for detailed microscopic examination.	
	4.Technical Specification	
	Section thickness range should be between 0.25 to 100µm with increments	
	in the range of 0.5μm, 1μm, 5μm with LED display.	
	Trim thickness range should be 1-600μm with 1μm, 2μm, 5μm and 10μm	
	increments, respectively with LED display.	-
	Vertical stroke 70-80mm. Specimen advance 30-35mm.	
	Section counter, knife angle position locator and specimen orientation light	
	facility should be there.	1
	Emergency stopping facility and lockable hand wheel should be present.	
	It option of foot pedal operation and emergency stop button in automated mode.	
	Automatic object return to starting point and connection for backlighting	
	with cold light source.	
	Directional specimen holder fixture with quick clamping system, standard	
	clamp and universal cassette clamp.	1
	Round specimen holder with all accessories.	
	spacious, removable section waste tray with integrated armrest.	
	5.System Configuration Accessories, Spares, Consumables and other components:	
	Fully Automated Rotary Microtome with accessories	-
	Universal knife holder base, disposable blade holder, disposable blades,	-
	Stereo zoom microscope attachment for glass knife sectioning with cold	-
	light source using gooseneck.	
	Glass knife maker, Glass knife holder. Glass knife box, high quality glass	-
	strips for making glass knife (~30 pcs).	
	Glass knife maker and its accessories should complete the whole system	-
	from breaking to making of glass knife ready to use.	
	The specimen holder of microtome should be capable of holding resin	
	blocks for sectioning.	
	Instrument should be capable of making semi-thin section of resin	1
	embedded sections with the help of glass knife.]
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication	
	materials including items not specified above	_
	6. Operating Environment;	

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Mirm-90	1.Generic Name -Microtome Rotary, Manual	Laboratory
	2.GMDN/UMDN Code/ Name:	
	3.Clinical Purpose/Description:	
	Rotary microtomeis precision instruments designed to cut uniformly thin	
	sections of a variety of materials for detailed microscopic examination. The	
	microtome operation is based upon the rotary action of a hand wheel	
	activating the advancement of a block towards a rigidly held knife.	
	4.Technical Specification	
	Microtome with accessories	
	• 1 universal knife holder base	
	• 1 disp. blade holder	
	• disposable blades 75 x 8 mm.	
	• 1 standard knife holder N, w/o base	
	• 1 Knife, 16 cm, profile c, steel	
	• 1 knife, 22 cm., profile d. steel	
	• 1 specimen orientation device	
	• 1 stand spec. clamp, orient	
	• 1 cooling stage, 40 mm. diam. w/CO2 hose, 150 cm.	
	• 1 trolley stand, CO2 bottle	
	• 1 quick-freezing nozzle with hose for CO2 freezing	
	5.System Configuration Accessories, Spares, Consumables and other	
	components:	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	_
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC +10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for	
	Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

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Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Mivc-90	1.Generic name :Microscope - With Video Camera	Laboratory
	2.GMDN/UMDN Code/ Name:	
	3.Clinical Purpose/Description:	
	A digital microscope is a microscope that contains a tiny digital camera (CMOS) and is connected to a computer. dedicated to teaching to those intended for laboratory use,	
	4.Technical Specification	-
	Microscope frame with revolving, 30 degree inclined binocular tube and 360 degree rotatable head, illuminator LED light source with white light intensity control and LED light life more than 10,000 Hrs. Fixed graduated mechanical stage approx. 200 x 150 mm, travelling	
	approx. 80 x 50 mm Double slide holder	1
	Coarse focusing: approx. 3 mm per rotation	-
	Fine focusing: approx. 0.3 mm per rotation	1
	Reverse angle quadruple revolving nose-piece, with distinct click-stop, with rubber	
	grip for easy handling	
	Objectives, full plan achromatic: 4x (0.10 NA), 10x (0.25 NA), 20x(0.4NA) 40x (0.65 NA), 100x	
	(1.25 NA, oil) and 100X oil immersion	
	Condenser: Abbe with iris diaphragm aperture, 1.25 NA	
	Eyepieces: Focusable pair, 10x (FN 20), with inter-pupillary distance- and dioptre adjustment	
	High Definition Camera Specifications:	
	Digital camera resolution: 2048x1536 pixels (3.14Mp)	
	Direct output to HDMI Screen for viewing live images. USB Camera, USB Mouse or SD Card.	
	CMOS sensor.	
	High light sensitivity, CCD camera.]
	Image capture to SD Card (included).	
	Camera control panel for exposure, gain, white balance, color, sharpness and noise control.	
	Includes on-screen monitor toolbar for measuring, mirror, comparison, zoom, freeze, cross & browser when using mouse control.	
	Includes: Camera, Software, Power Adapter 220V, HDMI Cable, USB Mouse HD Camera has a bracket for connecting an 12" HD Monitor directly to the camera	
	directly to the camera. The camera is attached to a 12" HD monitor.	1
	Output: 2.0 USB port	1
	· · ·	-

Software: Windows XP/Vista/Seven,64 bit

5.System Configuration Accessories, Spares, Consumables and other components:

supplied with:

12" HD Monitor

High Definition camera

HDMI Cable

USB Cable

Power Cord

SD Card

Software

USB Mouse for On-Screen HDMI Control

1 x Pair eye shades

1 x Pair of tube caps

1 x Oil, immersion

1 x Lens cleaning kit consisting of lens cleaning tissue, 100 ml cleaning solution.

dust blower

2 x Fuse

1 x Power cord

dust cove and storage box

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Department
Dase Code	Ittiii Detaii	Department
Aeli-90	1. Generic Name: Analyzer – ELISA	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	ELISA (enzyme-linked immuno sorbent assay) is a plate-based assay	
	technique designed for detecting and quantifying substances such as	
	peptides, proteins, antibodies and hormones.	
	4. Technical Specification:	
	Micro plate ELISA Reader with printer	
	Description: Reader with 8 channel and 12 channel modes	
	Micro plate reader and evaluation unit for ELISA evaluation	
	Multi channel auto reader with on-board data reduction and reporting.	
	• For kinetics, endpoint and scanning read modes. Shaking mode.	
	Technical features:	
	• Wavelength range: 300-900 nm.	
	• Absorbency ranges 0.000-4.000 O.D.	
	Serial and parallel interfaces.	
	Accommodates all 96-well micro plates.	
	• Six filter capacity. Filters supplied: 405nm, 450nm, 490nm, 630 nm.	
	Soft ware but not limited to the following	
	Point to point curve fit	
	Polynomial regression, linear & sigmoid regression, log &linear	
	User programmable open system	
	Selective plate formatting	
	Alphanumeric test name	
	Duplicate well options	
	Curve plotting and editing	
	Flags and error massage	
	Built in printer	
	ELISA, incubator,	
	Description: Oven with 4 plates	
	Technical Specifications	
	Micro plate shaker / incubator suitable for all standard depth 96-well	
	plates	
	Heated lid and base cover the plate entirely	
	Positions to accommodate 4 plates	
	• Continuous or timed operation, with alarm buzzer and automatic switch-off	
	Temperature range: ambient plus 5 C to 60 C	

- Temperature stability: approx. 0.1 C, uniformity approx. 0.2 C
- Shaking speed: 250 to 1800 rpm, adjustable in steps of 10 rpm
- Orbit, approx. 2 mm
- LCD displays time set and elapsed, temperature set and actual
- Power requirements: 220 V / 50 Hz, with voltage surge protection
- Supplied with: UPS of sufficient capacity to ensure uninterrupted finalizing of ongoing testing, in case of power variations or power interruption

Micro plate ELISA Washer,

Description: Washer with 8 channel

Technical Specifications

- 8-channel strip manifold
- open system ,automatic
- Automatic rinse & prime programme
- 75 user-definable protocols
- Wash parameters include: 16-character assay name, number of cycles, wash volume, flow rate and variable soak times
- Dispense only and aspirate only modes for reagent addition and removal
- Built-in multi-speed shaker for improved CVs and reduced assay backgrounds
- Crosswise aspiration/double aspiration of flat bottom micro-plates for reduced residual liquid
- Bottom wash mode for rapid dilution of reagent
- Built-in vacuum & pressure pump assembly
- Bottles for waste rinse and wash
- Accommodates flat, U or V-shaped bottom plates
- Between 1 10 wash cycles
- Dispensing volumes from 25 to 3000 ul
- Soak time: 1-600 seconds
- Fluid flow rate in 150 to 1000 ul / well / sec to accommodate cellular assays
- Spill-over protection & electronics isolated from fluidics
- automatic buffer switching
- Flip out aerosol cover or similar

5. System Configuration Accessories, Spares, Consumables and other components:

• Supplied with: UPS of sufficient capacity to ensure uninterrupted finalizing of ongoing testing, in case of power variations or power interruption

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

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Tel: +251-11-276-32-65

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Base	Item Detail	Department
Code Afcc-90	1. Generic Name: Analyzer – CD4	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	CD4 [abs] counter, provide absolute and percentage results of CD4 T lymphocytes) concentration in whole blood samples.	
	4. Technical Specification:	
	Output: Quantitative CD4 Absolute count, CD4 %	
	Sample type: Capillary or venous whole blood	
	Sample volume: 20 - 25 μL	
	Reading time to results: 20 - 22 min for first sample. Then≤ 4 minutes per sample	
	Throughput (per 8 hrs working day/operator):90 - 110 tests	
	System Batching capabilities	1
	System Built-in printer and optional external printer ,USB, RS232 connectivity	
	Number of tests results printed with 1 paper roll: 100 - 120	
	Data storage: Approx. 10,000 test results	
	Connectivity	
	System Built-in voltage surge protection	
	Capacity battery life (in hours and test runs): 8 hours	
	System Factory calibrated	
	System Internal quality control (IQC)	
	System Compatible with external quality control scheme(s)	
	5. System Configuration Accessories, Consumables and other components:	
	probes, different types of tubes, with all standard accessories and consumables must be provided.	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	

Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base Code	Item Detail	Department
Seal-90	1. Generic Name: Tube Sealer	Laboratory
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	Tube Sealer is used in sealing of blood bag tube without causing hemolysis and leakage of blood.	
	4. Technical Specification:	
	Bench-top use	1
	Digital temperature display]
	Compatible with Polyvinyl chloride (PVC) tube with different type and size of tube	
	Radiofrequency sealing with no risk of hemolysis of blood in tube segment	
	Radiofrequency wave only heat the tube not the liquid inside	
	No warm-up time]
	The sealing time ≤ 2 seconds.	
	Automated tube detection]
	Automatic Sealing]
	Anti-spark and overheat protection system to avoid damage to system & tubing	
	Tear seal feature to make segments Easily separate the tube segment after sealing	
	Splash gurd to protect phlebotomist from any risk of contamination.	
	Easily accessible tube sealer electrode for disinfection and cleaning	1
	Well Electrodes protected by a cover to prevent blood splutter.	1
	Audio Visual Indication for ready to seal, seal process and detailing the functional status of sealer.	
	Number of sealing: simultaneous multiple tube sealing not less than 4/time	1
	No. of seals per charge more than 2,000 continuous seals from a fully charged battery.	
	Provided with sensors which adapt with sealing time Automatic protection system for over temperature welding fully automated	-
	Automatic adjustment for RF power and sealing type	1
	Easy to clean; stainless steel External feature	1
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1x Main Unit	1

1x Battery Charger

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

With all standared and complete accessories

6. Operating Environment;

Operating Temperature:+10 °C to +43°C

Relative humidity : < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package each item with all accessories /spare part configured and packed in one unit.

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Addis Ababa	

Base Code	Item Detail	Department
Pcrm-90	1. Generic Name: Thermo cycler - PCR machine or DNA amplifier	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	It is a laboratory apparatus which most commonly used in genotyping, cloning, mutation detection, sequencing, microarrays, forensics, and paternity testing to amplify segments of DNA via the polymerase chain reaction and to facilitate other temperature-sensitive reactions,	
	4. Technical Specification:	
	Running facility of different temperature in the same plate with user defined time determines the optimal annealing temperatures. Fits all standard Thermo cycler, real time PCR systems and DNA sequencers Individually wrapped sterile, RNase and DNase free Well edges slightly raised facilitates plate sealing	
	Thin walls for optimal thermal transfer On board calculating facility to approximate the optimal annealing temperature.	
	The system support PCR volumes. Choice of saving the methods to USB memory stick. Programmable heat lid cover for efficient PCR optimization. The system allows easy product updates via USB port. Peltier based heating and cooling.	
	Thermo block made of silver. Capable of testing temperatures at Denaturation, Annealing & Extension steps Gradient technology ensure identical ramp rates in both gradient and normal operations.	
	Inbuilt advance scheduling feature for users convenience will be a preference Programmed templates and protocols. Auto Restart facility with user defined time interval when power fails and resumes. Email notification to the logged-in user whenever certain errors, warnings, and system events occur.	
	Temperature control modes providing flexibility for different applications Adjustable user defined ramp rate to meet sensitive experimental conditions. Advanced security features. Monitor indicates the step, cycle and remaining runtime. Minimum two USB ports. Ethernet port. Log book function for error messages and new calibration.	
	Automated for both real-time PCR and post-PCR (end point). Analysis using inbuilt Peltier based PCR machine. Excitation source LED light source. System flexible to support 96 well plates.	
	Easy door design for loading and unloading 96-well plates. The instrument have display with an TFT touch screen about 8.5 in. ±0.1°C temperature uniformity across the whole block instantly after every temperature change means that any well, in any instrument Record every well, with every filter, in every cycle.	

Record every well, with every filter, in every cycle. 96-well format with 0.2 ml supported by 96 well plates and strips Well edges slightly raised facilitate plate Thin walls for optimal thermal transfer Well shape:U-bottom Laser Printer Type

Paper Size A4 Automatic 2–sided (Duplex) Print Resolution: 2400×600 dpi Print Speed: Up to 40 ppm single side print and 20ppm duplex side print

PC with at minimum: 3GHz CPU Quad Core i7, 64-bit operating system Medical Grade 21-inch LCD monitor with a minimum 1920 x 1080 resolution 8 GB RAM 500-GB hard drive 1000x sheet of paper UPS system with minimum 2Hr back-up Voltage stabilizer of appropriate rating

5. System Configuration Accessories, Spares, Consumables and other components:

High-Power USB Wi-Fi Module x (1set)

Temperature Verification Kit x (1set) Thermal Cycler Power Cord x (1set) Thermal Isolation Frame x (1set)

Complete Reagent startup kit

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Document: Capital Medical Device Technical Specification

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Additional packing and labeling requirements should bear in each package

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Tel: +251-11-276-32-65

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Base Code	Item Detail	Department
Staa -90	1. Generic Name: Slide Stainer - Cytology/Histology, Auto	Laboratory
2000	oj vologj/mistologi/mistol	Zazoratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Slide stainer automates the staining of prepared cytology and/or histology	
	tissue specimens by diffusing dyes into the specimens through surface adsorption, direct staining, indirect staining, or mordant staining.	
	4. Technical Specification:	-
	Automatic Slide Staining Machine ,One touch, walkway automation – from	_
	drying to glass cover slipping to ensure high levels of laboratory efficiency	
	user	
	Menu-driven Safe and homogeneous Slide staining mechanism.	
	Fully automatic and programmable reagent management system.	
	Flexible transmission mechanism & Precise positioning system ensure	
	stable staining, and with two water station and 24 work stations with timing	
	in minutes and seconds, facility for single and double load.	-
	Self-contained bench-top unit that is menu-driven, microprocessor controlled, and fully programmable.	
	Windows in closed fume hood that allow easy loading and unloading	
	without opening the entire hood.	
	Automatic Slide Staining Machine equipped with slide washing and	-
	charcoal filtering system	
	Staining capacity > 60 testing:	
	With rinsing station, heating station and heating station for drying.	
	Easy refilling of reagent troughs by simple removal from instrument.	
	Adjustable agitation of the slide basket	
	Compatible with all standard slide baskets	
	Processing parameters printed using a printer.	
	All process parameters displayed by TFT Touch screen display with touch	
	controls and menu.	
	Infiltration time separately programmable for each station	
	Easy editing and changing of programs, even during processing	
	Audiovisual alarms, error messages and warning codes	
	Fume Extraction Active carbon filter	
	UPS system with minimum 8Hr back-up	
	Voltage stabilizer of appropriate rating	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	-
	Tank covering lid x (1set)	4
	Charcoal filter x (1set)	-
	Water tank x (1set)]

Hose for water fill x (1set)

Tank holder basket x (1set)

Slide holder basket x (1set)

Reagent tank x (1set)

With all standard and complete accessories /Consumable startup kit

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one

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Referral/Specialized Hospital Capital Medical Equipment Technical Specification

Base Code	Item Detail	Department
Cenb-90	1. Generic Name: Centrifuge - Blood Bank, Refrigerated	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	It used for separating blood and blood components from whole blood like platelet, plasma, RBC and Cryoprecipitate and Functions as a centrifuge and cell washer specifically for blood banking procedures. 4. Technical Specification:	
	Microprocessor control, operated by touch panel, LED or LCD display, operated data can be saved automatically, RCF value can be set directly for working	
	Must have Rotor identification system over speedover temperaturedoor interlock, unbalanced protection	
	Display: RPM, RCF, Time, Temperature, Program, Accel/Decel, Rotor Number, Rotor Radius	
	Capacity :12x6000ml(12 blood bags) Speed Accuracy :±20rpm Time Range :0-99H59min59s	
	castor with break	
	Noise Level \leq 60 dB(A) Acceleration/ Deceleration :0~9. The shortest Acceleration time : Speed 0~6000rpm)	
	5. System Configuration Accessories, Spares, Consumables and other components:	-
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	5. System Configuration Accessories, Spares, Consumables and]
	other components:	1
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	1
	Operating Temperature:+10 °C to + 30°C 10-43°C	1

Document: Capital Medical Device Technical Specification

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Base Code	Item Detail	Department
Mif-90	1. Generic Name: Microscope – Fluorescence	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Fluorescence microscope observation visualizes intracellular structures,	
	particularly protein and molecular structures, using fluorescent proteins or	
	dyes, Using the phenomena of fluorescence and phosphorescence	
	4. Technical Specification:	
	Fixed Kohler with reflected and Fluorescent illumination	
	Objectives	
	Plan-APOCHROMAT with magnifications of 10x NA 0.25 WD 10.6	
	mm, 20×NA 0.40 WD 1.2 mm, 40×NA 0.75 WD 0.51mm and 100×NA	
	1.30 WD 0.13 - 0.2 mm optimized for specimens without cover slip (D =	
	0),Illumination	
	Transmitted light	
	*LED Reflected light and Fluorescence module with 455 nm LED light	
	source and Halogen Lamp: 6 V/12V, 30 W/100W with Light source	
	adjustment range: Fully adjustable between 1.5 V and 6 V DC(100W	
	mercury, 75W xenon, and 150W metal halide arc lamps are commonly	
	used)	_
	Color temperature at 6 V:2,800 K and Luminous power:280 lumens	
	Average life:1,000 hours ,and Illuminated area:1.5 \times 3 mm	
	LED Module: Max. 40 mW, 365 – 625 nm; LED hazard group 2 according to DIN EN 62471	
	Switching objectives: Manually using four-way objective revolver	
	Objectives: Range of infinite focus objectives with W 0.8 screw thread	
	Eyepieces:30 mm diameter, With visual field number 18: PL 10× / 18 Br. foc.	
	With visual field number 20:PL 10× / 20 Br. foc.	
	Object stage:XY stage, 75×30 right/left, and Dimensions (width × depth)	
	$ \begin{array}{c} :140 \times 135 \text{ mm} \\ \hline \text{Range of adjustment (width \times depth):} 75 \times 30 \text{ mm} \end{array} $	
		_
	Coaxial drive: Optionally right or left	_
	Verniers:Can be read off from left	-
	Object holder: With spring lever left	
	Abbe condenser 0.9/1.25; fixed Kohler For Vobj 4× to 100×	
	Abbe condenser 0.9/1.25; full Kohler For Vobj 4× to 100×	
	Binocular Tube 30°/20	
	Maximum field of view:20	
	Eyepiece distance (pupil distance): Adjustable from 48 to 75 mm	

Viewing angle:30°

Viewing height: 380 to 415 mm and Visual output: Tube factor 1

5. System Configuration Accessories, Spares, Consumables and other components:

Transport case

*Rechargeable battery pack

*Illuminating mirror

rechargeable battery: Fuses according to IEC 127 T4.0 A/H

Halogen Lamp

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Frev-90	1. Generic Name: Freezer - Vaccine, 500 L/700 L	Pharmacy
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	1
	Freezer is an horizontal Pharmaceutical Freezers for storage of vaccines and other sensitive materials under stable temperature conditions at-15°C to -50°C.	
	4. Technical Specification:]
	Compression type, CFC-free refrigerant, with spark free ignition]
	Fan-cooled for even distribution of air in the cabinet	1
	Stainless steel structure	
	The Chamber is Double Walled with PUF Insulation, inside 304 Stainless Steel, CFC Free (eco-friendly)	
	Lockable door, solid	
	Freezer must have battery back-up and PIN security lock for unauthorized	
	tampering Audible and visible alarms for temperature, power failure, system failure, battery	-
	low etc.	
	Freezer ≥3 Compartments	-
	Freezers with heated air vent and front panel air filter.	-
	Slow motion Lid opening: Pneumatic door opening system	-
	Door gasket made of silicone rubber and with stand the temperature variation	_
	throughout the range.	
	Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.	
	Heavy duty hinge for closure and un-interruptive service.	
	Informative display and control screen with history tracking	1
	Easy data transportation through USB port and it must also have on board diagnostic software.	
	Attachable external remote alarm system	1
	Independent Dual Compressor System	=
	Electronic temperature control: -15°C to -50°C with 1°C Increment	-
	Accuracy, whatever the load: +/- 1°C	-
	Temperature monitoring:	-
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device, with connection/interface for external read-out	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording	

device

Integrated four castors with break

Minimum compressor starting voltage: 22% below nominal voltage

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Laum-90	1. Generic Name: Laundry Machine	Hospital Equ.
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Used to receive contaminated items for cleaning and to provide an adequate efficient, economic,	
	continues quality supply of clean disinfected linen to all patient care services in the hospital.	
	4. Technical Specification:	
	Washer Extractor machine:	
	Both hot and cold water washing Horizontal drum type made of non-magnetic stainless steel,	
	Front loading type,	
	Method of washing should be tumble wash.	
	• Machine should be made of 304 grade of stainless steel (Inner cage should have	
	die-sunk perforations on adequate area and thickness should be of 14 SWG S.S	
	and outer body thickness 16 SWG 304 S.S).	
	Machine should have large stainless steel front door with toughened glass.	
	Machine should have automatic door locking system while machine is in operation.	
	Large loading and unloading doors with up to 180 degree opening angle for easy access	
	• Machine should have auto-reverse / open pocket with low spin extract.	
	Machine should have level indicator.]
	Capacity of 65 kg to 75 kg dry linen.	
	Nose level (dB) <70	
	Wash speed / Spin speed r.p.m. Not less than 33	
	Extracting speed r.p.m,:- Not less than 670	
	Machine should have heavy duty Motor Power Not more than 7.5 kwt	
	Machine should have Dual operating system options i.e. both electrical	
	and steam heating provisions.	

Steam pressure :-0.2 to 0.6 MPa

Air pressure :-0.4 to o.6 Mpa

Drum volume :- Not less than 700 Liter

Heating power :- 40 -55kw

Rotation direction::-forward/reverse/stop, one way drive With electrical water heater,

adjustable rotation speed of greater than 1000rpm (max).

With operating valves Material: stainless steel

Automatic stop alarming mechanism

With washing options for dirty and colored clothes

Automatic stopping and stop signaling when finishing With braking system.

The machine shall have features like wash timer, automatic forward/reverse cyclic timer. Sensor to detect level in soap tank and easy refilling system.

Sensor for water in chamber to avoid dry run.

Built in steam condenser for washing and drain.

Single phase motor invertor

Programmable water temperature for each bath

Freely programable control with advanced 7 " colour display for easy operation

Programmable overnight bath soak

Programmeble water temprature for each bath

Long, short and extra short program

Temperature adjustment

Fresh water flashing chemical manifold

Shock absorbing system

Two way circulation pump

hose with flat inner surface

Auto wash feature

Dirt resistant drain hose

Emergency stop switch

Connections:

voltage inlet: 380V frequency of 50Hz

Connections:

voltage inlet: 380V frequency of 50Hz

Hot and Cold Water connections: Machine should have adequate

water inlet and drain

outlet size with appropriate connection, pressure and satisfactory flow rate.

Dryer:

Tumble dryers are used, machines in which textiles are dried by tumbling in a rotating drum through which heated air is passed.

Capacity 70 to 80 kg of wet linen

Dryer/tumbler should be ,Electrically Heated, Heavy duty, Front Loading, Cool down

Feature, Auto-timed, Auto-reversible, Auto digital temperature control, Dual Motor drive,

Open Pocket & Front display

Programmable microprocessor controlled with touch panel, color screen LCD/TFT

display for working parameters and multi-level interface

Heating Power: Not more than 40 Kw

Motor power: 1.10 kwt to 1.5 kwt

Electric, steam heating type

Steam pressure: 0.3-0.5mpa

Equipped with removable lint screen

Automatic signal display when finishing

Tumble dryers with stainless steel drum

Alarms and free display of operating parameters

Auto adjustable vacuum power to the existing condition

Professional brushless motor

Bi-directional drum movement, with auto reversing and exhaust sytem

Perfect tumble dry system

Tumble dryers with humidity sensor and display

Large wide opening door, with semi-perforated inner drum for easy removal of hot air

Easy water emptying to accessible drain out

Noise < 50dB

Adjustable drum speed and rotation

Trap system to remove fine particles

Exact dry moisture sensor

Door minimal heat loss

Less steam consumption but quick dry time

Stainless steel dryer drum

Outer chamber dryer should be made of stainless steel 304 sheet

Inner chamber dryer should be made of s.s 316

Heating and time control should be done digital temperature, time controller

Trays should be made from SS 316 sheets

Racks and trolleys racks should be provided for trays inside the dryer

Racks should be provided with wheels to slide them in and out of the dryer

Machine should be fitted with anchor bolt with vibration damper

Safety micro switches on door, depression and filter check

Self-diagnostic fault alarm systems, safety protection system

Power supply: 380v,+- 10%, 50hz

With all standard accessories

Equipped with removable lint screen Automatic and gives signal when finishing

Stainless steel drum Safety micros witches on door, Electrical heating system,

Air particle filter to ensure the drying air is free from particles.

Tumbler drier of solid steel construction

machine should have thermal overload protection system

cycle programming should be by varying temp or time

Ironing machine

Roller type:- Heater temperature adjustment for various types of clothes/garments

Having maximum and minimum speeds and reversing Roller length used to dry ironing.

Water spray. Variable thermostat contro

Roller length: - 2.5 meter

Roller diameter:= not less than 500mm

Ironing speed (Rotation speed:) m/minute - 0 -8

Motor power (KW):- 1.1 to 1.5

Electric heating power (KW)33 to 39

Roller type, stainless steel body

Electrical heating system

Heating range: max 200degC

Heater temperature adjustment for various types of garments

Having maximum and minimum adjustable speed

Noise level <65dB

Automatic control of overheating

Built in electric heating system with temperature setting unit

The machine must have Emergency stop button

Having driving and exhaust motors with brake system

Indication of ironing speed and temperature

Separate delivering and receiving table for dirty and clean linen

Variable setups for folding

Built-in feeding and length folding system

Frequency controlled motor

Automatic cool down

Power supply: three phase, 380v, +- 10% 50hz

an ironer with exhaust fan for the removal of vapors produced while ironing is preferable

the roller padding should ensure uniform pressure throughout its length

final cover of the roller should be made with NOMEX which is high temp. resistant

The machine must have Emergency stop button

Ironing speed must be adjustable

Laundry trolley for wet clothes:

Material: chrome plated steel/polymers Capacity of not less than 60kg Built on heavy

duty castors. Mobile box of non-rust polymer construction for solidity and durability.

Dimensions: approx. 736 x 660 x 965 mm (h x w x l). With 2 rigid and 2 swivel castors.

With outlet tap.

Laundry trolley for dry clothes:

Material: chrome plated steel Capacity of not less than 40kg about 55kg

Built on heavy duty castors Material: chrome plated steel/polymers

Capacity of not less than 40kg Built on heavy duty castors. Mobile

box of non-rust polymer construction for solidity and durability.

Dimensions: approx. 736 x 660 x 965 mm (h x w x 1).

With 2 rigid and 2 swivel castors.

Gloves:- Heavy duty type Rubber Gloves For laundry purpose

5. System Configuration Accessories, Spares, Consumables and other componenets:

Washer extractor, dryer and ironer should provide With all standard and complete accessories

6. Operating Environment;

Operating Temperature:+10 °C to + 40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power supply: Three phase, $380VAC \pm 10\%$, 50hz

The system must be inclusive of water supply with proper pressure

Should have proper drainage system

Should have heat ventilation and air cerculation system

8. Standards & Safety Requirements:

Shal meet, ISO, and CE, Certification, This shall include standard and safety

requirement and also meet the following:

Shall meet IEC-6060 General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 1042 ,safety requirements for hospital laundry machine

machine should have thermal overload protection system

Overall Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

b). Drain Connection:

Bidder shall do drain outlet via either drilled floor or any other for drainage purpose

c). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (Proper grounding should be included)

Three phase breaker with size as per manufacturer recommendation near to the machine.

d). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

e). Evacuation system:

To allow dryer, ironer to work at its best, air inlet passes through an opening outside

Air inlet opening should be standard and placed behind the machine

Exhaust duct is made from galvanized steel not be from plastic ducting

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on site technical and end user training

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

10. Documentation:

The supplier must provide user manuals/operation manuals and Services manuals in English.

11. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

O Box 21904

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Peri-90	1. Generic Name: Perimetry/ Automated Visual Field Analyzer	Ophthalmic
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A device provides visual field assessment for glaucoma detection as well as numerous other eye conditions.	
	4. Technical Specification:	
	ergonomically designed and easily use with button/touch screen digital display color LCD/TFT monitor	
	integrated/external compatible printer	
	automatic chin rest operation	
	source to image distance of approx. 0.30 m	1
	full threshold mode test comprises of Peripheral, macular and central coverage up to 70°	
	quick mode test for shortening test times in both screening and threshold modes.	
	supra threshold mode for fast screening	
	projection type of stimulus method	
	stimulus time of 0.1-1s	1
	stimulus time interval approx. 0.8s to 2.8s	
	stimulus color: green, red, white and blue	1
	stimulus size: Goldman I, II, III, IV, V	1
	automatic background light intensity adjustment	1
	a complete package of visual field analysis software including normal eye database	
	patient information entry; Name, ID, Sex, Birth date, Visual acuity, Diagnosis, Correction, etc	
	storage of approx. 15,000 images on hard disc	
	Connectivity:	
	Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.	
	Integrated facility documentation with DVD/CD or USB	
	a capability of link Fundus images from other devices like OCT, Fundus	
	camera, etc. 5. System Configuration Accessories, Spares, Consumables and other	-
	componenets :	
	Ups with stabilizer	1
	All standard accessories, consumables and parts required to operate the	-
	equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer.	
	6. Operating Environment;	

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code		Department
Ilto-90	1. Generic Name: Ultrasound - Ophthalmic	Ophthalmic
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	1
	A-Scan can be used for biometric calculation and quantifying the	
	reflectivity of lesions in the eye and orbit where as B-Scan is used for	
	imaging the anatomy.	
	4. Technical Specification:	
	A-scan and B-scan mode	
	A scan probe frequency: not less than 10MHz	
	B scan probe frequency: not less than 10MHz	
	facility for IOL power calculations (all formulas)	
	auto & manual measurement function.	1
	distance & area measurement on B-scan images	1
	vector A-scan measurement	1
	simultaneous B-scan with vector A-scan measurement	
	A-scan dynamic recording with gain adjustments	1
	video CD recording facility	1
	dynamic movie archiving	1
	integrated or external compatible printer	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	A scan probe1	-
	B scan probe1	-
	Printer and CD recorder	-
	All standard accessories, consumables and parts required to operate the	-
	equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer.	
	6. Operating Environment;	1
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	1
	7. Utility Requirements:	1
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical	1
	Safety	_
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Yagl-90	1. Generic Name: YAG Laser	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	A Laser System which includes Neodymium-doped Yttrium Aluminum Garnet	1
	(Nd: YAG Photodisruptor Mode ,SLT mode) and Argon Laser is Fully	
	integrated laser workstation used in Ophthalmic surgery.	_
	4.Technical Specification:	
	Motorized table and chair	
	Continuously adjustable brightness	
	Adjustable slit height	
	Vertically-adjustable instrument table is also suitable for patients in wheelchairs.	
	Continuously adjustable slit width	
	Straight binocular tube with eyepieces	
	Aiming Beam: Red diode, continuously variable with adjustable intensity	
	LASER delivery system:	1
	Combined Argon /YAG Laser, YAG:SLT for ophthalmological procedures that deliver laser treatment for dual Anterior segment and posterior segment conditions	
	Medical grade Monitor: 21-inch LED with a minimum 1920 x 1080 resolution	1
	High-intensity light source that can be focused to shine a thin sheet of light into the eye with a conjunction bio microscope	
	Straight binocular tube with eyepieces	
	Tower illumination system and incorporated filters.	7
	The image on the monitor screen is equal to the image Seen through the oculars of the slit lamp	
	Blue, Red-Free, Amber filter which improves Contrast and color of retinal images	
	Heat insulation and Exciter / Barrier filter	
	Zoom magnification changer, which provides continuous observation through the magnification range	
	USB interface	
	Joystick, quick action brake and easy grip controls for precise slit adjustments	1
	Choice of ≥5 magnification steps for observation from overview to detail	1
	Width of slit image: Continuous from 0 to 10 mm	7
	Rotation of slit image: Continuous ±90°	1
	Travel of instrument base: vertical, lateral and axial	1
	Continuously adjustable brightness	
	Vertically-adjustable instrument table is also suitable for patients in	=
	reflectly adjustable instrument table is also suitable for patients in	

wheelchairs.

Adjustable slit height

Continuously adjustable slit width

Horizontal movement range

Wheel for vertical movement

Short frontal distance to the patient's eye

Internal fixation mechanism

Safety stop when light intensity more than limit value

Optimized illuminated area on the eye, for safety

UPS system with minimum 30 minute back-up

Voltage stabilizer of appropriate rating

Nd:YAG laser:

Laser Source; Q switched Nd:YAG

Wavelength: 1064 nm
Attenuation level >10

Four-point He-Ne aiming beam, coaxial to Nd: YAG beam

Maximum energy in single pulse: 10 mJ

Maximum energy in double pulse: 25 mJ

Maximum energy in triple pulse: 40 mJ

YAG:SLT (Selective Laser Trabeculoplasty) Mode

Laser Source; Q switched frequency doubled Nd:YAG

Wavelength: 532nm

Burst Mode: single pulse

Cooling: air cooling

Argon laser:

Run on self-contained air cooling

Wavelengths: 488/514/529 nm

Power total spectrum: 50 mW to 2.5 W

Power green spectrum: 50 mW to 1.1 W

Red diode aiming beam with adjustable setting

Modes of operation:

Single pulse with adjustable power and duration

Auto repeat in steps up to maximum of 6 Hz

Continuous wave

Safety goggles for Nd:YAG

Elbow rest (handcrafted wood)

Chinrest paper (Box of 1000)

UPS system with minimum 30min back-up

Voltage stabilizer of appropriate rating

5. Accessories/Consumables/Spare part and other component

With all standard and complete accessories safety eyeglasses for YAG, contact

Document: Capital Medical Device Technical Specification

lenses, (optional) laser indirect ophthalmoscope and endo probe

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Refa -90	1.Generic Name : Refractometer – Automated	Ophthalmic
	2.GMDN/UMDN Name/Code:	
	3.Clinical Purpose/Description:	
	Auto Ref-Keratometer is computerized vision testing machine used obtain and	
	objective measure the eye's refractive error. This measurement provides the most	
	accurate prescription for corrective lenses. It should be with full auto mode and	
	complete unit with all standard accessories.	
	4.Technical Specifications automatic radius measurement.	
	automatic peripheral measurement.	
	It must have adjustable tilt color LCD monitor at least 5inch	
	active accommodation relaxation.	
	IOL measuring mode	
	reliable PD measurement.	
	large cylinder measuring range up to 10 D.	
	Measurement as from 2.3mm pupillary diameter	
	In-built printer with paper cutter function.	
	Refractometer:	
	• Sphere (SPH): -30 to + 22D in steps of 0.12/0.25D	
	• Cylinder (CYL): 0 to +/- 10D in steps of 0.12/0.25D	
	• Axis (AX): 1 to 180° in 1 deg steps	
	Measurable pupil diameter: min 2.0mm diameter	
	• Automatic measurement (release) in the case of correct centering.	
	• 1 to 10 automatic measurements possible.	
	Radius Measurement:	
	• Surface refraction power 33.75D-67.5D in 0.01/0.12/0.25D steps.	
	• Radius 5.0-10.0mm in 0.01mm steps.	
	• Cylinder size 0-10D (Axis 0-180° in 1° steps).	
	Cornea vertex distance: 0, 10, 12, 13.5, 15mm.	
	Minimum pupillary diameter: 2.3mm.	
	Pupillary distance up to 85mm in 1mm steps.	
	an inbuilt thermal printer.	
	RS232C and video NTSC.	
	5.System Configuration Accessories, Spares, Consumables and other	
	components:	
	Trolley: 01 no. All standard accessories, consumables and parts required to	
	operate the equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer (including items not specified above	

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Octm - 90	1. Generic Name: Optical Coherence Tomography	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Optical coherence tomography (OCT) is an interferometry, non-invasive optical	
	tomography imaging technique offering millimeter penetration with micrometer	
	scale axial and lateral resolution.	
	4. Technical Specification:	
	Tomography imaging	
	Signal type: CCD image	
	Signal source: Super luminescent Diode, 840 nm	
	Longitude/Axial resolution: ≤ 5 um in tissue	
	Methodology :spectral Domain	
	Transverse resolution :<20um	
	Longitudinal (depth) range: 2mm in tissue	
	Scan speed :> 26000A scan per second	
	Normative database: RNFL(retina nerve fiber layer) GCC(ganglion cell complex)	
	and macular thickness,.	
	Fundus Alignment, Documentation	
	Signal type: CCD image	
	Field of view: 36 degree w * 22degree h or more	
	Viewing method: Flat panel display	
	Illumination: Near IR/Red free	
	Internal fixation: 32 x 16 LED dot matrix	
	External fixation: Slit lamp type adjustable blinking LED	
	Minimum pupil diameter: 2.5 -3mm	
	PC workstation with Core i7 CPU with laser printer (color),1T HDD, DVD	
	Read/Write, Image capture card and software loaded for digitization of	
	imagesRAM 16 GB and interfaces to RVG and Intraoral digitization.	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	
	Ups with stabilizer (30min)	
	Motorized table that accommodate main unit with all accessories.	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items	
	not specified above.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30 °C	-
	Relative humidity: < 85%	-

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Sla-90	1. Generic Name: Slit Lamp	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Complete eye exam to get a better look of structures eyes	1
	4. Technical Specification:	
	4.1 Microscopic Units	
	Should be Galilean-type converging binocular microscope type	-
	It 5 steps magnifications of 6/10/16/25/40x	-
	It overall visual field ø35.1mm, ø22.5mm, ø14.1mm, ø8.8mm, ø5.6mm	-
	4.2 Eyepiece lens	-
	It the magnification 12.5x	
	Diopter adjustment range -5D to +5D	-
	Binocular tubes inter pupillary distance 55 – 75 mm	-
	4.3 Illumination unit	-
	It the Slit width 0 to14mm, Slit length 14 to 1mm and aperture diameter ø14, 10, 5, 2, 1, 0.2 mm	
	4.5 Slit direction	
	It Vertical to horizontal inclination: 5°/10°/15°/20° for the Side swing	
	Filters Blue, red-free (green), grey (10 %)	
	4.6 Chinrest unit	1
	a longitudinal movement of at least 90mm	
	a lateral movement of at least 95mm.	
	a chin rest vertical movement of at least 80mm.	
	4.7 slit lamp stand	
	Should be supplied with motorized table.	
	It move all direction movements and with automatic and manual	1

operations

5. System Configuration Accessories, Spares, Consumables and other components:

with all standard and complete accessories

Eyepiece lens 4 pairs

LED 10 pieces

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC $\pm 10\%$

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one

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Base Code	Item Detail	Department
Arga-90	1. Generic Name: Argon laser	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	It is a laser system that uses noble gas as the active medium and used in many	
	applications such as forensic medicine, general surgery, ophthalmic surgery, and	
	holography and as an optical pumping source.	
	4. Technical Specification:	
	Selectable Argon Wavelengths 457.9nm, 488nm, 514.5nm and Multi-Line	
	Maximum. Output Power 16mW at 457.9nm, 80mW at 488nm, 100mW at	
	514.5nm and 300mW Multi-Line.	4
	Beam Diameter 1/e^2 0.75mm Beam. Divergence 0.95mrad.	4
	Beam Pointing Stability <30urad. Output Power Drift (after warm-up) < +/- 1%.	_
	Beam Amplitude Noise < 1% RMS Polarization Ratio > 250:1	
	Warm-up Time 10 Minutes Dimensions (LxWxH – inches) 19.2" x 7.6" x 5.4"	
	Weight (lbs/Kg) 22lbs / 10Kg	_
	Cooling method: laser cooled	
	Output power stability (over 2 hour period after warm up): $< \pm /- 1\%$. Beam pointing stability (over 2 hour period after warm up, ± 2 °C): < 30 µrad	-
	Manufacturer, Country of Origin and Model of Equipment Part which is	
	Manufactured by other Company Must be Clearly indicate The standard length	
	of the cooling hose is 6	
	5. System Configuration Accessories, Spares, Consumables and other	1
	components:	
	Power supply, cooling system, Wavelength Select Modules, Safety Interlock	
	Accessories, Safety Eyewear minimum 100 quantity and all the necessary	
	accessories	4
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	1
	Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
	10. Warranty and After Sale service:	

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Base Code	Item Detail	Department
Func-90	1. Generic Name:Fundus Camera	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A Fundus camera or retinal camera is a specialized low power microscope with	
	an attached camera designed to photograph the interior surface of the eye,	
	including the retina, optic disc, macula, and posterior pole i.e. the Fundus. A	
	digital camera converts these images into digital images.	
	4. Technical Specification:	
	Digital Fundus Camera provides color and Fundus auto fluorescence (FAF)	
	imaging within a small compact design.	
	Field angles 30-60 deg.	
	Image captures (Color, Fluorescein Angiography, Green, Blue and Red).	
	Capture: 1 chip sensor color 1 chip sensor black & white	
	Monitor 15 inches LCD for direct display.	
	Fixation light: internal and external fixation lights both.	
	Exposure interval 0.5 - 1 sec.	
	Facility for data storage, data transfer, image archiving, image analysis.	
	Instrument table: asymmetrical motorized suitable for patients in wheel chair.	
	Supporting latest computer hardware & software.	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	Suitable UPS with maintenance free batteries, voltage regulation and spike	
	protection for minimum 30 min. back-up supplied with the system.	
	Digital Fundus Camera, complete with compatible printer for reporting and all	
	standard accessories.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical	
	Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
		_

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Department
Cryo-90	1. Generic Name: Ophthalmic Cryo unit	Ophthalmic
	· · · · · · · · · · · · · · · · · · ·	· F
	2. GMDN/UMDN Code/Name::	_
	3. Clinical Purpose/Description:	
	Used most often to treat retinal tears, is a procedure that uses intense	
	cold to induce a chorioretinal scar and to destroy retinal or choroidal tissue.	
	4. Technical Specification:	-
	Digital temperature display	-
	Safe and effective low pressure freeze and defrost	-
	Complete gas scavenging	-
	Wide array of interchangeable probes	1
	Freezing temperatures -89 degrees	1
	Curved glaucoma type probe necessary and retinal probe	-
	Probe specs-completely non electric and autoclavable	-
	5. System Configuration Accessories, Spares, Consumables and	-
	other components:	
	with all standard and complete accessories	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:]
	Shall meet IEC-60601(Or Equivalent) General Requirements of]
	electrical Safety	_
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent) 9. Installation, Training and Commissioning:	-
	The supplier must provide installation, and commissioning of the	-
	device at health Facility	
	The supplier must provide onsite technical and end user training	†
	10. Warranty and After Sale service:	†
	The supplier must be provide minimum of Two years warranty	1
	including labor and spare part from the date of commissioning.	
	After basic warranty the supplier must agree for after sales service	
	11. Documentation:	1
	User and service manual in English	
	12. Packaging and Labeling;	1
	Packing of all the goods clearly marked and securely packed.]

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base Code	Item Detail	Department
Pham-90	1. Generic Name: Phaco + Vitrectomy Machine	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Phaco + Vitrectomy Machines are used to break up and remove	
	cataractous lenses and to performs anterior and posterior microsurgical	
	procedure in which to repair retinal disordersof the eye. It possess	
	irrigation, irrigation, aspiration and ultrasound, diathermy, and vitrectomy	
	operational modes 4. Technical Specification:	-
	The units should possess irrigation, irrigation, aspiration, ultrasound,	-
	diathermy, and vitrectomy operational modes.	
	Phaco power 0-100%	1
	Phaco Vacuum Level: 0-500mmHg	
	Pump Flow Rate 10 to 40 cc per min	1
	Ultrasound delivery mode: continuous, micro pulse and burst mode -	1
	without generating significant heat.	
	The units should possess irrigation, irrigation/aspiration, ultrasound,	
	diathermy, and vitrectomy operational modes.	 -
	For effective cold Phaco it software for adjustable duty cycle.	<u> </u>
	Advanced fluidics with sensor system for vacuum and irrigation.	-
	Digital pulse pump with vertically designed fluitics panel, vacuum	
	sensitive proportional fluid venting.	<u> </u>
	Facilities for Bipolar Coagulation, Phaco emulsification, ultrasound Aspiration and Anterior Vitrectomy	
	Machine good panel display with digital control good audio, memory set	-
	up for surgical parameters	
	Digital LCD color display screen 15"	
	Computer microprocessors - Intel chipset for medical applications.	
	Simple to service and upgrade, customized surgeons programs,	
	programmable power pole with automatic programmed adjustment of	
	bottle height during each procedurals phase.	
	Constant anterior chamber volume by means of micro-processor controlled	
	venting-pressure equalization system	-
	Advanced technology multifunctional foot switch,	-
	Vitrectomy attachment should be available upto 600 cuts/minute.	-
	Machine with good track record will be preferred.	-
	Two IA straight hand pieces with 4 piezo electric crystals.	-
	Display for relative and absolute ultrasonic time and dose	_
	Bipolar Coagulation: 2 to 6 watts; Foot controlled	-
	Phaco emulsification:]

- a) Ultrasonic tip frequency: 29-60 KHz
- b) Phaco power in both linear and pulse mode
- c) Ultrasound pulse rate 1-14 pulses/sec
- d) Micro flow tip
- e) Auto priming, auto fluidic and auto tuning

Aspiration: 0-500 mmHg linear vacuum

Anterior Vitrectomy: 30-600 cuts/min

Multifunctional foot pedal with a reflux switch

Machine stainless steel trolley with 4 lockable wheels

5. System Configuration Accessories, spares, Consumables and other consumables:

Aspiration/irrigation unit: 5 hand pieces

Re-usable silicone hose system: 10 hand pieces

Foot switch

Irrigation cannula: 10 pieces

Infusion stand.

Hand piece: 5 pieces

Titanium tips: 30 degree US tips: 30

Pars-plana titanium tips

Pneumatic vitrectomy 20 G

Electromagnetic vitrectomy

Phaco-keratome

Diathermy cord: 1

Tubing: 6

Silicon Sleeves: 5

Test chambers: 5

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+30 \,^{\circ}\text{C}$

Relative humidity: < 85% 75

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of three years warranty spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base Code	Item Detail	Department
Refg-90	1. Generic Name: Refrigerator - General Purpose, 300L/500L/700L	Pharmacy
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	General purpose Refrigerator is an Upright refrigerator for storage and	
	conservation of vaccine, chemicals and reagents in clinical laboratory and	
	pharmacy @ 0°C to 10°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	Internal net volume: 300L/500L/700L	
	Easily adjustable ≥ 3 shelves	
	Insulation material: polyurethane, CFC-free	
	Lockable door, solid	
	Electronic temperature control: 0°C to 10°C.	
	Accuracy, whatever the load: +/- 1°C	
	Lighting System: Top LED	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature	
	recording device	
	Integrated four castors with break	
	Minimum compressor starting voltage: 22% below nominal voltage	
	Microprocessor controlled spike and surge protection, and protection against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status,	
	Electronic fuse disconnects and reconnects automatically	
	KVA rating matches power consumption of the refrigerator	
	PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure,	
	battery low, Door Ajar etc.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	
	Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.	

Heavy duty hinge for closure and un-interruptive service.

Informative display and control screen with history tracking

Easy data transportation through USB port and it must also have on board diagnostic software.

Adjustable LED lighting for efficient energy

Illumination with auto-on feature and ON/OFF switch

Forced-air circulation maintains chamber uniformity and provides

Quick recovery after door openings

Bacteria-resistant interior, exterior, and door handle

Voltage stabilizer of appropriate rating

Keeping inside temperature for 8Hr during power failure

Accepted input range: -20 % to +20 %

Response time: <15 ms

Power consumption: 500 W

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +43°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

Document: Capital Medical Device Technical Specification

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Name	Department
Eegm-90	1.Generic Name: EEG Machine	Neurology
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	1
	An electroencephalograph have electrodes placed on a patient's scalp to	1
	measure, amplify, display in graphic form, and record the weak electrical	
	signals generated by the brain.	_
	4. Technical Specification:	
	Number of EEG Channels should be 32 with color coding, and another	
	eight channels for Polygraph. Also any two channels can be configured as	
	Bipolar, AC or DC through software Facility for simultaneous sampling of all EEG channels and multiple	-
	sampling rates.	
	Phonics Stimulator with software programmable for manual or automatic	1
	sequences.	
	Networking facility	
	DICOM compatible	
	32 Channel Amplifiers needed.	
	CMRR≥ 110 dB or better	
	Noise ≤ 2uV peak to peak	
	Input Impedance 100 Mohm	
	16 bit ADC resolution voltage of 0.15 uV	1
	Low filter adjustable between 0.16 to 5 Hz.	
	High Filter Adjustable between 50 to 100Hz.	1
	Notch Filter Adjustable to software.	1
	Acquisition Sensitivity from 1 microvolt per mm to 2000 microvolt per	1
	mm.	
	Networking facility	
	Acquisition Software:	
	Facility to combine all user defined settings into templates or protocol, for	
	use in different applications.	
	Facility for Individual Channel Control, Customization of Montages,	
	along with Remontage Capabilities.	-
	Graphical view of the current montage during the EEG recording.	_
	Facility to define New Sensors should be possible as standard i.e. assign to amplifier inputs, define traces in a mintage, define calculated channels	
	(Average, Source/Laplacian)	
	Facility to click any point to display corresponding traces & Slide pointer	1
	to change displayed duration of the Overview.	
	Facility for sortable list of all events placed in the recording, both	1
	automatically and manually.	

Facility to review and add events to recorded traces.

Facility for automatic time counters and event insertion during Hyperventilation.

Facility to controlled display Sensitivity for User defined value.

Facility to choose Low & High Cut Filters along with facility to enter any user defined value.

Facility to file zip

Facility of configurable Time Base

Spike & Seizure software

1Trend Analysis software

Review Software:

Paging facility as Automatic Paging, Mouse controlled Paging and/ or Keyboard Paging.

Playback of EEG for more channels.

Facility for Zoom/ Magnify EEG trace

Facility for Copy & Paste of EEG or Trends to reports and presentations

Facility for Automatic generation of reports.

Facility for viewing several recordings in tiled or cascading windows

Patient Administration Software:

Network supported patient and test management software, archive to CD or DVD, powerful search, patient folder, workspaces

Upgrading the digital EEG to Video EEG with day/night camera using MPEG-2 latest a generation technology

Video camera to control patient movement

all components for video EEG up gradation

Resettable over current breaker shall be fitted for protection

5. System Configuration Accessories, Spares, Consumables and other components:

Compatible Laser Printer with 600 DPI Resolution and A4 Size printing facility $-\,01$

Patient cable and connectors with electrodes and electrodes with head cape, Papers for at least 1000 EEG Exams and all the necessary power cables and other interfaces.

Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications.

Suitable UPS with maintenance free batteries for minimum three-hour back-up should be supplied with the system.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Referral/Specialized Hospital Capital Medical Equipment Technical Specification

Base Code	Item Detail	Departmen
Wari-90	1. Generic Name: Warmer - Radiant, Infant	NICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	•
	Infant radiant warmer used for the treatment of hypothermia on infants and it consists of a biocompatible bed, overhead heater and suction unit.	
	4. Technical Specification:	
	Mobile, mounted on 4 double swiveling castors wheels, all 4 with brakes.	-
	Antistatic castors, with breaks	-
	Table surface with conductive mattress with infant head/shoulder support	•
	Mattress-padding: foam density approx 25 kg/m3.	•
	Mattress cover: Memory Foam Mattress, waterproof, washable.	
	resistant to cleaning with chlorine based solution and flame retardant	
	Side boards transparent acryl, drop down and lockable	-
	Bassinet trolley; bed should be tilt able and have provision for X-Ray cassette holder.	
	Markings on the bassinet and X-Ray cassette holder are mandatory to enable proper positioning of the baby while doing the X-Ray.	
	Integrated T-piece resuscitator with adjustable controls of PIP and PEEP.	
	Integrated Balance Scale.	
	With built-in blender for controlling levels of Oxygen concentration from 21% to at least 60% With Built in Medical air compressor.	
	Under table 2 storage drawers.	
	Side rails allow for mounting of accessories.	
	Hood suspended above the table integrates heating element and overhead light.	
	Overhead light: LED	
	Base should be height adjustable with electrical foot switches on both sides.	
	Integrated support for two not less than 10L oxygen cylinder.	
	Display with LED screen full color for displaying graphics and trends of air temperature, skin temperature (main temperature and peripheral temperature), Oxygen concentration in the environment, newborn's weight, Respiration, heart pulse and newborn data.	
	Feather touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection	
	Control unit has flow meter and displays pressure.	
	Heating element: emitter with parabolic reflector and protected by metal grid Control unit allows air and skin temperature preset (LED indicator) and drives radiant heater Output (servo and manual)	
	Equipped with Oxygen analyzer module to monitor O2 levels at the ambient. Combined with an acrylic helmet, can be used to administer a closed environment with higher concentrations of O ₂	

Integrated timer: 1 to 59 min, with count-up and count-down feature

Temperature range, skin: 34 to 38 deg C (user pre-settable)

Bed can tilt continuously up to \pm 12° for Trendelenburg proclive & declive positions, through electric command buttons.

Monitoring of skin temperature by means of sensor, range: 30°C to 42°C

Heater output: 0 to 100% in increments of 5%

Built-in SpO_2 module to measure O_2 saturation and heart pulse with information to be displayed on the control panel LED screen.

Audio and visual alarms for: Power failure, Probe failure or disconnected, Heater failure, Temperature higher or lower than set temperature, Oxygen concentration higher or lower than set, SpO₂ probe failure or disconnected.

Display reports systems errors, sensor failure.

Control unit: audiovisual alarms according to timer and temperature presets avoiding overheating

Protection: OVP, earth leakage protection.

5. System Configuration Accessories, Spares, Consumables and other components:

- 1 x Memory Foam Mattress
- 3 x skin temperature probe (including connection cable)
- 3 x spare skin temperature probe (including connection cable)
- 1 x spare heating element
- 2 x empty 10L and Medical oxygen cylinders

Skin adhesive for fixing probe -100 units

Acrylic helmet – 1 set of 3 sizes

5 x spare of set fuses

Eye pads for use during phototherapy -50 units

IV pole

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including

labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

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Addis Ababa

Base code	Item detail	Departmen
BiP-90	1. Generic Name: BiPAP	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway pressure (CPAP)	
	that gives a constant flow of oxygen/air to the patient at a preselected pressure,	
	thereby imposing a small overpressure within the lungs that assists the gas	
	exchange	
	4. Technical specification	
	The system should meet all the numerical values given in the technical	
	specifications within a tolerance of +/- 10 %	
	IPAP 4 to 30 cmH2O	
	EPAP 4 to 25 cmH2O	
	Breath rate 0 to 30 BPM with spontaneous for time mode	
	Timed inspiration: 0.5 to 3.0 sec	
	Rise Time: 100 to 600 m-sec	
	Machine should be based on the solenoid valve technology and should offer	
	preferably auto track sensitivity and adjustable risetime. Filter: foam and ultrafine	
	LCD digital control	
	Altitude compensation: auto	
	Light weight, portable hand	
	Limiting the delivered pressure in the event of an occlusion	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 db at mid pressure range	
	User adjustable settings	
	Patient alarms	
	Equipment alarms to alert user to power failure,	
	low battery,	
	overheating,	
	mask / tube fault Inlet air filter to be fitted.	
	5. System Configuration Accessories, Spares, Consumables and other	
	Components:	
	Five of each size of reusable, sterilizable masks and tubes (adult, pediatric,	
	neonatal)	
	Two sets of fuses, if replaceable type used Five replacement inlet air filters	
	Supplier to specify if the following are available as options:	
	flow meter, humidifier, oxygen analyzer	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 45°C	
	Relative humidity: < 85%	
	7. utility requirement	
	Electrical Power Supply: 220VAC +/-10%, 50Hz	
	UPS of suitable rating with voltage regulation, spike protection and	
	maintenance free inbuilt batteries for 2hrsback up	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of	

Safety for Electromagnetic compatibility. Or should comply with 89/366/EEC; EMC-directive.

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

CE marked

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

b). Drain Connection:

Drain outlet via either drilled floor or any other for drainage purpose

Connection: Ø 50 / 45 mm or copper Ø 35 / 30 mm

Capacity: ≥10 L/min

c). Electrical Connection:

Single phase electrical line from hospital MDB/Generator near to the machine (with grounding)

Single phase breaker with size as per manufacturer recommendation near to the machine.

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User/operating and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

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Document: Capital Medical Device Technical Specification

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Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item detail	Department
CP-90	1. Generic Name: CPAP	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway	
	pressure (CPAP) that gives a constant flow of oxygen/air to the patient	
	at a preselected pressure, thereby imposing a small overpressure within	
	the lungs that assists the gas exchange	
	4. Technical specification	
	Light weight, portable by hand	
	Pressure range to be user settable and to include the range 4 to 20 mbar.	
	Controls to be easy to operate, numbers and displays to be clearly	
	visible.	
	Pressure support: 0 - 45 cm H2O	
	Pressure ramp function required to assist falling asleep	
	Manual breath button	
	Feedback control of the warming.	
	Digital display of temperature.	
	Working flow range between 4 and 40 l/m.	
	No External compressed gas required	
	FiO2 concentration should be adjustable from 21-100%	
	Self-contained unit generating oxygen and its own medical graded air	
	Alarms at least for: lack of water; sensor failure; high, low temperature.	
	Monitoring of the air temperature: precision \pm 1° C.	
	Limiting the delivered pressure in the event of an occlusion	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 dbA at mid pressure range	
	Humidifier	
	Humidity compensation system	
	Should regulate the required temperature	
	Should be closed system for filling-up system	
	Should have port for heater wire as well as temperature probe	
	Should display chamber temperature and temperature at the patient end	
	Patient circuit	
	Should have the option of using both disposal and reusable circuits	
	Disposal circuits should be readily available	
	Should be able to accommodate a heater wire:	
	Minimal heat loss	
	Displayed parameters	
	Tidal volume,	
	Inspiratory pressure,	
	Inspiratory time,	

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Page 186 ISBN No: expiratory time,

IE ratio,

FiO2

User adjustable settings

Patient alarms

Equipment alarms to alert user to power failure, low oxygen concentration, high & low pressure, no flowlow battery, overheating, mask / tube fault Inlet air filter to be fitted.

5. System Configuration Accessories, Spares, Consumables and other Components:

Five of each size of reusable, sterilizable masks and tubes (adult, pediatric, neonatal)

Two sets of fuses, if replaceable type used

Five replacement inlet air filters

Supplier to specify if the following are available as options:

flow meter, humidifier, oxygen analyzer

Bubble CPAP ventilator:

- 1) 400 to 700 ml container.
- 2) Mean positive pressure provided between 2 and 12 cm of H2O.
- 3) Single use entry and exit connectors.
- 4) Patient circuits for adult, pediatric or neonatal patients. AirO2 mixer
- 5) Oxygen regulation scale between 21% and 100%.
- 6) Stainless steel or metallic antioxidant material.
- 7) Different connectors for Air and O2.
- 8) Flow meter for low flow values from 0 to 1 lt/min.

6. Operating Environment;

Operating Temperature:+ $10 \, ^{\circ}\text{C}$ to + $45 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. utility requirement

Electrical Power Supply: 220VAC +/-10%, 50HZ

UPS of suitable rating with voltage regulation, spike protection and maintenance free batteries for 2hrs back up

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

certified according CE93/42 FDA 510k or equivalent

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

b). Drain Connection:

Drain outlet via either drilled floor or any other for drainage purpose

Connection: Ø 50 / 45 mm or copper Ø 35 / 30 mm

Capacity: ≥10 L/min

c). Electrical Connection:

Single phase electrical line from hospital MDB/Generator near to the machine (with grounding)

Single phase breaker with size as per manufacturer recommendation near to the machine.

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

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Addis Ababa

Base Code	Item Detail	Department
Incn-90	1. Generic Name: Incubator - New born	NICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Used to maintain appropriate temperature and humidity levels mainly for	
	premature infants and other newborns that cannot effectively regulate their	
	body temperature.	
	4. Technical Specification:	
	Electronic control of humidity, air temperature and infant skin temperature.	
	Clear, hard cabinet for infant viewing.	
	Double wall with air circulation.	
	Easy access control panel, with light touch/button operation switches.	
	Facility to elevate base, adjustable range.	
	Self-test functions are performed.	
	Built for stable, stationary operation in ward environment	
	Controlled by microprocessor or microcontroller.	
	Servo controlled mode to adjust patient's skin temperature not lower than 34°C up to 38°C.	
	Servo controlled mode to adjust air temperature from 23°C or less to 39°C.	
	Equipped with balance scale	
	Air filter	
	Minimal resolution of 0.1 °C.	
	Monitored parameters: air temperature, patient's skin temperature, oxygen concentration and humidity	
	Micro controlled humidifier with range 40 to 90%	
	Oxygen input flow rate 3 to 15 litres/min or oxygen concentration range 21 to 70%.	
	Maximum CO2 concentration inside incubator 0.2%.	
	Noise level in the interior of the hood less than dBA.	
	Head end raise facility with auto lock.	
	Capable of use in X-ray without removing baby	
	Trendelenburg and inverse Trendelenburg positions.	
	Auto-calibration of measurement circuits.	
	Displayed parameters	
	Patient temperature	
	Air Temperature: humidity and oxygen concentration	
	Visual and audible alarms for:	
	Patient and air high/low temperature alarm.	

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Air circulation / probe / system / power failure alarm.

Humidity alarm.

Power failure.

Temporal alarm silencer.

Heater power indicator

User Adjustable Parameters

Air temperature control from 23°C/73.4°F to 37°C/98.6°F

Patient temperature control from 34°C/93.2°F to 37°C/98.6°F

Humidity control from 40 to 80%

Oxygen input flow rate from 3 to 15 lpm

Components:

Transparent cabinet.

Double-wall with air circulation between the hood and the double wall.

One door with air curtain.

Mattress with washable and water proof cover; removable and not smaller than 55 cm (length) x 34 cm (wide).

Accommodates shelves and I/V poles.

Mounted on stationary table, base of which is at least 80 cm high

At least four ports for tubes access to the interior of the hood.

At least four ports to access the patient.

At least one door or drawer or accessories base

Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes. Mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium.

Humidifier Water tank capacity not less than 1 liter.

5. System Configuration Accessories, spares, Consumables and other consumables:

One extra mattresses

Two extra sets of sensors

Two extra sets of air temp sensors

Two extra sets of air filters

Two reusable temperature sensor probes.

A reusable or disposable skin temperature sensor probe.

Sticky reflective patches.

Sleeves

oxygen analyzer

Two extra sets of fuses

Washable and waterproof Mattress cover.

• Internal Quality control and calibration system and control material

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

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10. Warranty and After Sale service:

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Addis Ababa

		1 _
Base Code	Item Detail	Department
Venm-90	1. Generic Name: Ventilator - ICU, Mechanical	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Mechanical Ventilator used for patients to breathe by assisting inhalation	
	of oxygen into lungs and exhalation of carbon dioxide.	
	4. Technical Specification	
	Display ≥10" LED/TFT touch screen	
	Resolution of 1280 X 1024	
	Menu of functions appear on the screen.	1
	User interface with controls and display	
	Pneumatic with electronic control and alarm	
	Patient category: Adult, Pediatric and Neonate	-
	Mounting Trolley/Cast mounting for easy transportation: 4 Castor Dia. 10cm with brakes	
	Integrated printer	-
	Ventilation parameters:	-
	Tidal volume: 10 - 2000 mL	-
	Respiratory rate: 5 - 80 BPM.	-
	Pressure: 1 - 100 cm H2O.	-
	Inspiratory Peak Flow: 4 - 100 1/min.	-
	Minute volume: 1 - 30 1/min.	-
	Oxygen Concentration: 21 -100 %	-
	Inspiratory pause: 0.1 - 5.5 sec.	-
	I:E ratio : 1:2 – 1:6 / 2:1	-
	PEEP/CPAP: 0-30 cm H2O.	-
	Graphical Display of flow(t), TV(t)	-
	Pneumatic Gas Sources:	-
		-
	Gas delivery system by sound less in built compressor / external integrated compressor with the unit.	
	In case of compressor failure also be operable with compressed air /	-
	oxygen supply of 45 to 60 psi.	
	Automatic gas switch over if O2 supply fails	
	Enables spontaneous breathing with filtered ambient air if air and O2 supply failed	
	Digital output and input via interface	1
	Internal battery (maintenance free) with 4 hour minimum operating time for the ventilator	
	Direct access to vital settings	†
	Transducer Sterilizable and reusable	-

Document: Capital Medical Device Technical Specification

PEEP valve built in Patient circuit separate inspiratory and expiratory limb Back up mode for apnea Full alarm system for all ventilator settings and monitored values Time simultaneous display of two waveforms. Display minimum 3 graphs and 2 loops Automatic leakage compensation Adjustable resistance compensation for endotracheal tubes Trans pulmonary pressure monitoring via esophageal catheter Automatic maneuver for static compliance assessment and lung recruitment including trans pulmonary pressure Mainstream (volumetric) or side stream Co2 sensor Integrated continuous cuff pressure controller With independent oxygen supply Inspiration time 0.1 to 10sec Nebulizer: Integrated pneumatic nebulizer Humidifier control Ventilation modes Therapy mode: High flow oxygen therapy Ventilation modes Adaptive Support Ventilation. Guaranteed minute volume and respiratory rate Fully closed loop ventilation and oxygenation **Ventilation Mode:** A/C VC A/C PC A/C PR VC SIMV VC SIMV PC **CPAP** NIV **PSV** SIMV/PSV Pressure support ventilation with bidirectional backup Dual positive airway pressure (biphasic positive airway pressure) Airway pressure release ventilation Synchronized controlled mandatory ventilation Synchronized intermittent mandatory ventilation Volume support, tidal volume guaranteed with bidirectional backup Noninvasive ventilation with bidirectional backup Noninvasive ventilation with mandatory rate

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Monitoring parameter:

Synchronized nasal CPAP
High flow oxygen therapy
Real-time airway pressure
Real-time auxiliary pressure
Peak airway pressure
Mean airway pressure
Minimum airway pressure
Plateau airway pressure
Positive-end expiratory pressure / cont. positive
Airway pressure
Inspiratory pressure
Cuff pressure
Trans pulmonary pressure at the end of inspiration
Trans pulmonary pressure at the end of expiration
Real time trans pulmonary pressure
Real-time inspiratory / expiratory flow
Peak inspiratory flow
Peak expiratory flow
Real-time tidal volume
Expiratory tidal volume / Inspiratory
Tidal volume
Expiratory minute volume / Spont minute volume
Leakage volume at the airway
Avoid excessive VT
Temperature Y-piece
Chamber outlet temperature
Temperature difference between humidifier chamber and Y-piece
Inspiratory / expiratory ratio
Total breathing frequency
Spontaneous breathing frequency
Inspiratory time
Expiratory time
Index of spontaneous respiratory rate variability
Percentage of spontaneous breathing rate
Static compliance
Airway occlusion pressure
Auto PEEP
Pressure-time product
Expiratory time constant
Inspiratory time constant
Expiratory flow resistance
L ·

Inspiratory flow resistance Rapid shallow breathing index Imposed work of breathing Airway oxygen concentration (FiO2) Fractional end-tidal Co2 concentration End-tidal Co2 partial pressure V/Q status of the lung Alveolar tidal ventilation Alveolar minute ventilation Elimination of Co2 Airway dead space Dead space fraction measured at the airway opening Exhaled volume of Co2 Inspired volume of Co2 Real-time plethysmogram Saturation (pulse oximetry) Heart Lung Interaction Index Pulse rate Carbon monoxide concentration Methaemoglobin concentration Total oxygen content Alarm Audio Visual with Silent Feature 5. Accessories/Consumables/Spare parts/Other component: Ix AC Power Cord Ix Humidifier Bracket Kit Ix Humidifier Mounting Adapter Ix O2 Cylinder Holder Kit Ix O2 High Pressure Hose Ix O2 Manifold Ix O2 Sensor Kit
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1x O2 High Pressure Hose 1x O2 Manifold
1x O2 Manifold
1x O2 Sensor Kit
3x RS-232 serial communications cable
10x roll of paper
Adult, Ped. And Neonate Test Lung
3x Adult, Ped. and Neonatal Reusable Patient Circuit/Each
5x Reusable Inspiratory Bacteria Filter
3x Reusable Exhalation Bacteria Filter
2x Water Traps
2x Coupling, Straight Silicone
1x Water Collection
2x humidifier bottle
Full software package for all ventilation mode indicated above

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Femo-90	1. Generic Name: Monitor-Fetal	NICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Electronic fetal monitoring (EFM) provides graphic and numeric information	-
	on fetal heart rate (FHR) and maternal uterine activity (UA) to assess fetal	
	well-being before and during labor.	
	4. Technical Specification:	
	Measure, record, and display FHR, uterine contractions, and maternal blood pressure, heart rate before and during childbirth.	
	Sense FHR and uterine contraction indirectly through the mother's abdomen and/or directly by placing an electrode on the fetal scalp (or exposed skin surface) and by Measuring the change in pressure within the uterus.	
	Ultrasound working frequency in the range 2MHz -10% to 3MHz +10%.	1
	Heart rate measurement range not smaller than 50-210 bpm with resolution not higher than 2 bpm.	1
	Record fetal and maternal ECG recording.	1
	Integrated monitoring of fetus and mother.	
	Twins monitoring capability	
	Thermal printer or inkjet printer	†
	Support external thermal printer or inkjet printer	1
	Built-in rechargeable battery, DC/AC power supply	1
	Built-in network capability	
	15"Color TFT screen display waveforms and digitals	1
	Maternal Parameters: ECG, SPO2, NIBP, RESP, TEMP	
	Automatic Fetal Movement Detection, AFM waveform display	
	24 hours monitoring data storage and reload	
	Acceleration and Deceleration measurement ability	
	Baseline, acceleration and deceleration analysis capability	
	Easy operation by with shortcut key and rotary knob	
	Super printing functions	1
	Automatic monitoring mode, parameters configurable	
	At least two high sensitivity equipment compatible probes provided: 2 and 3 MHz	
	Sensitivity to detect fetal heart beats of at least a 10-12 weeks fetus.	
	Clinical data management, can be reload, reanalysis, reprint	1
	Visual and audio alarm, comply with international standard	
	2 MHz pulse wave	
	Precision: ±1-2 bpm	1
	Record differentiated: 30bpm/cm	1

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Temperature: 5°C-40°C

Brightness LED power supply indicator light

audible and visual alarm

Alarm: upper and lower limit alarm

5. System Configuration Accessories, Spares, Consumables and other Components:

At least 1 of system compatible headphones provided.

At least one integrated serial port for PC connection and data transmission.

Memory storage capacity of at least 4 hours of working data.

Cable for data transmission.

1 pair of spare system compatible headphones.

At least 1 bottle of gel for patient application.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Document: Capital Medical Device Technical Specification

Tender and Purchase Order No.
Name and Model of the product
PO Box 25-11-276-32-65
Tel: +251-11-276-32-65
Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Detail	Department
Pamo-90	1.Generic Name: Monitor - Patient	ICU
	2. GMDN/UMDN Name /Code:	
	3. Clinical Purpose/Description: A device used to measureand display	
	physiological signal of patient.	
	4. Technical Specification	
	Adult, pediatric and neonate patient monitoring	
	15" TFT color display with 12 waveforms	
	Measuring Parameters: ECG, Respiration Rate, NIBP, SpO2, Temperature, IBP, Cardiac output, EtCO2 capnography, , and with all its measuring	
	accessories and spares. SPO2 Range 0 – 100%	
	10-lead: I; II; III; avR; avL; avF; V1-V6	$\overline{}$
	Automatic Sweep Speeds 12, 25, 50 mm/s	
	Heart Rate Range Adult: 15 – 300 bpm Neonate/Pediatric: 15 – 350 bpm	_
	RESPIRATION	
	Method: Thoracic Impedance	\dashv
	Modes: Automatic / Manual	
	Range: Adult: 0 – 120 BrPM Neonate/Pediatric: 0 – 150 BrPM	
	with Apnea and Audio Visual Alarm recallable Alarm Events	
	NIBP	
	Method: Automatic Oscillometric	
	Modes: Manual / Automatic / Continuous	
	Types :Systolic, Diastolic, Mean	
	Measurement Range	
	Range of Systolic Pressure	
	Adult Mode: 40 – 270 mmHg	
	Pediatric Mode: 40 – 200 mmHg	
	Neonate Mode: 40 – 130 mmHg	
	Range of Diastolic Pressure Adult Mode: 10 – 210 mmHg	
	Pediatric Mode: 10 – 210 mmHg	
	Neonate Mode: 10 – 90 mmHg	
	Range of Mean Pressure	
	Adult Mode: 20 – 230 mmHg	
	Pediatric Mode: 20 – 160 mmHg	
	Neonate Mode: 20 – 110 mmHg	_
	Accuracy of Blood Pressure Measurement	
	The Mean error less than ±3 mmHg.	
	The Standard deviation less than 5 mmHg	

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Over-Pressure Protection: Double safety protection

Alarm Systolic, Diastolic, Mean

CO₂

Range 0 - 99 mmHg

Temperature

Range $0 - 50^{\circ}$ C

Resolution 0.1°C

Accuracy ±0.1°C

Channel: Dual channel

12-lead ECG with 10 hour data storage, ST Segment and Arrhythmia Analysis

Micro stream ETCO2 disposable kit for adult- 50 nos, pediatric & Neonatal – 4 nos, each

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

 $Should\ provide\ hemodynamic,\ oxygenation,\ Ventilation\ calculation\ package.$

- Should have drug calculation package.

Audiovisual alarm in case of Apnea and physiological measurements are outside preset range

Automatic Zoom In Facility in the monitor display.

Silencing feature for audio alarms

Trend display of 48hours

Data interface (for ECG): RS232, BNC or equivalent

Defibrillator sync and protection during defibrillation

Pacemaker detection/rejection

Display reports system errors, leads and sensors failure and built-in battery status

Automatic switch to batteries in case of power failure

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

Should provide hemodynamic, oxygenation, Ventilation calculation package.

- Should have drug calculation package.

Audiovisual alarm in case of Apnea and physiological measurements are outside preset range

Automatic Zoom In Facility in the monitor display.

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Pacemaker detection/rejection

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Automatic switch to batteries in case of power failure

Thermal recorder and printer (4Roll)

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- 1 x Spare rechargeable battery pack
- 1 x Set of spare fuses

NIBP accessories:

- 3 x NIBP hose (1 x neonate, 1 pediatric, 1 x adult)
- 3 x Blood pressure cuff (1 x neonate, 1 x pediatric, 1 x adult, 1 obese adult)
- 20 Nos of Disposable IBP transducers with all standard accessories & 6 nos of reusable adapter cable.

ECG accessories:

- 5 x Patient cable extremities (1x neonate/pediatric, 1 x adult)
- 5 x Set of electrodes (1x neonate/pediatric, 1 x adult)
- 1 x Electrode gel, 350 ml

Temperature accessories:

2 x Skin temperature probes and rectal probe (including connection cable)

Pulse Oximetry (SpO2) sensors with cable and plug:

- 5 x Adult size, reusable clip-on type
- 5 x Infant size, reusable clip-on type
- 6 x Newborn size, reusable clip-on type
- 10 x Newborn size, single use wrap-around type

Disposable SpO2 probes for neonatal use - 50 nos.

IBP accessories:

4 x Reusable pressure transducer with bracket, holder

100 x Disposable domes

EtCO2 module with all accessories:

In case of side stream EtCO2-10 sets of sampling tubes for each module to be included.

Micro stream ETCO2 disposable kit for adult- 50 nos, pediatric & Neonatal – 4 nos.

Cardiac Output:

Should be by thermo dilution method with all accessories

EEG Modules with all accessories and display at least two channels

5. System Configuration Accessories, Spares, Consumables and other components:

Reusable adult, neonate and pediatric SpO2 finger probes – 5 each

Disposable SpO2 probes for neonatal use- 50 nos.

NIBP cuffs for standard Adult, Obese Adult, Child and infant – all 1 each

20 Nos of Disposable IBP transducers with all standard accessories & 3 nos of reusable adapter cable.

Rechargeable Li-ion battery with a capacity of 6hr

wireless and cable networking

Prompt knob and touch screen control

Intelligent cooling system keeps the unit running quietly during use

Separate indicator lights for technical and physiological alarms

memory card for increased data storage

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Rolling stand trolley, carrying handle with bed-hooks

Thermal recorder and printer (4Roll)

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Mopc-90	1. Generic Name: Monitor - Patient, Central	ICU
	2. GMDN/UMDN Name Code:	
	3. Clinical Purpose/Description:	
	Central Patient Monitoring System is a full-featured system that can monitor SPO2,	
	ECG, NIBP, TEMP, RESP, CO, Temp, IBP, PR, ETCo2 and other comprehensive	
	patient data centrally.	
	4. Technical Specification:	
	Suitable for performing continuous monitoring of several patients in CCU and ICU wards simultaneously.	
	21" color TFT, dual screen display&Waveform: 32@ a time	
	Each of the channels shall be user selectable to display any selected parameter from any bed in the system.	
	Trend information from the bedside monitor shall be available at the central station in the same format as the bedside monitor.	_
	Support more than 25 patient monitors centrally	
	The system central station monitor that displays the information	
	ECG channel with interpretation with a facility to operate on ECG mode	
	The central station shall permit automatic display and control of any alarm	
	parameter waveform from any bedside in the system.	
	This display shall not interrupt the viewing of any normal parameter display on the central monitor if necessary.	
	Bed specific audio visual alarms to indicate electrodes misuse, physiologic	
	parameters error (high/low pressure, high/medium/low temperature,	
	high/medium/low SpO2, high/low HR, loose electrode, sensor disconnection, pulsation undetected, interference, high/low S-T segment etc)	
	Integrated package of software for interpretation, analysis, measurement and	
	visualization of S-T segment as well as other parameters	
	Provide the service of radio transmitters, receiver and telemetry systems	
	Wi-Fi enabled workstation for continual capture and broadcasts patient data at	
	remote place of patient with daily activity	
	Central monitor shall have the capability to act as a bedside monitor	
	Protection against defibrillation shocks and high frequency current	
	Perform hemodynamic, ventilator, oxygenation and renal assessment computations	
	Audible and visual alarm for technical and physiological parameters error	
	Display real time waveforms, readings, emergency status and personal profile of the patient specific to the bed	
	integrated With advanced pc work station, with necessary network device	
	The processing station must have 8 GB RAM higher, intel core i7 latest generation, at least 1TB HDD and 21 inch or higher medical grade high definition color display TFT/LED touch screen dual displays with external keyboard, mouse and all	1
	necessary software package with LAN, and USB ports	

Built in speaker

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included. (Including items not specified above).

5. System Configuration Accessories, Spares, Consumables and other components:

Recording device with printer print out values and uninterrupted power supply(UPS \geq 2Hr)

3 x Box thermal paper

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

UPS with 4hr capacity

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Defi-90	Generic Name: Defibrillator	Emergency
	2. GMDN/UMDN Name/Code:	-
	3. Clinical Purpose/Description:	-
	Fully automated external defibrillators (AEDs) deliver a high amplitude current impulse to the heart in order to restore normal rhythm and contractile function in patients who are experiencing ventricular fibrillation (VF) or ventricular tachycardia (VT) that is not accompanied by a palpable pulse.	
	4. Technical Specification	-
	High-resolution TFT color LCD display not less than 5.8 inches for showing 12 lead ECG, pulse, selected energy and delivered energy charge, mains, battery charge, led indicator	
	Defibrillator with ECG. DC defibrillator for short time depolarization, impulse energy adjustable for extra- and intracranial defibrillation with 2 electrodes (anterior/ posterior). Defibrillator with pediatric and adult paddles and cardioverter	
	The machine should be compact, portable with built in rechargeable battery & light weight.	
	Operation Modes: synchrony defibrillation and extrathoracical stimulation	
	Defibrillator with pediatric and adult paddles minimum of 4.5cm and 8cm respectively	
	The instruments with a bi-phasic wave form Defibrillation	_
	Monitor vital parameters and display them (ECG, SpO2, NIBP, and temperature)	
	Able to print the ECG on thermal recorders	
	Output energy ranges across 50Ω: 2J-360 J	
	Able to work on manual and automated external defibrillation (AED)	
	Charging time:-	
	Manual mode_ Charging time should be less than 5 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)	

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Page 206 ISBN No: AED mode: Charging time should be from 8-15 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)

Should have rechargeable battery (Lithium-ion battery) that is capable of monitoring for minimum of 180 minutes

Thermal array ECG Recorder for Lead selection, II, III aVR, aVL, V, paddles

Heart frequency monitoring with alarms for exceeding or falling below set limits.

A low energy biphasic defibrillator monitor with recorder, having capability to arrest all arrhythmia within a maximum energy of 360 Joules

Monitor ECG through paddles, pads and monitoring electrodes and defibrillate through pads and paddles.

Should have automatic lead switching to see patient ECG through paddles or leads

Able to measure and compensate for chest impedance for a range of 25 to 150 ohms

The machine should have inbuilt auto & manual thermal recorder for printing ECG trace & stored information.

Charge indicator: audible and graphic.

Facility for self-test/check before usage.

The machine should have AED feature as inbuilt with manual override for manual operations.

SPO2 and NIBP integrated facility

5. System Configuration Accessories, Spares, Consumables and other components:

Paddles Adult (pair)-01

Paddles pediatrics (pair)-01

Patient cable-02

Compatible thermal paper for printer - 20 roll

Compatible Gel; 300mL

Disposable pads – 20

NIBP Cuff Adult – 02

NIBP Cuff Pediatrics- 02

NIBP Cuff Infants-02

SPO2 Finger Probe - pediatric 01

SPO2 probe Adult -01

Ear Probe – 02

Complete set of ECG Leads – 02

Carrying case-01

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

ISO 14971:Medical devices -- Application of risk management to medical devices

IEC 60601-2-4: Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Document: Capital Medical Device Technical Specification

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare parts shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

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Addis Ababa

D 0 1		
Base Code	Item Detail	Department
Enbr-90	1. Generic Name: Endoscope - Video Bronchoscope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Video Bronchoscope is inserted into airway and lungs in order to diagnosis	
	and therapeutic interventions for airway disease.	
	4. Technical Specification:	
	Flexible Adult video bronchoscope:	
	Observational Depth(mm): 5-100	
	Angle of view: 120°	
	Distal end (mm): \leq 6mm	
	Operating channel (mm): 2mm	
	Bending capacity (up/down/Right/Left): 130°/130°	
	Working length 1000mm	
	Fully immersible in disinfectant solution	
	Flexible Pediatric video bronchoscope:	
	Observational Depth (mm): 3-50	
	Angle of view:120 degrees	
	Distal end (mm): ≤3mm	
	Operating channel (mm): ≤ 1.5mm	
	Bending capacity(up/down): 180°/130°	
	Working length: 600 mm	
	Fully immersible in disinfectant solution	
	Equipment cart:	
	Cart with at least 4 shelves and drawer, for accommodation of all	
	components for video flexible endoscopy procedures	
	Sturdy medical grade stainless steel main structure	
	Mobile on antistatic castors, with front breaks and lateral bumpers	
	Complete with isolation transformer with main switch	
	Multiple sockets block (indicative sockets quantity 6 or more), with	
	dedicated socket type Complete with lateral panels, cable ducts and back protection panels	
	Supplied with holders for endoscopes and camera cables	
	Complete with halder for Co2 insufflations cylinders	
	Complete with holder for Co2 insufflations cylinders	
	Endoscopy Monitor:	
	≥21", medical grade HDTV, DVI inputs/output/HDSDI/RGB/SVIDEO	
	Menu of functions appear on the screen.	
	Complete with robust anchoring accessories for the cart or holding arm	

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Complete with all cabling and connecting accessories

Endoscopy Video System:

Video processor for color standard definition high resolution endoscopy images

PAL/NTSC type video signal.

Controls to freeze images enhance a portion of frozen image (zoom & post-processing).

Patient and physician data input key board.

CCD compatibility scopes

Internal memory

Complete with all cabling and connectors

Accessories with endoscopes light source and monitor

Endoscopy Light source:

Operates on LED lamp, Automatic light control and saving

Emergency lamp with switchover mechanism

Automatic and manual variable light control

Front modes and setting controls with intuitive user interface

Easy access for lamp substitution

Complete with hours counter for bulb utilization

Integrated with Video Processing unit

Endoscopy Recorder, DVD

System for the recording (capture and storage) of videoendoscopy procedures and images in digital media, (DVD / SD / USB)

Suitable for the preparation of medical records

Standard common video and images format types input compatibility

Internal memory storage capacity (1TB)

Possibility of control via scope head buttons or footswitch.

User interface with controls and display

Irrigation pump unit:

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With "Stand-by" function mode

With special filters to ensure sterility.

Aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

5. System Configuration Accessories, Spares, Consumables and other components:

4 autoclavable blades-sets for adult and pediatric applications:

2x Spare LED

a) Macintosh 2 (pediatric)

b) Macintosh 4 (adult)

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c) Miller 2 (pediatric)

d) Miller 3 (adult)

Hard transport case with dedicated space for at least 3 blames, one handle and batteries.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Referral/Specialized Hospital Capital Medical Device Technical Specification

Base Code	Item Detail	Department
Eneu-90	1. Generic Name: Endo-Urology Set	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Endourology set is used to diagnose the internal part of urinary and reproductive tracts.	
	4. Technical Specification:	
	Cystoscope and Resectoscope for TURP	
	Rigid Uretero-Renoscope	
	Flexible Uretero-Renoscopes	
	Light source, camera system and monitor	
	Ultrasonic / Pneumatic Lithotripter with Integrated Suction Pump	
	Irrigation System	
	Equipment cart	
	Cystoscope:	
	Telescope: 30 degree Telescope of size: 4mm, working length 30cm	
	High quality of rod lens system	
	Fiber optic light transmission incorporated.	
	Optical system: Field of view: 120°	
	Direction of view: Forward-viewing	
	Depth of field: 3–50 mm	
	Insertion section: Outer diameter of distal end 11.7 Fr (4.6 mm × 2.6mm)	-
	Outer diameter of insertion tube 16.5 Fr (5.5mm)	-
	Instrument channel: Diameter of inner channel 2.4 mm	

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Compatible Endotherapy accessories for 2 mm channel

Minimal visible distance: 5 mm

Bending section: Angulation range Up 210°/down 120°

Autoclavable telescope

1x Cystoscope sheath: Cystoscope sheath with leur lock connection of two different size x1

20Fr and 17Fr sheath one each with slot for instrument with obutrator.

Graduated sheath

1x Telescope bridge with one instrument channel to fit with the cystoscope

1x Flexible Grasping forceps: 7Fr Grasping forceps to be provided to fit the purpose

1x Flexible biopsy forceps: 7Fr Biopsy forceps to be provided to fit the purpose

1x Compatible with 20Fr Cystoscope sheath to be provided

1x Toomey syringe 100 Cc: Toomey syringe of 100 cc with adaptor to fit with sheath

1x Toomey syringe 100 Cc: Toomey syringe of 100 cc with adaptor to fit with sheath

1x Evacuator: Evacuation with spare rubber bulb and adaptor to be provided

1x Urethrotonie sheath: 21Fr optical Uietlirotom sheath with one channel to be provided

2x Cold knife: Straight cold knife 2 nos

Resectoscope sheath: 26 Fr continues irrigation Resectoscope sheath

With ceramic beak to be provided to fit the purpose with set of silicon tube.

1x Sheath Provided with deflecting obutrator

Working element set: passive type with standard accessories like, Knife, HF cord, Protection tube, cutting loop to be provided

2x Cutting loop 24Fr: No 1 and 12

1x High Frequency cord No 2

Rigid Uretero-Renoscope

Length more than 41 cm, with an offset eyepiece (10deg with oval irrigation)

Outer diameter at the tip of about 6Fr- 8Fr with a working channel 4Fr to 5Fr

Two irrigation and preferably 2 instrument ports

Adaptor to connect the endoscope to light source of any make

Sterilizable with liquid, gas and autoclave

Flexible Uretero-Renoscopes

Instrument Channel: 3.5-3.8Fr

Style: Flexible

Flexible biopsy forceps

Angulation Range: 270 $^{\circ}$ Up / 270 $^{\circ}$

Field of view 80-90 ° forward

Distal shaft size of 8.8Fr or less.

Depth of view: 2-50 mm

Working length 650mm or more

Stone holding flexible forceps.

Easy to use

Resectoscope

Bipolar

Monopolar

Bipolar Electrodes for the Resectoscope System

Mono polar Electrodes for the Resectoscope System

Outer & inner Resectoscope sheath

Optical urothotomy sheath

High frequency cable & loops

Light Source: Rechargeable miniature light source with LED

1x Brief case: Plastic good quality brief case with slot for instruments is to

be provided for storage

Endovision camera system: Single Chip Endoscopy Camera system

1x With Digital Image Process module.

Image Sensor: 1/2" CCD Chip

Pixels - 752 (H) x 582 (V)

Resolution - 450 Lines Horizontal

AGC - Microprocessor based

Minimum Sensitivity: 3 Lux (f- 1.4 mm)

Exposure Control: 1/50 Sec - 1/10000 Sec

Freezing function & Antomoire filter function

Camera control unit have accessories output to control external devices Like video printer from the camera head buttons

Programmable Functional Keys on camera head for various functions like

Automatic white balance, gain control and brightness control

Integrated focus control

Digital zoom

Integrated Optical Parfocal zoom lens 25-50MM

DV output and S-VHS and Composite video output

Contrast enhancement and digital filter

Video Monitor:

20" TFT screen with pedestal.

Viewing angle of 170 degree vertical and brightness of 450cd/m2

Resolution of 1280 X 1024

Take RGB, SDI and S-Video signals

Electrosurgical cutting and coagulation unit, mobile x1

Electrosurgical unit, with accessories

Ultrasonic / Pneumatic Lithotripter with

Integrated Suction Pump

Pneumatic section

Supply Pressure: Compressed Medical Air (3.5 - 6.5 bar)

Pulse Mode: Single or multiple pulses

Pulse Frequency: 1-12 Hz increments

Applied Energy: Adjustable

Energy Transmission: Mechanical

Pneumatic Probes

Different lengths and diameters for rigid and flexible endoscopes.

Hand piece sterilization: steam, chemical sterilization

Ultrasonic Section:

Power: 150W

Applied Energy: Adjustable

Ultrasonic Probes

Combined Probes

Different lengths and diameters available

Hand piece Sterilization: Steam, Chemical.

Irrigation pump unit

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With Stand-by function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Equipment cart

Cart with at least 4 shelves and 1 low drawer, for accommodation of all components for video flexible endoscopy procedures sturdy medical grade stainless steel main structure, mobile on antistatic castors, with front breaks and lateral bumpers

Complete with isolation transformer, with main switch and multiple sockets block (indicative sockets quantity 6), with dedicated socket type

Complete with lateral panels, cable ducts and back protection panels

Supplied with holders for endoscopes and camera cables

Complete with hanger for irrigation bottle

5. System Configuration Accessories, Spares, Consumables and other components:

1x Cystoscope and Resectoscope for TURP

1x Rigid Uretero-Renoscope

1x Flexible Uretero-Renoscopes

1x Light source, camera system and monitor

1x Ultrasonic / Pneumatic Lithotripter with Integrated Suction Pump

1x Irrigation System

1x Equipment cart

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or

Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Enhy-90	1. Generic Name: Endoscope - Hysteroscope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A device used for observation and treatment of abnormalities in the cervix	
	and inside of uterus of patient.	
	4. Technical Specification:	
	Video Hysteroscope:	
	Direction of View: Forward	
	Observation Range: 6 - 100mm	
	Field of View: minimum 120°	
	Distal End Diameter: ~5 mm	
	Flexible Portion Diameter: 4.8 mm	
	Bending Capability (Angulation Up/Down): 120°/ 120°	
	Forceps Channel Diameter: ≥ 1.8 mm	
	Working Length: ≥ 200 mm	
	Examination sheath of suitable size with lock adapter.	
	Operating sheath with instrument channel for operating hysteroscopy of suitable size.	
	Video output to be compatible with the video processor specified.	
	Endoscopy Light source	
	Operates on LED lamp, Automatic light control and saving	
	Automatic and manual variable light control	
	Emergency lamp with switchover mechanism	•
	Microprocessor controlled	
	Front modes and setting controls with intuitive user interface	
	Easy access for lamp substitution	-
	Complete with hours counter, for bulb utilization	
	With light weight flexible fiber optic light cable	-
	Should be Integrated with Video Processing unit	-
	Endoscopy Video system:	-
	Video processor for color standard definition high resolution endoscopy	-
	images	
	PAL/NTSC type video signal.	
	Controls to freeze images enhance a portion of frozen image (zoom &	•
	post-processing).	
	Patient and physician data input key board.	
	1x CCD compatibility scopes]
	Internal memory	1

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System complete with all cabling and connectors accessories with endoscopes, light source and monitor

Endoscopy Monitor

≥19"or more , medical grade HDTV,DVI inputs/output/HDSDI/RGB/SVIDEO

Menu of functions appear on the screen.

Complete with robust anchoring accessories for the cart or holding arm for the cart.

Complete with all cabling and connecting accessories

Endoscopy Recorder, DVD

System for the recording (capture and storage) of videoendoscopy procedures and images in digital media, (DVD / SD / USB)

Suitable for the preparation of medical records

Standard common video and images format types input compatibility

Internal memory storage capacity

Possibility of control via scope head buttons or footswitch.

User interface with controls and display

Irrigation pump unit:

Fully automatic

Able to aspirates & irrigates up to 3L per min.

With large 2L aspiration container.

With Stand-by function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Equipment cart

Cart with at least 4 shelves and 1 low drawer, for accommodation of all components for video flexible endoscopy procedures

Sturdy medical grade stainless steel main structure,

mobile on antistatic castors, with front breaks and lateral bumpers

Complete with isolation transformer, with main switch and

Multiple sockets block (indicative sockets quantity 6), with dedicated socket type

Preferably complete with lateral panels, cable ducts and back protection panels

Supplied with holders for endoscopes and camera cables

Complete with hanger for irrigation bottle

Complete with holder for Co2 insufflations cylinders

5. System Configuration Accessories, Spares, Consumables and other components:

Color printer compatabile with the endoscopy

Leakage tester

Cleaning brush

2x Sealing cup

Luer-lock sealing cup

Luer-lock tube connector

Biopsy and grasping forceps

Coagulation electrode

Examination sheath of suitable size with lock adapter.

Operating sheath with instrument channel for operating hysteroscopy of suitable size.

6. Operating Environment:

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Engi-90	1. Generic Name: Endoscope - Video Gastro Intestinal	Endoscopy
	2. UMDN/GMDN Code/Name:	
	3. Clinical Purpose/Description:]
	Gastro Intestinal video endoscope source is fiber-optic cable inserted to GI	
	Tract for Diagnostic and therapeutic purpose.	-
	4.Technical specification	
	Endoscopy system include:	
	Equipment cart	
	Endoscopy Monitor	
	Endoscopy Video System	
	Endoscopy Light source	
	Video Gastroscope	
	Video Colonscope]
	Video Duodenoscope for ERCP	
	Video Sigmoidoscopy	
	Endoscopy Recorder, DVD	
	Irrigation System	1
	Electrosurgical unit (Diathermy Unit), with all standard accessories	1
	Co2 Insufflator	
	Equipment cart	-
	Cart with at least 4 shelves and 1 drawer, for accommodation of all	1
	components for video flexible endoscopy procedures sturdy medical grade	
	stainless steel main structure, mobile on antistatic castors, with front breaks and lateral bumpers	
	Complete with isolation transformer, with main switch	
	Multiple sockets block (indicative sockets quantity 6), with dedicated socket type	
	Complete with lateral panels, cable ducts and back protection panels	
	Supplied with holders for endoscopes and camera cables	
	Complete with hanger for irrigation bottle	•
	Complete with holder for Co2 insufflations cylinders	-
	Endoscopy Monitor	1
	>21", medical grade HDTV ,DVI inputs/output/HDSDI/RGB/VIDEO	1
	Menu of functions appear on the screen with scope guide	1
	Complete with robust anchoring accessories for the cart or holding arm for	1
	the cart.	
	Complete with all cabling and connecting accessories	1
	Endoscopy Video System	1

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Video processor for color standard definition high resolution endoscopy images

PAL/NTSC type video signal.

Controls to freeze images enhance a portion of frozen image (zoom & post-processing).

Patient and physician data input key board.

1 CCD compatibility scopes

Internal memory

System with all cabling and connectors accessories with endoscopes, light source and monitor

Endoscopy Light source

Operates on LED lamp, Automatic light control and saving

Emergency lamp with switchover mechanism

Microprocessor controlled

Automatic and manual variable light control

Front modes and setting controls with intuitive user interface

Easy access for lamp substitution

Complete with hours counter, for bulb utilization

Integrated with Video Processing unit

Video Gastroscope

Direction of view should be zero degree.

Minimum of 130 degree of field of view.

Range of observation at least from 5 mm to 100 mm

Angulations of tip up at least 180 degrees and down 180 degrees with right and left movement of at least 120/120 degrees.

Insertion tube diameter of less than 10 mm.

Distal end diameter of not more than 10.5 mm

Instrument channel > 2.5 mm

Working length >1000mm

Compatible with the video system

Endotherapy compatible

Fully immersible in disinfectant solution

Video Colonscope

Direction of view zero degree

Minimum of 130 degree of field of view.

Range of observation at least from 5 mm to 100 mm.

Angulations of tip up at least 180 degrees and down 180 degrees with right and left movement of at least 120/120 degrees.

Inner diameter optimal

Distal end diameter of not more than 10.5 mm

Instrument channel of $\geq 2.5 \text{ mm}$

Working length ≥2000mm

Compatible with the video system

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Endotherapy compatible

Fully immersible in disinfectant solution

Video Duodenoscope for ERCP

Field of vision more than 100 deg.

Direction of view 5deg backward / oblique

Depth of view app 5-50 mm

Distal end outer diameter not exceeding 13.5

Insertion tube outer diameter not exceeding 13 mm

Bending angulation should be at least up 120 deg, down 90 deg, Right 110deg and Left 90 deg

Working length not below 1200 mm

Instrumental channel >4 mm

Compatible with video system

Video Sigmoidoscopy

Viewing Direction: Forward
Observation range: 3-100 mm

Field of view : ≥140 degree
Distal and Diameter: 12.8 mm

Flexible portion diameter: 12.8 mm

Bending Capability:

Up 180 degree

Down 180 degree

Left 120 degree

Right 120 degree

Forceps channel diameter: 3.8 mm

Working length: 1330 mm

Printer

color printer compatabile with the endoscopy

Irrigation pump unit

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With "Stand-by" function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Co2 Insufflator

Electronic Co2 insufflator with pin index connection.

Adjustable flow rate of 0 to 30 litres per minute and a pressure range adjustable between 0 - 30 mm Hg.

Pressure and flow rate displayed on the front panel with displays of actual

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and set values.

Provided with silicon autoclavable tubing with luer lock attachment.

Optical and acoustic warning signals for pressure exceeding set limits.

Constant monitoring of intra abdominal pressure with safety to reduce overpressure.

Provision for preheating gas to body temperature.

Fully automatic gas refill.

High Pressure Hose suitable to connect the insufflator with pin indexed Co2 cylinder

Supplied with Co2 cylinder, connecting pipe, main cord and silicon tubing set

Autoclavable wrench & Co2 gas filters disposable

5. System Configuration Accessories, Spares, Consumables and other components:

2x Spare bulbs

20x Snares (ESU Accessory)

20x Injection Needles

20x Clips

20 x Set of Rubber Band ligation

Suction machine: 60L/Min & -900mmHg

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

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Addis Ababa

Code	Item Detail	Departmen
-90	1. Generic Name: Endoscope - Video Laryngoscope	Endoscopy
	. 2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: - Video Laryngoscopes used to perform	
	medical procedures in the larynx for removing foreign objects in the	
	throat, collecting tissue samples, removing polyps from vocal cords, and	
	performing laser treatments.	
	4. Technical Specification:	
	Video laryngoscope with blades and with integrated video monitor and it	
	is portable battery operated airway visualization system.	
	Video laryngoscope convenient for tracheal intubation.	
	Camera for live Image capturing	
	LED light illumination	
	Color Image display facility LCD/TFT display	
	Provision to insert all sizes of endotracheal tube	
	Provision to introduce all sizes of suction catheters	
	Water proof protection	
	Battery backup facility ≥ 1 hr.	
	All blade sizes/adjustable for adult and pediatric laryngoscope.	
	Color TFT LCD	
	Batteries : DC 3 AAA batteries	
	Battery Life: ≥ 90 minute	
	Video adapter	
	Adapter with camera and white Led Light	
	Blades: Disposable channeled and Not Channeled blades	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	
	Rechargeable battery and provision for re-charge.	
	Blade 2c: 4.5-5.5 mm	
	Blade 3c: 6.0-8.0 mm	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials,	
	with items not specified above.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	

Document: Capital Medical Device Technical Specification

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Enco-90	1. Generic Name: Endoscope - Colposcope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	Colposcope used indiagnosing the internal part of Vagina and cervix.	1
	4. Technical Specification:	1
	Digital camera(CCD)	7
	Effective 14 Mega Pixels	
	40x Magnification	
	3D perception with Digital Matrix processor	
	Facility to choose from 3 color images	
	Facility for fast accessing images, deleting, collecting, focusing, Zooming & Image freezing	
	High MCD super bright white shadow less LED light for true color reproduction	
	Facility for Fast auto/manual focusing.	
	Auto Focal length: 300 mm	
	Side by Side Powerful Comparison of Colposcope images	
	LED lamp life $\geq 50,000$ hrs	
	Filter: green light filters	
	Light source type: white LED Ring Light	
	Variable Electronic Green Filter facility to choose from 3 different grades of EGF	
	Digital Video Colposcope with Management Software	
	Integrated Digital video Colposcope with HD≥19 inch monitor	
	HDMI/AV connection	
	Can be integrated to LAN and HIS	
	Statistical Analysis function	
	Multi Format Report Facility	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	Colposcope head with camera	
	Post & rolling base with wheels	
	Connecting device to the computer	
	Software in English.	7
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.	
	6. Operating Environment;	1

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Trea-90	1. Generic Name: Treadmill	Physiotherapy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Treadmill provide safe and effective walking and running exercise, also provide partial weight bearing by support of portion of body weight under the supervision of therapists in the physical therapy gymnasium	
	4. Technical Specification:	
	Maintenance free brushless motor AC motor	
	Bi directional speeding system	
	Motor: 3.0 CHP	-
	Patient carrying capacity: 220 kg	
	Treadmill with variable speed (0.5 - 25 km/hr, graduation 0.1km/hr)	
	Reverse speed: up to 3 Km/hr	
	Positive slope angle: 0% to +15%	
	Negative slope angle: 0% to -10%, graduation 0.5%	
	Patient carrying capacity: not less than 220Kg	
	Treadmill belt run across deck providing low friction and noise when in use.	
	Digital display of speed elevation	
	Reduced shock and non-slip belt surface	
	Automatic center tracking	
	Feature for speed control from high to zero level	
	Display of stage no., stage time, distance covered, pace, calories/minute METS and others	
	Heart rate control and monitoring should be possible with polar transmitter and receiver wireless system	
	The patient heart rate should be seen on the screen	
	An emergency stop button should be mounted on the control panel, it should be visible and easy to reach	
	The treadmill shall be provided with electrically adjustable side bars and step up aid	
	Hip belt with safety switch for automatic stop while the client cannot maintain the running speed of the belt	
	Treadmill running surface (lxw), m:1.5x0.5	
	Overall dimension (lxdxh), m:1.8x0.8x0.9	
	Material: stainless steel	
	Running bed should absorb shock and Stable	
	Should have side rails	

Document: Capital Medical Device Technical Specification

The system must have an integrated monitoring system with a display of parameters

Should have side rail

5. System Configuration Accessories, spares, Consumables and other consumables:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Sttm-90	1. Generic Name: Stress Testing Machine	Physiotherapy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Cardiopulmonary Exercise test machine with Treadmill is used in testing and treatment of proper functioning of pulmonary, cardiovascular and skeletal muscle systems.	
	The Treadmill Stress Test System should be complete with acquisition of resting and stress ECG, Treadmill Unit with interface with all the protocols and provision of printing the resting as well as Stress ECG and analyzing the same.	
	Should be able to be interfaced to Hospital Information System/ LAN/WLAN	
	4. Technical Specification:	
	Compact & Trolley mounted system comprising:	
	State of the art computerized exercise test assembly for on-line measurement of work load. ventilation, tidal volume, anaerobic, threshold, oxygen consumption, Co2 production, cardiac frequency, respiratory rate, ventilator equivalent, O2 pulse, respiratory exchange ratio, EtCo2, stroke volume, cardiac output and nutritional assessment	
	Acquire and analyze 12/15 simultaneous ECG Leads	1
	Facility for display of all 12/15 leads real time Rhythm ECG on screen	
	Capable of doing complete Spirometry, Resting & Exercise ECG (12 Lead). The ECG can be configured for 3 leads, 6 leads & simultaneously12 leads measurement	-
	During recording all relevant parameters should be displayed on a selectable screen including ECG Trend – graph for ST- Level , ST- Slope.	
	Facility should be there for viewing the stress test, click to heart symbols & all saved ECG samples are displayed together with all 12 average complexes.	
	Facility for spiro test, ECG signal test, treadmill ergo meter, facility for pulse oximetry, facility for blood pressure and temperature measure	
	Should have facility of on line storage of patient ECG data. Storage of at least 500 patients	
	Filters with facility to eliminate artifact due to respiration muscle/noise, AC interference, baseline wandering without compromising/distortion in ST segment changes	
	Should have facility to do the reanalysis of stored ECG report with reanalysis of the current stress report by changing the measurement point	

The monitor should display auto comparison of resting versus current lead of maximum ST depression separately with color coded protocol, stage, clocks for

The monitor should display auto comparison of resting versus current lead of maximum ST depression separately with color coded protocol, stage, clocks for elapsed time, total time, Target HR, Treadmill speed & grade, PVC counts/minute, warning messages & prompts, lead check torso.

The system have user defined report generation in different formats including the ST/HR loops and ST/HR index up to 15 leads formats for close diagnosis.

Provision of software driven, user programmable exercise protocols or standard protocols. Facility should be available for choice for both staged and ramp protocols

System should print comprehensive final report on a minute by minute record of ST segment changes ST segment trend plot and acceleration of ST segment

Display should have facility to amplify a normal gain along with a sample of resting ECG complex for close test.

System should have dynamic scan facility to display automatically the worst ECG lead

Signal acquisition from patient and analysis should be performed at the patient itself to eliminate the environmental noise

Automatic arrhythmia detection and documentation

Facility for display of processed ECG vectors after signal averaging allowing view of artifact free ECG complexes.

Facility for display of processed ECG vectors after signal averaging allowing view of artifact free ECG complexes.

Should have beat to beat online storage and event review

System should be able to provide the real time printing by auto or manual mode in desired formats. Writer resolution should be thermal $1000 \text{ line/sec} \times 200 \text{ dpi}$ for printing

The system should have built-in barometric/sample pressure transducers & temperature sensors for monitoring of ambient condition.

should be supplied with wireless heart rate monitoring and heart rate detector on a lightweight material that can be worn by the patient

Should be capable of doing variable orifice flow transducer with very low flow resistance and should not be influenced by humidity.

Flow Resistance: < 40 ml

Precision: 0.1%

Volume Resolution : < 5 ml

Flow Resolution : < 1ml

Fast response Co2 analyzer (Infra red absorption principle)

Range: 0-16% Co2 Resolution: 0.1% O2

Linearity: 0.1% Co2 Precision 0.1 % Co2

Should have fast response O2 analyzer (spectrometry principle)

Range: 0-100% Resolution: 0.1%

Linearity: 0.1 % 02 Precision: 0.1 % O2

Response Time: < 90 m sec.

Auto calibration facility for analyzers & volume transducer with internal quality assurance

CPET system should be integrated/compacted with treadmill and ergo meter

The treadmill Ergo meter:

Treadmill provide safe and effective walking and running exercise, also provide partial weight bearing by support of portion of body weight under the supervision of therapists in the physical therapy gymnasium

System should have automatic noise free programmable treadmill

System should be able to be integrated with HIS/LAN/WLAN

Should be able to transfer data through modem card(optional)

Treadmill should have two stop modes with digital Microprocessor control, including one patient activated stop mode.

The same should be interfaced to the main analysis system

Bidirectional speeding system

Motor: 3.0 CHP

Treadmill with variable speed (0.5 - 25km/hr, graduation 0.1km/hr)

Reverse speed: Up to 3Km/hr

Positive slope angle: 0% to +15%

Negative slope angle: 0% to -10%, graduation 0.5%

Patient carrying capacity: not less than 220Kg

Treadmill belt run across deck providing low friction and noise when in use.

The belt size should enable for walking and running of up to 2.1 m tall users

Document: Capital Medical Device Technical Specification

Digital display of speed elevation

Display of stage no., stage time, distance covered, pace, calories/minute METS and others

Heart rate control and monitoring should be possible with polar transmitter and receiver wireless system

The patient heart rate should be seen on the screen

An emergency stop button should be mounted on the control panel, it should be visible and easy to reach

The treadmill shall be provided with electrically adjustable side bars and step up aid

Hip belt with safety switch for automatic stop while the client cannot maintain the running speed of the belt

Treadmill running surface (lxw), m:1.5x0.5

Overall dimension (lxdxh), m:1.8x0.8x0.9

Material: stainless steel

Should have side rail

The system must have an integrated monitoring system with a display of parameters

The processing station must have 8 GB RAM, intel core i7 latest generation, at least 1TB HDD and 21 inch or higher medical grade high definition color display TFT/LED touch screen dual displays with external keyboard, mouse and all necessary software package

Printer:

Inbuilt thermal printer

Should be supplied with latest computer and printer

Color laser printer

Paper speed: Up to 40ppm, single side

Paper size: A4

Automatic two side duplex print, 20ppm

Resolution 2400x600dpi

Noise < 60

5. System Configuration Accessories, spares, Consumables and other consumable:

Stress Test System - 01

Treadmill - 01

Interface cable - 01

Hip belt with magnetic emergency stop

Polar transmitter and receiver wireless system with elastic chest band

Step-up aid (set of 2 side supports)

Printer – 01&Patient cable - 02

Body wear - 01

Paper - 1000 A4 Sheets

6. Operating Environment:

Operating Temperature: +10°C to +43°C

Relative Humidity: <85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Document: Capital Medical Device Technical Specification

Base Code	Item Detail	Department
Ultg-90	1. Generic Name: Ultrasound- Ob/Gyn	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Used for obstetrics, gynecology, Abdomen, Urology and Emergency Medicine Packages scanning	
	4. Technical Specification:	
	The system with one active probe ports for easy use and convenient operation.	
	Controls for depth, gain compensation preferably automatic gain and depth control	
	The system have dedicated calculation software package including Obstetrics, Gynecology, Abdomen, Urology and Emergency Medicine Packages)	
	The system have image storage and archiving with CD, USB flash and DICOM	
	System with 15 inch LCD monitor and also can connect to external display	
	Probe: Convex (2-5MHz)	
	Number of elements:192	
	FOV:58	
	Physical foot print:55x18 mm	
	Convex radius:60mmR	
	with battery support to operate the machine in case of power failure	
	5. System Configuration Accessories and Consumables	
	System with main unit and mobile cart (trolley)	
	Laser Printer for direct image and report print out1pcs	
	Convex probe1pcs	
	Ultrasound paper100 rolls	
	Gel: 250 ml 2pcs	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC <u>+</u> 10%	
	8. Standards & Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation/Training/Commissioning	

Document: Capital Medical Device Technical Specification

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Ugcd-90	1. Generic Name: Ultrasound-General Purpose, Color Doppler, Mobile	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A robust state of art fully digital high end latest color Doppler ultrasound system under current production capable of performing imaging applications in abdominal Ob/Gyn, musculoskeletal, cardiovascular, small parts, Urology, Cardiology, Real time 4D, Tissue elastography contrast and Rectum.	
	4. Technical Specification:	
	System broad band beam former capable of processing signals from 2-15 MHZ	
	Should incorporate facility for high resolution 2D, M-mode, color M-mode, THI mode, PW, CW mode, Color Flow imaging, Color power Angio imaging, Directional Color Power Angio imaging modes, live real time 3D/4D. Full spectrum imaging, Speckle Reduction Filter, Spatial Compound imaging, Pulse Inversion Harmonic Imaging, Trapezoidal Imaging & Contrast Enhanced	
	Imaging (Low –MI)	
	Row data management.	
	Post processing technology.	
	Tissue harmonic imaging.	
	The capability of analyzing 3D data set.	
	Real time triplex mode facility in 2D, color and Doppler modes.	
	Dynamic range of 250 db or higher.	
	High pulse repetition frequency (PRF)	
	256 shades of gray display	
	Minimum 1000 frame per second or more.	
	Facilities for real time and frozen, pan or point zoom.	
	Cine loop review minimum 4000 frames/sec	
	Panoramic extended field of view.	
	Independent steering of B mode and color on linear probe.	
	Advanced real time 4D capabilities	
	Advanced tissue elastography	
	Extensive software and automatic and user programmable calculation package for gray scale, color Doppler, 3D and 4D applications. Minimum 19" high resolution medical grade TFT/LCD screen monitor display	
	Should be provided with following transducers:	
	a) Curved (Convex) Probe (2-5 MHz) for Abdomen and OB/GYN, etc (Specify model/cat no)	
	Number of elements:192	
	FOV: 65 deg	
	Physical foot print: 61 x 17	
	Convex diameter:55 mmR	

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b) Micro-curved Probe (4-9MHz) for neonatal and pediatrics, etc.. (Specify model/cat no)

Number of elements:128

FOV:134 deg

Physical foot print: 22 x 6mm

Convex radius:10 mm

c) Linear probe (5-12 MHz) with 4D capability for small parts, vascular, musculoskeletal, etc.. (Specify model/cat no)

Number of elements:192

FOV:40 deg

Physical foot print:42 x 6 mm

d) Phased Array Probe (2-6 MHz) with 4D capability for Cardiology (Specify model/cat no)

Number of elements: 64

FOV: 128 deg

e) Endo cavity probe (Trans-vaginal + Trans rectal) (4-9MHz) applicable for examining internal organs such as vagina, cervix, uterus, fallopian, ovaries, rectum, etc... (Specify model/cat no)

Number of elements: 128

FOV:150 deg

Physical foot print:25 x 5 mm

Capable of supporting at least four or more transducers ports with switching form console.

Built in image Management software, for off line application when patient has gone after examination, such as image manipulation, Multi Planner reformatting, surface & volume rendering etc.

Skin line scaling markers, curved distance measurement tool and zoom, pan, rotate and trim facility to trim panoramic images from start or end of the panoramic capture.

Hard disk memory of One (1TB) TB or more with built in CD/DVD read write.

Capable to perform Elastography with convex probe and compression / strain or better technology based elastography in TV and linear probes.

Should be capable to do Contrast Enhanced Ultra sonography

Should be DICOM Compatible, RIS/HIS

Shall have push handle for pushing.

Four Double Castors with Brake.

Upgradeable to Fusion / navigation to allow fusing real time ultrasound images with images acquired from other imaging modalities such as eg. CT and MRI.

should be seamlessly upgradeable on site to automated whole breast 3D functionality

- 5. System Configuration Accessories, Consumables and other componenets:
- a) On line UPS with 60 minutes backup
- b) Color Laser Printer for direct image and report print out
- c) For parallel processing of Imaging Data, System should be provided with a External latest configuration 1 Tera Byte Hard Disk based work station with USB and serial port with 19" TFT/LCD monitor with very high quality image Management Software (with proper license) with same capabilities as main

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machine such as retrieving data along Zoom, Pan, Volume Rendering, Multiplanar Reformatting, MIP, retrieving information from CD/DVD with reporting and software exporting JPG & AVI file format to ink other stations in the hospital.

- d) Ultrasound paper----100 rolls
- e) Gel 250 ml ---- 2
- f) Curved (Convex) Probe ---1
- g) Micro-curved Probe ---1
- h) Linear probe ---1
- i) Phased Array Probe with 4D capability ----1
- j) Endo cavity probe (Trans-vaginal + Trans rectal) ----1

All standard accessories and parts required to operate the equipment and cleaning materials with their quantity to be included in the offer.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

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Addis Ababa

Referral/Specialized Hospital Capital Medical Device Technical Specification

Base Code	Item Detail	Department
Ugcd-90	1. Generic Name: Ultrasound - General Purpose, Color Doppler, Portable	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A portable laptop type and detachable diagnostic imaging ultrasound with mobile cart used to see internal body structures in Abdomen, Obstetrics, Gynecological,	1
	Vascular, Urology, Musculoskeletal, Small Parts, pediatrics and neonatal.	
	4. Technical Specification:]
	With internal battery capable of operation 60 minutes	_
	System broad band beam former capable of processing signals from 2-13 MHZ	
	should incorporate facility for high resolution 2D, M-mode, color M-mode, THI	
	mode, PW, CW mode, Color Flow imaging, Duplex mode, triplex mode etc.	_
	Full spectrum imaging, Speckle Reduction Filter, Spatial Compound imaging,	
	Beam steering Imaging,	-
	Post processing technology Tissue harmonic imaging	-
	Tissue harmonic imaging Capability of analyzing 3D data set.	-
	Real time triplex mode facility in 2D, color and Doppler modes.	1
	Real time triplex mode facility in 2D, color and Doppler modes.	-
	Dynamic range of 150 dB or higher	
	High Pulse repetition frequency (PRF)	
	Minimum 254 gray shades	
	1000 frames per second or more.	_
	Panoramic extended field of view.	_
	Software packages: Abdomen, Obs/Gyn, Vascular, Musculoskeletal, Urological,	
	Small Parts, pediatrics and neonatal	-
	Skin line scaling markers, curved distance measurement tool and zoom, pan,	
	rotate and trim facility to trim panoramic images from start or end of the panoramic capture.	
	Independent steering of B mode and color/PW/CW mode in linear probe.	1
	Minimum 15" high resolution medical grade TFT/LCD screen monitor display	1
	Should be provided with following transducers	1
	a) Curved (Convex) Probe (2-5 MHz) applicable for Abdomen and OB/GYN,	1
	etc (Specify model/cat no)	
	Number of elements: 192	1
	FOV: 65 deg	1
	Physical foot print: 61 x 17	
	Convex diameter: 55 mm	
	b) Micro-curved Probe (4-9MHz) applicable for neonatal and pediatrics, etc]
	(Specify model/cat no)]
	Number of elements:128]
	FOV:134 deg	
	Physical foot print: 22 x 6mm	1
	c) Linear probe (5-12 MHz) applicable for small parts, vascular, peripheral,	
	musculoskeletal, etc (Specify model/cat no)	

Number of elements: 64

FOV: 128 deg

Number of elements: 64

d) Endo cavity probe (Trans-vaginal + Trans rectal) (4-9MHz) applicable for examining internal organs such as vagina, cervix, uterus, fallopian, ovaries, rectum, etc... (Specify model/cat no)

Number of elements: 128

FOV:150 deg

Physical foot print:25 x 5 mm

Number of elements: 128

Capable of supporting at least three or more transducers ports with switching form console.

System built in image Management software, such as image manipulation, Multi Planner reformatting, surface & volume rendering etc.

Hard disk memory of 400 GB or more with built in CD/DVD read write.

System Should be DICOM Compatible, RIS/HIS

Shall have push handle for pushing

Double Castors with Brake

5. System Configuration Accessories, Consumables and other Components:

Color Laser Printer----1

Ultrasound paper--- 100 rolls

Gel 250 ml ---- 2

Trolley with gel and transducer holder

Linear probe---1

Convex probe---1

Endo cavity probe (Trans-vaginal + Trans-rectal)---1

Micro-convex probe ----1

Phased Array Probe with 4D capability ----1

All standard accessories, consumables and parts required to operate the equipment, cleaning and lubrication materials with their quantity to be included in the offer. (Including not specified on the above).

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

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Name and Model of the product

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Addis Ababa

Base Code	Item Detail	Department
Carg-90	1. Generic Name: ECG Machine	Emergency
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	ECG Machine is primary equipment to record ECG Signal in various configurations. With 12 channels with interpretation are required for recording and analyzing the waveforms with a special software.	
	4. Technical Specification:	
	LCD/TFT color monitor display of at least 7 inches	
	Resolution should be Not less than 800 x 480 dots	
	Display should include ,12 lead ECG waveform, patient information, recording settings, operation mode, heart rate, QRS sync mark, error message, electrode detachment, noise Real time display of ECG waveforms with signal quality indication	
	for each lead	
	Artifact, AC, low and high pass frequency filters.	
	Acquisition mode: simultaneous 12-lead acquisition (10-24s adjustable)	
	Sampling rate:10KHZ for pacemaker detection	
	CMRR: >105dB	
	Sensitivity:5, 10, 20mm/mV	
	Noise Level:<15uVp-p	
	The machine should have the following filters: EMG interference filter, Anti-baseline drift, High and Low-pass Filter:	
	AC Filter: 50Hz	
	Input Impedance: $\geq 50M\Omega$	
	Patient leak current: <10µA	
	Input Voltage Range:± 5mVpp	
	Input Circuit Current:<10nA	
	Visual alarm for open lead	
	Modes of operation – Automatic, Manual & Rhythm (Not Arrhythmia)	
	Compact and portable, and should have carry handle for portability.	
	Should have defibrillation protection	
	Frequency response 0.05 Hz to 150 Hz with digital filter for AC and EMG	
	Should have full screen preview of ECG report for quality assessmet checks prior to print. 12-lead ECG waveform view to be seen on one screen.	

Interpretation facility of the amplitudes, durations and morphologies of ECG waveforms and associated rhythm for pediatric and neonatal patients. (For all patients)

Alphanumeric keyboard for patient data Entry. (virtual or hard keys) and one touch operation

Integrated thermal Printer: High resolution (200 dpix500dpi on 25 mm/sec speed) digital array A4 size

Recording speed should be 5, 10, 12.5, 25, 50 mm/s

Recording paper should be 110 mm width, 30 m long Z fold.

It should show the following recording data, ECG waveform, heart rate, lead name, version, date and time, paper speed, sensitivity, filter setting, patient information, measured information, marks

Report formats of 3 x4; 6 x2, Rhythm for up to 12 selected leads; 12 Lead. Extended measurements, 1 minute of continuous waveform data for 1 selected lead.

Should be supplied with built in rechargeable battery with capability of minimum of one hour power backup

It should have features with the capability to transfer the ECG data to a PC using USB/ HIS /LAN/Wireless LAN system.

USB Support for Storage on external portable memories.

At least 4GB internal memory for ECG data storage

Trolley:

Trolley should be made of Stainless Steel

Shelf with a drawer for storing the accessories and consumables.

Four superior castors (two with brakes)

Trolley should have a suitable cable arm firmly affixed having holder for ECG cables while not in use

5. System Configuration Accessories, Spares, Consumables and other components:

1x ECG Machine 12 Leads with Interpretation – 01

2x Lead ECG Patient Cable -02

4 set of chest electrodes adult size-(each set of six electrodes), reusable

4 set of chest electrodes pediatric size-(each set of six electrodes), reusable

4 set of color coded clip clamp limb electrodes adult size (each set of four electrodes), reusable

4 set of color coded clip clamp limb electrodes pediatric size (each set of four electrodes), reusable

5x Standard thermal paper(Roll)

5x Gel of 300mL

All standard accessories, consumables and spare parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%,50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601-General Requirements of electrical safety

Shall meet IEC 60601-2-51-Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

ISO 14971: Medical devices -- Application of risk management to medical devices

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User, technical and maintenance manual in English. Certification of calibration and inspection should be provided.

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare parts shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 21904

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Stel-90	1. Generic Name: Sterilizer - Chemical, H ₂ O ₂ , Low Temperature	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Instrument to provide simple & fast sterilization of surgical instruments/ medical items like rigid endoscopes, lumen & non lumen, metal, non metal, heat & moisture sensitive instruments at low temperature using H ₂ O ₂ / EtCO ₂ gas plasma technology	
	4. Technical Specification:	
	Front loading with chamber of usable volume of more than 100 liters, and removable shelf	1
	The sterilization temperature inside the chamber should be less than 55°C	
	Cycle time should be 35 to 60 min	
	The sterility should be in a cassette/ bottle with H ₂ O ₂ concentration more than 55%	
	Sterilizer endorsed by leading instruments and scopes	
	The system should use minimum quantity of sterility which is less than 6-8 ml per injection to deliver dry terminal sterilization to ensure safety of instruments against corrosion.	
	LCD display control interface that shows cycle/ phase/ control parameters; storage of cycle records data's.	_
	Inbuilt printer and touch screen LCD control panel	
	Should not have a need for to have additional dryer machine.	
	Facility to store/upload data on Ethernet/USB port for sterilization cycle recall and printing.	_
	Facility to seal and store sterilized items of different sizes.	
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator.	-
	Forced air convection (hot air circulation).	
	Fully automatic provided with timer and fan.	
	Temperature range: Room temperature to 250 degree Celsius (adjustable)	
	Temperature Variation: +/- 1 deg C.	
	Temperature and time display unit	
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel	
	With two adjustable mesh shelves of stainless steel	
	Capacity of mesh: 25L	
	5. System Configuration Accessories, spares and consumables -	
	All consumables required for installation and standardization of system to be given free of cost.	
	Should be supplied with all startup chemical indicator tape/strips which change	

Document: Capital Medical Device Technical Specification

from red to yellow or gold and so show exposure to hydrogen peroxide.

Pouches and Rolls of different size which display directly on the bag chemical exposure to hydrogen peroxide

Should be supplied with all startup incubators, instrument tray of all sizes

3x set of readymade gasket

3x fuse

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Steh-90	1. Generic Name:Instrument - Sterilizer Hot Air 60L	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:-	
	Hot air sterilizers are required for sterilizing an object in high temperature by using dry heat to sterilize and operate in the principle of patented fine air circulation achieved by means of a fan in an electrically heated chamber.	
	4. Technical Specification:	
	Table top and front loading	
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator. Thermostatically controlled system. Hot air circulation	
	Fully automatic provided with timer and fan.	
	Temperature range: room temperature to 250 degree Celsius (adjustable)	
	Temperature Variation: +/- 1 deg C.	
	Temperature display unit	7
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel	
	With three adjustable mesh shelves of stainless steel	
	Capacity: 60 liters/ above	
	5. System Configuration Accessories, spares and consumables -	
	All consumables required for installation and standardization of system to be given free of cost.	
	Timer and touching pad	_
	3x set of Spare Heater	
	3x set of readymade gasket 3x thermostat, 3x fuse	\dashv
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment; Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	_
	7. Utility Requirements:	-
	Electrical Power Supply: 220VAC ±10%	-
	8. Standards and Safety Requirements:	\dashv
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	_
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Addis Ababa

Base Code	Item Detail	Department
Stds-90	1. Generic Name: (Instrument - Washer/Disinfector)	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Washer/Disinfector: An automated washing unit that uses high-temperature water and detergent to clean and high-level disinfects instruments and trays.	
	4. Technical Specification:	
	Front loading, Electronically controlled, Single door with forced air drying system Volume: 60L	
	Touch screen, with LED/TFT control panel, about 7" or above screen size	
	Motor driven sliding door made of stainless steel medical grade of 316 with thermal insulation.	
	Freshwater circulating system	
	Hot water Connections:	1
	Total Power: 9KW	-
	Pump Power: 150W	
	Dryer Blower: 150m3	
	Total Power: 3KW	
	Dryer Heater: 750W	
	Cold Water Connection:	
	Min/max pressure: 0.5 – 2bar	
	Min/max temperature: 55 – 60 Celsius	
	Flow rate: 30L/min	
	Hydraulic connection: 25mm	
	Heating up to 95 degrees C.	
	Automatic dosing systems for liquid and powder cleaning substances	
	Interior parts of stainless steel, 2 shelves	
	Machine is insulated against noise and works also with low-water pressure of 0.5 bars.	
	With specially selected insert and baskets for cleaning surgical instruments.	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Stes- 90	1. Generic Name: Sterilizer - Steam, 300/500L	OR
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	1
	Steam Sterilizer used in the destruction of all forms of microbial life on medical	
	instrument by exposing the object to moist heat at 121°C-134°C under high pressure	
	4. Technical Specification:	
	Front Loading 300/500L	
	Touch screen, with LED/TFT control panel, about 7" or above screen size	
	Motor driven sliding door made of stainless steel medical grade of 316 with thermal insulation.	
	Fitted with load indicator and safety thermostat take over indicator lamp. LED Indicator	
	High Grade strong stainless steel 316, Triple walled construction	
	Positive radial self-locking safety doors	
	Hydrostatically tested to withstand 2.5 times the working pressure	
	Manual and automatic filling option	1
	Internal data archiving with 5000 cycle capacity	
	Air ballast system for fast and safe processing of fluids	1
	Control System: Microcontroller based	
	The safety value will be open automatically when the inner pressure over and the	
	steam be exhausting to the water tank	
	The door opening mechanism cannot be operated until the pressure in the chamber reached atmospheric pressure	
	A complete record of every cycle is produced on the built-in thermal printer, with 1 box of thermal paper	
	316 stainless steel pressure vessel	
	Fan cooling system	
	Automatic and real time self diagnosis system in case of failure and have means of reporting to the operator	
	Having alarm for preventive maintenance	
	A safety micro switch is fitted to the door which will only allow the cycle to start if the door is properly closed and locked.	
	Water system: Automatic water fill with inbuilt/external reverse osmotic water softener in the system	
	water supply line fitted with extra water filter	
	Sealed with Silicon long-lasting and durable gasket.	
	Digital display for jacket and chamber pressure, steam generator and temperature with gauge display	
	Outer jacket of stainless steel 316 to prevent heat loss	
	Mounted on tubular stainless steel 316 frame with ground leveling flanges	
	Integral drip tray	7

Double chamber made of medical grade 316 stainless steel

Internal chamber with capacity not less than 300L

The steam generator made of medical grade 316 stainless steel

Thermal insulation to prevent overheat

Heat dissipation: maintain nominal temp and the heat dispersed through a cooling mechanism

Input voltage: 380VAC, 50Hz, 3-phase

Pressure gauge: 0-2.2Kgf/cm²

Operating pressure from: 15-31 psi

Sterilizing pressure: 1.2-2.2Kgf/cm(15-31 psi) at 121°C-134°C

Protection: over-charging cut-off with visual symbol

Pressure control switch

Low water level cut-off device

Vacuum breaker

Barcode reader and software

Modem link

Mounted Air compressor

3x Readymade Spare Gaskets

Steam generator

Rapid water re-cooling

Inbuilt vacuum pump

Low water protection device

Air removal filter

Timer with alarm system

Digital temperature indicator

Printer & Digital chart recorder

Stainless steel flush mounting

Carriages, trays, and baskets

Overpressure release valve

Sterilization indicator

Indicator color must not fade when it is exposed to light

Distinctive color change

Dual strip can be divided into two for economy of use

1x 300pcs/box, Dimension 150×90×200mm

Lead free steam indicator tape

5. System Configuration Accessories, Spares, Consumables and other components:

2x Trolleys for contaminated and sterilized instruments can be fitted the sterilizer door

Pneumatic valves, Pressure switch

Temperature sensor

3x Spare heater

Document: Capital Medical Device Technical Specification

2x Door gasket

1x Spare contactor

3x Spare fuse

5x Gasket lubricant

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	II D / 2	Departm
Toeh-90	Item Detail	OR
10011 > 0	1. Generic Name: Table – Operating, Electro hydraulic	021
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Operating room table, is the table on which the patient lies during a surgical operation	
	4. Technical Specification:	
	Five section table, electro-hydraulic table	
	Should be adjustable to all essential positions.	
	Frame and bottom made of 304 grade Stainless Steel material	
	Height should be adjustable by oil pump, foot step control.	
	Detachable head rest which can be easily adjustable to any desired position, above or below the table top.	
	Table top can be rotated 360° through base. Durable and leak-proof hydraulic pump.	
	Kidney-position should be achievable by breaking the table.	
	Should have handset for position selection by in-built stand-by control.	
	Table-top should be radio-translucent	
	Can be controlled with and without Remote controlled with battery and battery indicator, electro-hydraulic operated	
	Facility to remove or interchange head and leg sections	
	Antistatic and liquid-tight mattresses with shock absorbing foam	
	Table made of corrosion resistant and disinfectant- proof stainless steel and Traction facility	
	High density memory foam, 1-piece mattress, with cut- outs to fit the mattress frame at all positions with mattress size of 60mm	
	Powered height adjustment from 0.6m to 1.2m	
	Powered Trendelenburg adjustment: -30 deg up to +45 deg	
	Lower Back:+100°/-30° and Upper Back:+80°/-30	
	Lateral tilt (left/right): ±30 deg	
	Adjustment of backrest: -25 to +70	
	Adjustment to flex/reflex position	
	Adjustment leg section: +70° / -90°	
	Table dimension: (1 x w x h) 970mm x 500mm x 2000mm	
	Support at least: 250 Kg	
	Leg Sections (UP/Down):+25°/-90° and Head Sections (Up/Down):±40° 5. System Configuration Accessories, Spares, Consumables and other	
	components:	-
	1x Screen frame	J

2 x I.V. stands

Shoulder support (pair): Lateral support (pair)

2x Arm table

6x Clamps

1x Jelly mattress for each parts to prevent nerve distort all over the body

1x Restraint strap

Orthopedic Surgery's accessories: Orthopedic extension, Raised arm tabled / Adjustable arm support

ENT accessories:

Head rest

Gynecology Surgery's accessories: Knee crunches (Pair) Rotary clamps (2 pcs)

Neuro Surgery's accessories: Mayfield and head rest

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Document: Capital Medical Device Technical Specification

Name and Model of the product
PO Box 25-11-276-32-65
Tel: +251-11-276-32-65
Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Detail	Department
Mioe-90	1. Generic Name: Operating Microscope	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	An operating microscope is an optical microscope specifically designed to be used in a surgical setting, typically to perform microsurgery.	
	4. Technical Specification:	
	Optics:	
	Apo chromatic optics	
	Binocular tube 0-180 degrees of rotation.	
	Should have high quality red reflex/enhance for better red reflex or stereo coaxial illumination	
	Standard magnification for operating microscope (3.4x, 5.3x, 8.5x, 13.6x, 21.2x)	
	Eye piece should be minimum 10x or 12.5x wide with eye guards.	
	Have universal coupling	
	Should have tools free design for stand-by bulb change over and for failed bulb replacement.	
	Monitor and Camera	
	Standard Display and Camera	
	Illumination	1
	Integrated LED	1
	90 degree binocular with converging optics.	
	Cold light coaxial illumination by fiber light guide	
	Heat absorbing, IR and UV filters for protection eye	
	Floor stand system:	
	Should be floor standing type with fiber wheels with 4 castors brake	
	Foot switch functions	
	Stand height adjustment	1
	Weight carry capacity stand	1
	Should have counter balanced arm mechanism.	1
	Should have rust free design.	
	X-Y Coupling	1
	Should have motorized x-y movement	1
	Adjustment range not less than +30mm	1
	Key for initial position of x-y coupling and focus	1
	5. System Configuration Accessories, Spares, Consumables and other components:	
	Objective lens	
	1x Chip camera CCTV camera	
	Suitable adapter for 1 chip Camera	

Eye pieces

Halogen lamp/LED

Beam filters

Sterilization process for accessories

Comply with standard cleansing and disinfection

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Tel: +251-11-276-32-65

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Addis Ababa

Base Code	Item Detail	Department
Mins-90	1. Generic Name : Microscope-Neuro surgical	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Operating microscopes equipped with features that enable the surgeon to concentrate on the surgery rather than on the manipulation of the microscope, such as powered focusing and zoom magnification capabilities, as well as eyepiece tubes that permit the surgeon to see the field from a vertical perspective while keeping the head erect. Surgeons use operating microscopes to magnify minute structures (e.g., nerves, blood and lymphatic vessels, lesions) in the operating field.	
	4. Technical Specification	_
	Motorized zoom magnification, 6:1 ratio	1
	Magnification from 1.8x to 24.0x.	
	Variable working distance: 207 mm (+/- 25 mm) to 510 mm (+/- 25 mm) through motorized multi focal lens.	-
	Pair of wide-field eyepieces for spectacle wearers 10x, dioptric setting + 5D to - 8D	
	Ergonomic handles with buttons for motorized control of focus, zoom, axis movement, video control & still photography with programmable keys.	
	Facility for adjusting speed of the focusing motor to adapt for different magnifications.	-
	300W xenon illumination with 300W xenon back up through fiber optic cable.	_
	Inclinable binocular tube, inclinable over range of minimum 0-360 Deg.	_
	Facility for spot illumination	
	Floor stand with electromagnetic brakes with freedom of movement in all axes.	
	System should be compatible for neuron navigation.	
	Complete auto balance by push at one button, intra operative auto balance.	
	Should have interface for integrated heads up display for monocular image injection from endoscope & MR/CT (PIP).	
	Intra operative diagnostic ICG.	
	Stereoscopic co-observation attachment for second observer with tilt able eyepieces, minimum 0-180 Deg.	
	Integrated dual beam splitter	
	Integrated 3-Chip CCD camera with c-mount for connecting with the microscope.	

Integrated digital video recording facility with appropriate video editing software.

Diploscope (face to face attachment)

Full multifunction footswitch

Digital still camera for attachment with microscope

5. System Configuration Accessories, Spares, Consumables and other components:

2x Spare xenon lamp 300 W

1x Dust cover for covering the microscope

1x Set of sterilizable silicon caps

3x Fuses

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220/380VAC $\pm 10\%$ with UPS supporting the whole system

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Document: Capital Medical Device Technical Specification

Additional packing and labeling requirements should bear in each package

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Addis Ababa

Base Code	Item Detail	Departmen
Lith-90	1. Generic Name: Lithotripter	Nephrology
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Extra corporeal shockwave lithotripsy (ESWL) used in urinary stone treatment	
	4. Technical Specification:	
	Electromagnetic shock waves emitter (EMSE)	
	The shock head which has a wider focal length is preferable (More than 150mm)	
	Shockwave head facility for variable energy level and fully motorized for under, over and parking position of head.	
	Shock wave source motorized to enable different treatment windows of urethral and renal stone.	
	Integrated, isocentric fluoroscopy and ultrasound system with inline ultrasound probe.	
	Shock wave source depth of≥150mm incorporating the latest electromagnetic	
	Easily variable levels of energy in proportionate steps	
	Optimum focal size capable of treating large stones well as small stones	
	Fixed frequency shock release between 60-120 shocks per minute, with ECG	
	Shock wave source should be preferably motorized so as to enable different treatment	
	State life time for coil, therapy and high voltage generator	
	Monitor: Facility for ECG with ECG monitoring	
	Table: Fully motorized treatment table on wheels to shift and treat the patients, with symmetric table top design and therapy window.	
	Table top load 200kg	
	Possibility to use an endourological procedure on table	
	Patient table should be of standard quality, motorized, compatible with c arm and therapy head	
	Accommodate the c arm movements in both CC directions	
	Symmetrical table - top design with treatment window	
	Simultaneous treatment of both kidney of different procedure (stent and ESWL) without patient reposition.	
	Able to focus in obese patient	
	Windows for urethral and renal stones.	
	3 Axis movements in addition to motorized angular movement isocentric to the focus to provide 0-25 degrees of variable window for billiary and urethral stones and up to 50 degrees of variable window for renal stones.	
	Cushion height and pressure auto adjustable to suit various contours of different patients	
	Localization System:	_
	Truly integrated x-ray and color Doppler ultrasound localizing and targeting system both isocentric to the shock wave source	

Simultaneous imaging for localization and treatment, with x-ray and ultrasound system

Able to change the therapy head from under the table to over the table position for treatment of all kinds of stone when the patient is placed in supine position

X-Ray:

High frequency x-ray generator, fixed anode, double focus x-ray tube, 9" image intensifier with TV chain with CCD camera

Fluoroscopy:

Kv range: 40 -110Kv mA range: 0.2- 4 mA

Able to move 30 degrees in both CC axis x-ray image should have clarity with minimum scatter and maximum field of view on the monitor with the possibly hold the last image

X-Ray image should have minimum shadow of the cushion of the shock source

Stone localization and targeting simultaneously with integrated ultrasound and x-ray system with both the systems being in use for targeting at the same time

Integrated Ultra-sound system:

Localization done through integrated color Doppler ultra-sound isocentric to the shock wave source with inline/outline transducer for best image quality

3.5/4.0 MHz electronic small foot print transducer for lithotripsy & urological scanning

6.0-7.5 MHz electronic biplane trans rectal probe with simultaneous live imaging of the planes on the ultrasound monitor

The probe should be supplied with biopsy attachment and needle guide

Transducer movable around the shock source as well as over the source in arc so as to enable monitoring and targeting in different planes

All the movements should be isocentric to the focus of the source

The ultrasound system should be light weight and preferably portable so that can be used independent of the machine if necessary

Motorized inline transducer movement in Z axis

ECG Triggering:

Should have ECG machine for monitoring as well as triggering of shock release

Printer and recording system with PC

Black & white thermal paper printer with 5 rolls to be provided

5. System Configuration Accessories, Spares, Consumables and other components:

Endo urology accessories:

Drain tray

IV stand

Leg holder

Mobile lead shield 2mx 2m(l xw) lead shield, 1mx1.8m lead glass with two lockable caster and self standing type of mobile lead shield

12 x Lead aprons with standard specification weight and should meet safety norms.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

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Operating Temperature:+10 °C to +30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220/380VAC \pm 10% with UPS supporting the whole system

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code		
base Code	Item Detail	Depart
Lioc-90	1. Generic Name: Light-Operating, Ceiling	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A ceiling type provides an optimal shadow free lighting for carrying out surgical	
	procedures in an emergency environment.	
	4. Technical Specification:	
	The unit consists of spring balanced articulating arm with one large copula and two satellite heads and camera system	
	Capablerotating 360° around vertical axes	
	Control unit to regulate light intensity and to switch on/off the unit	
	Shall have continuous dimmer, continuous focus adjustment, continuous field adjustment	
	Sterilizable removable handle to regulate light field size	
	Diameter of domes: large copula, approx. 0.70 m, and satellite heads of each not less than 0.45 m	
	Light intensity: for large copula not less than 130,000 lux at 1m distance from light source and for each satellite heads not less than 100,000 lux at 1m distance from light source	
	Brightness control to allow full adjustment from zero to maximum illumination.	
	Color rendering index: 95	
	Heat filtrating: 99%	
	Luminance Field size: 14 - 25 cm	
	Vertical adjustment: not less than 110 cm	
	Working distance range (focal length): 70 - 140 cm	
	Depth of field with focused light: > 60 cm	
	Color temperature: ≥ 4300 K	
	Light source: LED, lifetime of $\geq 50,000 \text{ hrs}$	
	Adjustable light and color temperature Indicator	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1 x Ceiling anchoring ring, extension and fixation material	
	1x spare of Sterilizable removable handle	
	3x Spare, spare fuse for each place, and one power supply bord	
	1x LED matrix board	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	1

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7. Utility Requirements:

Electrical Power Supply: 100 - 240VAC

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Liom-90	1. Generic Name: Light-Operating, Mobile	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A mobile type provides an optimal shadow free lighting for carrying out surgical procedures in an emergency environment.	
	4. Technical Specification:	
	The unit comprises of spring balanced articulating arm	
	Head with button/touch screen digital control to regulate light intensity and to switch on/off the unit	
	Have continuous dimmer, continuous focus adjustment, continuous field adjustment	
	Auxiliary light source included for extra operations	
	No infrared or ultraviolet radiation	
	Sterilizable removable handle to regulate light field size	
	Light intensity: not less than 100,000 lux at 1m distance from light source	
	Color rendering index: 95	
	Heat filtrating: 99%	
	Color temperature: ≥ 4300 K	
	Luminance Field size: 14 - 25 cm	
	Diameter of light head: not less than 0.60cm	
	Working distance range (focal length): 70 - 140 cm	
	Depth of field with focused light: > 60 cm	
	Lifetime of LEDs ≥ 50,000 hrs	
	Adjustable light and color temperature indicator	
	Mobile stand:	
	Light weight easily moveable stable support with at least 4 castors with locking counter balance mechanism in order to ensure stability of light head in all positions and with swivel arm.	
	Castor must be medical chemical resistant	
	Battery:	
	Built in rechargeable batteries with capacity sufficient for operating in battery mode (fully charged) for minimum of 45 min	
	Battery power (charge) indicator	
	5. System Configuration Accessories, Spares, Consumables and other components :	
	1x spare of Sterilizable removable handle	
	1	

2x spare of fuses

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 100 - 240VAC

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

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Addis Ababa

Base Code	Item Detail	Departmen
Cryu-90	1. Generic Name: Cryo Therapy Unit - Gynecology	Gyn
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (N ₂), nitrous oxide (N ₂ O), carbon dioxide (CO ₂)] to a target tissue for its destruction and removal.	
	4. Technical Specification:	4
	The system typically includes a mechanical regulator to control the flow of cryogen, contained in an attached cylinder, and the probe(s) to apply the cold.	
	Unit consist of a tank, a pressure regulator, and a probe attached by tubing to the tank	
	Fully mobile Cryo-surgical system with a wide array of interchangeable probes designed for the use of gynecologic surgical procedures	
	The interchangeable probes must include both different sizes for the cervix besides flat one for vaginal lesions	
	Nitrous oxide or carbon dioxide can be used as refrigerant	
	Units should support various probes and tips	
	Nitrous based unit should have scavenging ability	
	Adjustable freezing temperatures, gas flow and pressures through a regulation system	
	Non-electric defrosting system	
	Autoclavable Cryo probes	
	Operating pressure: 450 to 800 psi	
	Supplied with triggers/connection for N ₂ O or CO ₂	
	Rolling cart	
	Unfilled cylinder for N ₂ O or CO ₂	
	Supplied with all kinds of probes required for gynecology.	
	Require several different probe designs	
	Temperatures at the Cryo tip below -69°C with CO ₂ or -79°C with N ₂ O	
	Trigger mechanism to control the freeze/thaw cycle (active defrost preferred)	
	Removable circular, closed design Cryo tips	
	Diameter: 19 ±2 mm	
	Flat surfaces or with a cone extrusion < 5 mm	
	Insulated Cryo shaft	
	Length: 170 mm to 200 mm	
	Hose assembly (high pressure) with cylinder connector pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas	
	User adjustable Cryometer range	
	Portable and easy to transport	
	<u> </u>	

Hose assembly length of 150 cm

Hose is constructed with flexible plastic or rubber suitable for use with pressurized carbon dioxide or nitrous oxide

Indicator for which type of refrigerant gas is under use

Color coded Pressure gauge, to indicate the safe working range

Pressure relief valve, with an internal rupture disk to protect excessive tank pressure

Pressure regulator to maintain constant pressure

Silencer reduce noise levels

Timer to indicate duration of tissue exposure.

Cryo Tip:

Routinely sterilizable

Smooth and sharp less Cryo tip edges

Cryo tips shall be of closed design

Cryo tips shall be rounded in shape and should be 19 ±2mm in diameter

The surface that contacts the tissue should be either flat or with a cone extrusion (nipple shaped), not exceeding 5 mm

Length of the Cryo shaft and Cryo tip assembly should be between 170 and 200 mm.

Hose assembly length of 150cm

Single-hand control from three-position trigger (freeze, off, defrost)

Instant defrost

Trigger position for immediate active defrost process

Autoclavable tips, Cryo shaft

"O" ring design to provide better gas seals where tips attach to probe system

Built-in regulators, control pressure at tips for added safety and gas economy

Change tip during procedure without shutting off gas tank

Nitrous Oxide (N₂O) and Carbon Dioxide (CO₂)

Cylinder Support of 20 lb.

Surgical grade Cryo Tips:

Micro, 2mm Diameter

Skin Lesion, 5mm 45°

Endocervical (Nulliparous)

Endocervical, Round

Skin Lesion, 8mm 45° angle

Ano-Rectal

Exocervical, 19mm Flat

Exocervical Convex, 19mm

Endo/Exocervical Small

Exocervical, 25mm Flat

Endo/Exocervical Large

5. System Configuration Accessories, spares, Consumables and other consumables:

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1x Hose assembly

1x Cryotips for each type

1x Cryoshafts

1x O-ring, and sealing washers

1x Compressed gas in cylinders (nitrous oxide or carbon dioxide)

Cryoprobes to according the specific use

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65 Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Anem-90	1. Generic Name: Anesthesia Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	-
	Anesthesia machine used to control the patients gas exchange and administer anesthetic agents to patient during surgery	
	4. Technical Specification:	
	The complete set-up shall included patient circuit, monitor and ventilator	
	Patient monitoring system with vital parameter ECG, EEG (optional), pulse oximeter(SpO ₂) for adult, pediatric and neonate, capnography (EtCO ₂), and Airway pressure, NIBP for adult, pediatric & neonatal with NIBP cuffs, rectal & skin temperature, anesthetic gases, IBP with necessary arterial lines, and CVP pressure transducers and other necessary parameters Anesthesia machine of closed breathing circuit configuration suitable for Adult and pediatric including maplson D neonatal and pediatric system.	
	Anesthesia gas delivery system.	1
	Equipped with anesthesia vaporizer (Halothane, & Isoflorine) and Anesthesia ventilator.	
	Independent attachments for connecting central gas supply and pin indexed cylinders and non interchangeable gas specific connection to pipe line inlets Drug dosage indicator calculation	
	Audio-visual oxygen failure warning system with nitrous oxide cut off.	1
	Trolley with upper shelf and medical utility rail integrated support for two 10L anesthetic gas cylinders (O ₂ , N ₂ O), Soda lime absorber, with 2.5kg reservoir and adjustable pressure limiting valve	
	Flow meter:]
	The apparatus should use gases (O ₂ and N ₂ O, air) accommodates the following main parameters:	
	For O ₂ : 0.1-10L/mi	-
	For N ₂ O: about 0.1-10L/mi	
	For Air: 0.1-10L/mi	
	Oxygen and Nitrous oxide anesthetic agent in the inspired mixture	
	Oxygen saturation of the blood with both adult, pediatric probes and sensors	
	Airway pressure monitoring should be present	
	Temperature monitoring with 2 probes esophageal/ rectal and skin probes	
	Mounting:	
	Mobile stand mount for the unit	
	Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes	
	Individual locking front castor brake	
	Vaporizer: Easily removable, refillable, and monitored. Gas tight and removed.	1

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O₂ flash valve: push button type O_2 flow volume approximately not less than 50-70 L/min.

Canister: easily detachable double chambered clear acrylic type. Its volume should be greater than 1400ml.

Extendable rear platform for two cylinders.

Features:

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Alarm safety system features:

Low O2 concentration alarm sound with indicator light

When O2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops below 1kgf/cm2

N2O shall not be obtained until at least 1.5lt of flow is surely obtained constantly.

POP of valve should prevent over pressure with surplus gas evacuation adaptor and open close circuit selector knops.

Ventilator:

Modes: Automatic Volumetric (IPPV), SIMV and Manual

Electrically powered compressor, minute volume: 2 to 25 L/min

Tidal volume: 20 - 1500 ml

Respiratory rate: 5 to 70 cycles/min

I/E ratio: (1:2 to 1:6)

Inspiration pressure: 0 to 80 mbar

Peak inspiratory flow: 0 to 60 L/min

Trigger sensitivity: 0 to -20 mbar

PEEP: 0-30 cm H20

Gas flow rate and volume indicator

Gas type indicator

FiO₂ monitoring sytem

Display fit with manometer, range approx:- 10 to 100 mbar

Front panel shows status, errors and sensors failure (low/high pressure, power failure)

Audio-visual alert on low/high pressure, apnea, power failure

Display of operational status, with set and measured values

Front panel shows status and errors (low/high pressure, power failure, battery status)

Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures

Self diagnosis with each start-up and integrity testing of all system parameters

With adjustable patient-circuit support arm

Anesthetic gas scavenging system

Inbuilt suction unit for direct patient suctioning in oral cavity during intubation and extubation

Oxygen flush: 25-75ml

5. System Configuration Accessories, Spares, Consumables and other components:

1x Oxygen sensor

1x reusable ECG sensors and connectors set.

2x adult and or pediatric cardiac output connector set.

5x EtCO2 sensor.

High and medium pressure regulating gauge compatible with the machine

1x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)

1x Adult reusable breathing circuits (tubes / balloons / valves / masks)

2x Maplson D neonatal reusable breathing circuit tube/(tubes / balloons / valves / masks)

5 x Spare parts/maintenance kit (air filters, tubing, O rings)

2 x Set of spare fuses.

Should be supplied with necessary attachments for use of the breathing circuits with a complete standard accessories

Consumables and parts required to operate the equipment, including all standard tools and cleaning as well as lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

Built-in rechargeable battery, autonomy approx 2 hrs with Automatic switch to battery in case of power failure, automatic recharge when connected to mains

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard

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accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Depai		
Elsu-90	1. Generic Name:Electrosurgical unit	OR		
	2. GMDN/UMDN Code/Name:			
	3. Clinical Purpose/Description:			
	Use high frequency electrical energy in a radio-frequency (RF) band to develop heat directly within targeted soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures 4. Technical Specification:			
	Modes of operation to include pure cut, pure coagulation and blended (combined)			
	Operation to be controlled by foot pedal, with minimum 2m connection cable, and also by hand switch on probe			
	RF generator to be within the range 0.5 to 3.5MHz, output to be electrically isolated from ground.			
	Monopolar maximum power to be at least 350W (cut) and 200W (coagulate)			
	Bipolar maximum power to be at least 50 W (coagulate)			
	Visual and audible activation indicators required			
	Visual and audible cable disconnection alarm required			
	Display and keyboard for all parameters visualization and setting.			
	Power control in the main panel.			
	Coagulation: high power for contact coagulation current with high crest factor for spray coagulation.			
	Memory for at least 10 programs with their waveforms and power levels.18) Monitoring system of the electrode-patient connection of at least 1 KHz measurement frequency.			
	Automatic power tuning with dynamic control and automatic stop in case of any working problem.			
	Protection against defibrillator discharges.			
	Convection refrigeration without ventilator.			
	Output Waveform: 445 kilohertz (kHz) square wave variable burst length Frequency Range: 445 kilohertz			
	Output Current Range: 10 - 641 mili amperes (mA rms) into a 50 non inductive load, continuously variable			
	Output Power: 0.5 - 21 watts into a 50 ohms non-inductive load			
	Continuously variable Test Load: 50 ohms non-inductive load			
	Neuro-surgical forceps input, using electrosurgical analyzer Rated Accessory Voltage: 210V Peak			
	Minimum nominal high frequency output powers for cutting:			
	Monopolar: 300W at 500 ohms;	1		

Bipolar: 100W at 500 ohms.

Minimum nominal high frequency output powers for coagulation:

- **Bipolar:**100 W at 125 ohms;
- Monopolar spray:100 W at 500 ohms;
- Monopolar forced:120 W at 350 ohms.

5. System Configuration Accessories, Spares, Consumables and other components:

Foot switch

5x spare fuses

Two reusable, sterilizable, monopolar patient plates with minimum 2m long connection cable

Two each of reusable, sterilizable, monopolar and bipolar probe with selection of tip sizes for each; pencils, ball electrodes, loop electrodes, reusable return electrodes, coagulators, adapters and blade electrodes

Monopolar pedal, bipolar pedal

Bipolar forceps,

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \, ^{\circ}\text{C}$ to + $30 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%, with appropriate UPS and stablizer

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Suct-90	1. Generic Name: Suction Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a	
	body cavity or lumen by means of suction. This system can be used in a wide variety of settings	
	within healthcare facilities ICU.	
	4. Technical Specification:	
	Vacuum Adjustment: Continuous	
	Must be able to generate a vacuum of at least 0.85 bar (650mmHg)	
	Maximum vacuum: 700 mmHg	
	Minimum open tube flow rate at least 3 liters liquid per minute	
	Twin suction bottles, minimum size 3 liters each made of non-glass materials	
	Bottles to have an automatic cut off when full to prevent ingress of fluid to motor	
	Airline to pump to incorporate bacterial filter	
	Tubing to patient to be minimum 3m long, non-collapsible type	
	Sound Level: < 60 dBA.	
	Castors: 100 mm diameter, with brakes	
	To be protected against fluid ingress from above	
	Machine cover should be open able for repair and maintenance	
	Oil-free pump operation preferred	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	2x Spare suction bottles	
	5x Spare inlet filters at least	
	2x Spare sets of fuses	
	3x Suction tubes`	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Protective replaceable fuses fitted on live and neutral supply lines	
	Electrical source requirements: Voltage: 220V ± 10, Frequency: 50Hz single phases	+
	Electrical source with line connection plug type.	_
	Protections against over-voltage and over-current line conditions	_
	8. Standards and Safety Requirements:	-
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	-
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	1
	,	

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9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65 Fax: +251-11-275-25-55

Addis Ababa

Ethiopian Pharmaceutical Supply Agency

Base Code	Item Detail	Department
Poxi-90	1. Generic Name: Pulse Oximetry	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement	1
	and display of hemoglobin oxygen saturation (SpO2).	
	4. Technical Specification:	
	SpO ₂ measurement range at least 60 to 99 %, minimum resolution 1%	
	Accuracy of SpO ₂ better than ±2%	
	Pulse rate range at least 30 to 250bpm, minimum gradation 1bpm	1
	Accuracy of pulse rate better than ± 2bpm	1
	Automatic power-off facility required after minimum of 1 minute	1
	Low battery display required	1
	Must supplied with rechargeable battery	1
	Digital equipment with autocorrelation algorithm	1
	Internal memory continuous data storage time not less than 12 hours	1
	Integrated display for data visualization with size not less than 5 inches.	1
	Audio visual display of at least the following parameters, SpO2 sensor connected, alarms	1
	disabled, low battery, battery in charge.	
	Plethysmography curves and tendency lines visualization capabilities for monitored parameters	
	At least the following audio alarms: high frequency, low frequency, low saturation.	
	Hard and splash proof case	
	Display must allow easy viewing in all ambient light levels	
	Supplied in protective case for clean storage and safe transport	1
	Handle bar or facilities for easy transportation.	1
	5. System Configuration Accessories, Spares, Consumables and other components:	1
	1x Cable with a length: 1.5m	1
	1x Patient reusable oximeter sensors for adult, pediatric and neonate	1
	6. Operating Environment;	1
	Operating Temperature: +10 °C to + 43°C	1
	Relative humidity: <85%	1
	7. Utility Requirements:	1
	Charger electrical source requirements: Voltage: 220V ± 10 /50Hz single phases	1
	Protections against over-voltage and over-current line conditions.	1
	Battery charger: wall output fitted and has AC to DC adapter	

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Battery: 12hr

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

Supplier to perform safety and operation checks before handover for some samples

Training of users in operation and basic maintenance shall be provided

The case is to be cleanable with alcohol or chlorine wipes

10. Warranty and After Sale service:

The supplier must provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

Certificate of calibration and inspection to be provided

Advanced maintenance tasks required shall be documented

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Oxy - 90	1. Generic Name: Oxygen Concentrator	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Oxygen concentrator is a device which concentrates oxygen from the atmosphere (typically ambient air) to supply medical grade oxygen to patient(s).	
	4. Technical Specification:	
	Compact and easy to transport (Mobile on Castors).	
	Dual-head Compressor.	
	Capacity: 1 to 5 l/Min of O2 at minimum of 90% concentration at maximum flow	
	Pressure-compensated Flow meter shall permit use of long cannula	
	Audible and visual Safety Alarms: Power Failure, Restricted Flow, Low O2	
	Equipped with Pressure-relief Valve and thermal protection of the Compressor.	
	Double-insulated Unit, Two-prong plug.	
	Flame-retardant Cabinet	
	Sound Level: 60dB	
	Fixed humidifier Port and Recess shall prevent bottle and connector breakage	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	O ₂ Tubing	
	3 Face Masks (Adult , Infant , New Born),	
	Humidifier	
	1x Set of Filters	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical source requirements: Voltage: 220V± 10 /60Hz single phases	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	ISO 8359 Oxygen concentrator safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	Supplier to perform safety and operation checks before handover for some samples	
	Training of users in operation and basic maintenance shall be provided	
	10. Warranty and After Sale service:	
	The supplier must provide minimum of one year warranty including labor and spare part from the date of commissioning.	

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11. Documentation:

User and service manual in English

12. Packaging and Labeling;

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Addis Ababa

Base Code	Item Detail	Department
Denu-90	1. Generic Name: Dental Unit	Dentistry
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Dental Unit is used to operate or treat the patient by looking into mouth easily	
	for the purpose of dental examination, minor surgery and other dental	
	procedures.	
	4. Technical Specification:	
	Dental chair with microprocessor controlled programmable dental chair with different programs	
	≥5 reprogrammable patient chair position with control panel	
	Foot Pedal to control the dental chair movement, hand piece and scaler	
	Adjustable Height	
	Backrest: slim and adjust table between 90° to 180°	
	Headrest: adjustable upward, backward and forward.	
	The movements are controlled through digital panel	
	Genuine leather chair with seamless washable cushion	
	Swivel arm	
	Carrying capacity: 200 kg	
	Pediatric Headrest	
	Rotatable ceramic spit on with auto-water flushing	
	Operating light	
	Adjustable to different heights with variable, horizontal and inverse	
	movements for proper focusing.	
	Light source: LED	
	Illumination of ≥30,000 Lux incidents in rectangular shape	
	Color temperature of ≥ 4000 K	
	Dual intensity control switch	
	Water Unit	
	Cold water	
	Automatic flush Bowl	
	Automatic Cup filler	
	Water bottle with switch	
	Clinician Side	
	Push button fiber optic Air turbine, 4 holes individual control of water and	
	air, autoclavable.	
	Fiber optic electric Motor with rotation of bur clockwise and anticlockwise,	
	autoclavable. The motor features high torque and quiet operation	

With micro motor from 300-50000 rpm with digital display of speed

Straight hand piece and contra Angle hand piece, autoclave able.

Automatic hand pieces selection through sensitive pneumatic valves

The quick locking connectors have also an integrated USB connection

6 way syringe with light

Straight or angled syringe

Adjustment for water, air and spray

Heating element for water and air inside the hand piece

Tips and cover are removable, autoclavable at 134°C

Monitor:

Integrated 19" medical grade LCD/TFT monitor

Resolution: 1080 x 1080

USB port with media player

Intra oral camera:

True lens intraoral camera, undistorted images with Not less than 6 lenses optics

Progressive video: No jagged edges

Instrument tray:

Tray table mounting arm swivels 360°

Tray table size: 300 x 380 mm

Assistant's Side

Triple syringe with removable nozzle, autoclave able

Saliva ejector (strong and weak)

Light control

Spray

Assistant control system

Portable Scaler with LED ultrasonic cleaner

Ultrasonic vibration between 25,000-35,000 per second

Micro processor based

Auto calibration and power control

Built in lens in the grip

Auto fault diagnosis

Water heated at the hand piece

The output power and water to be adjustable by controls on the front panel.

Complete with 6 different pieces of tips.

Sterilizable hand piece, tips holder and torque tools.

Autoclavable Scaler tip fixer and remover

Sterilization box

Portable light curing unit

Base unit with holder for hand piece

Hand piece

Digital Timer for adjusting of different time settings.

Standard cable operation

Standard light probe

Portable-tooth polishing unit

Flexible air polishing unit

Tooth cleaning and polishing

Interior and posterior teeth application

Twin flow system

Complete with powder holder and jet polishing/cleaning powder

Suction aspirator

High electric dry suction aspirator which is connected with central system and suction machine

Vacuum: 150 - 170 mbar

Flow rate: 500 - 800 L/min.

Connector accessory to central septic unit

Doctor's and assistant's stool

Adjustable height operating stool with anatomically shape seat.

Gas spring mechanism for adjustments.

Integrated four stable castors with brake

Arm support and adjustable backrest.

Compressor

Supply medical grade dry air which is absolutely oil free

Pressure gauge, air moisture filter and non-retraction valve

Auto cut-off switch

Maintenance free type covered in a cabinet

Noise level: ≤ 60 Db

Air Pressure range: 5 to 8 bar

Compressed air supply: 100 L/min

Air tank capacity: $\geq 40L$

Dental X-ray film viewer

Chair mounted type LED generated

5. System Configuration Accessories, Spares, Consumables and other Components:

3x Saliva ejector

2x Extra LED diodes that can fit for operating light and film viewer

4x set suction tip compatible with the dental chair suction aspirator

3x set of polishing tips

3x set of extra scaler tips

1x set extra piece low speed hand piece burs

1x set extra piece of high speed hand piece burs

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials

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including items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity : < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%, 50HZ

8. Standards and Safety Requirements:

Meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

- a). Water Connection
- b). Drain Connection
- c). Electrical Connection

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Department
Xrd-90	1. Generic Name: X-Ray- Dental	Dentistry
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	7
	Dental x-ray used in orthodontic/maxillofacial diagnostic and treatment	1
	planning of ear, nose, and throat (ENT) disorders.	
	4. Technical Specification:	
	Radiological exams: Full panoramic and cephalometric	
	X-ray system for dental exams and temporo mandibular joint (tmj with	
	panoramic program/cephalometric, facial bone program, maxillary sinus	
	program, dental program, tmj program)	_
	Automatic Facial Contour (AFC) method for soft tissue enhancement in lateral views.	
	Dose reduction is achieved for orthodontic applications with a fully	+
	adjustable lateral cephalometric imaging area.	
	Stand model with fiber wheels and locking system	1
	Compatible for digital radiograph.	1
	X-ray tube head swing angulations of at least 290° in the vertical plane and 360° continuous rotations in the horizontal plane	1
	X-ray tube head angle indication	+
	Counter balanced arm mechanism	+
	AEC Reduces Radiation Exposure	+
	Digital linear tomography in digital unit	+
	True linear tomography/Linear tomography in film unit	+
	Tube voltage: 70-90 kV	4
	Tube current: 2 - 20 mA	4
		4
	Frequency: 150 kHz	4
	Tube focal spot: 0.5 mm	4
	Cephalometric	_
	Image Detector: CCD	4
	Sensor Pixel Size: 50 x 50 µm	4
	Image Pixel Size: 96 x 96 μm	_
	Scan/Exposure Time: 2–10Sec	
	Panoramic	
	Sensor Pixel Size: 50 x 50 μm	
	Image Pixel Size: 96 x 96 μm	
	Scan/Exposure Time: 2–15seconds	
	Exposure mode: patient sizes (Ped., Adult: small, medium, large) / 3 dental arch morphology (normal, square, sharp)	

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Lateral TMJ (closed & open)

PA TMJ (closed & open)

PA sinus

Standard panoramic

User friendly graphical user interface on a computer and from the console on the machine

Exposure time 1 to 5secs. Depending upon the patient's type and programme selection.

Standard bite blocks, edentulous blocks, Panoramic chin rest, TMJ Nose rest sinos chin rest

Supports the most versatile range of 2D and 3D imaging modalities

DICOM, RIS and PACS compatible unit

Universal power input including power factor corrector, mains voltage fluctuations automatically compensated

Automatic primary collimator

Graphical user interface

Advanced collimation

Upgradable software

Optimized image geometry and constant magnification

High resolution CCD sensors with protective optical fibre layer for protection and longevity of the sensor and adjustable panel size

Ethernet connection to computer sensor

Motorized column

Laser patient positioning

Microcomputer controlled movements for multiple projection programs

CCD-type electronic x-ray detector with CsI, high resolution scintillator

Memory card slot

Connection to computer via high-speed USB port

Pedestal mount

Storage compartments

Face to Face patient positioning with laser beams for better patient comfort and accurate positioning

Cater to all types of patients including adult, pediatrics, standing, sitting and wheel chair patients.

Positioning accessories like, Standard Bite blocks, edentulous bite blocks, panoramic chin rest, Sinus chin rest, TMJ nose rest.

The patient information must be arranged in user friendly and simple format with built in patient information management service

Computer Intel core i5 Processor with 1T Hard disk, 8 GB RAM, Ethernet interface, Graphic Board, 19" TFT/LED Monitor

Online UPS with 30 minutes backup

Low radiation dose with good image quality, with computerized operator's guide and programs

Expose in either direction

25 plastic bite guides

3 point head positioning system

Lateral Cephalometric,

Anterior – Posterior (AP) & Posterior – Anterior (PA)

Submento-vertex (SMV)

Oblique Lateral

Hand image (carpus view)

Software provided with various orthodontic filters to enhance hard tissue / soft tissues on need basis.

Generator Constant potential, resonance mode high

Programs:

Adult/Ped. Panoramic

Adult/Ped. Hemi Panoramic Right

Adult/Ped. Hemi Panoramic Left

Adult/Ped. TMJ Open/Close Mouth

Adult/Ped. Bi-Axial TMJ

Adult/Ped. Maxillary Sinus P-A

Maxillary Sinus L-L

Improved Orthogonality Dentition

Implantologic

Full Panoramic (Adult and child)

Segmented panoramic

Lateral TMJ-2 views

Lateral TMJ-4 views

Maxillary sinus

Interproximal panoramic

Orthogonal (perio) panoramic

Lateral-PA TMJ

Lateral multiangle TMJ

PA multiangle TMJ

PA linear sinus

Lateral sinus

All required programs not disclosed above need to be included

5. System Configuration Accessories, Spares, Consumables and other components:

 $3x\ X$ - ray unit with lead apron, gonadal sheath and thyroid protection collar/Each

1x Wheel chair/Ped/Adult/each

Set of Quality assurance accessories

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment

Operating Temperature:+10 °C to +45°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%, 50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Mrim-90	1. Generic Name: MRI 1.5 Tesla	Imaging
	2. GMDN/UMDN Name:	
	3. Clinical Purpose/Description:	
	MRI Machine is a medical imaging device used in radiology to form Cross Sectional image of the anatomy and physiological processes of the body.	
	4. Technical Specifications:	-
	I. MAGNET & GRADIENT SYSTEM:	-
	1. Magnet Type : Super conduct	1
	2. Magnet Strength: 1.5 Tesla	1
	3. Magnet Homogeneity mentioned in relation to 10,20,30,40,45 cm DSV (Diameter of Spherical Volume).	
	4. Automatic in homogeneity correction	-
	5. Shielding Type: Active	
	6. Emergency Rundown Control at both Operator Console Room and Gantry room as well as console room Gantry Room to be provided in Gantry.	
	7. Dedicated Helium exhaust system into atmosphere	-
	8. The system should be zero helium boil off technology	
	9. Magnet Bore Diameter: not less than 70 cm	
	10. Magnet bore length: 125 - 150cm	
	11. Fringe field: 1/5 Gauss line radius	
	12. Magnet Weight: 3500 Kg approximately	
	13. Emergency quenching	
	II. GRADIENT SYSTEM:	
	1. The true slew rate of 200 T/m/s at true standard configuration gradient strength 44 mT/m simultaneously should be available in each true axis (X, Y, Z) independently, for overall better duty cycle performance of the gradient. (NB: gradient strength configuration should be standard not to be with upgradable option from least gradient strength to 44mT/m)	
	2. Gradient type resonant / non-resonant :	-
	3. Gradient shielding type: active	-
	4. Rise Time not more than: 0.22 ms	
	5. Duty Cycle: 100% the gradient power amplifier should be water cooled.	

- 6. Type of Cooling: Water
- 7. FOV: approx. 520 x 450 x 400 mm
- 8. Slice Thickness:
- 2D imaging minimum should be : 0.5mm or less

Multi slice imaging: 1 – 7mm

Multi slice 2D: 0.5 mm or less

- 3 D imaging minimum should be : 0.1 mm or less
- Minimum echo spacing EPI sequence for imaging FOV should be atleast 0.7 ms or less at 256 X 256 matrix
- 9. Acquisition Matrix Minimum range:
- 10. Gradient / Acoustic noise suppression :
- 11. Echo train length in both spin echo and gradient echo should be at least 256 or more
- 13. Shall have eddy current compensation

III RF SYSTEM:

- 1. RF system type: Fully, Digital with digital transmit and digital receive
- 2. Number of independent channels in single FOV and single scan that can acquire independent image minimum: 32 or more
- 3. RF system should be compatible with parallel imaging techniques. It should be able to support time reduction with compatible coils in 2D/3D imaging in body/neuro imaging. The acceleration factor should be at least 4. Higher PAT factor will be preferred
- 4. The RF system that can support connecting maximum number of coil elements at a time specify.
- 5. Digital RF power output (kW): approx. 15 kW 25kw

IV COILS:

The system shall provide capability of doing whole body scanning from head to toe using sufficient and optimal coil elements.

- 1. The main Body coils with 18 or more channels integrated into the Gantry/magnet must be quadrature/CP for both transmission and Receiving. In addition to this coil the following coils should be available.
- 1. Phased array Body coils capable of doing chest, abdomen, pelvis, Magnetic Resonance CholangioPancreatography (MRCP), Peripheral-vascular & Angio, cardiac imaging, etc... with 32 channel or more

- 2. 16 or more channel Dedicated head coil should be compatible to parallel acquisition techniques.
- 3. Dedicated Flexible coil large
- 5. CP/quadrature/phased array Dedicated neck coil: 4 channel or more
- 6. CP/ Quadrature Dedicated ankle/foot coil: 12channel or more
- 7. CP/ Quadrature Dedicated knee coil: 12 channel or more
- 8. Dedicated Phased array Spine coil: approx. 32 channel
- 9. Dedicated Wrist array coil: 12 channel or more
- 10. Dedicated Breast Coil should be PAT compatible: 12 channel or more
- 11. Dedicated Phased Array coil for Shoulder Imaging: 12 channel or more
- 12. Endorectal coil for higher resolution imaging of prostate, colon, rectum and cervix imaging
- 13.Additional Dedicated 16 channel head coil to image the brain compatible with steriotaxy frame should be provided.
- 14. CNS imaging surface coil if the combination of head, neck and spine coil should be PAT compatible seamless CNS imaging, please quote the Head to Sacrum imaging surface coil.
- 15. Tuning of coil (automatic)
- 16. Built in RF Pre Amplifiers
- 17. Multicoil connection-it should be possible to connect atleast 2 coils simultaneously

V. PATIENT HANDLING SYSTEM:

- 1. Max. Patient Weight (kg): Not less than 180 kg.
- 2. Light localizer for patient positioning and position accuracy, at least \pm 1mm or better
- 3. Physiological signals display
- 4. ECG, Pulse, Resp. Sensors for patient monitoring: points no.3 and 4 should be available in the examination room (gantry) as well as Control room through a slave monitor
- 5. Intercom for Communication with patient (Two way) for patient to call in case of Emergency
- 6. Remote monitoring CCTV Camera with LCD/LED/TFT display to observe patient
- 7. Patient Musical System
- 8. Hand Metal Detector

- 9. Metal Detector at Gantry Room Entry
- 10. Patient Accessories:
- 11. Rack in Gantry Room for keeping coils and accessories (2 Nos)
- 12. The table should have patient auto alarm system.
- 13. The table should be fully motorized with computer controlled table movements in vertical and horizontal directions.
- 14. The table should deliver the protocols for automatic bolus chasing in peripheral angio with automatic table movement.
- 15. The table should have facility for manual traction in case of emergency.
- 16 The system should consist of detachable and dockable non magnetic trolley integrated with IV pole, arm boards, safety handrails and carrying capacity at least 180kg.

Image Transfer, archieving & Networking

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined enduser lisence PACS (Picture Archieving and Communication System).

This system should be able to provide on-line accessibility of processed image data in six OT's, ICU, CCU, and radiology conference room at trauma centre etc.

The server hardware should consist of intel multi core i7 32GB RAM, 2000GB HDD, DVD, CD RIW, 28" or more flat monitor.

Each viewing terminal should have a PC with intel core i7 latest version,32GB RAM, 500 GB HDD, CD/DVD, combo drive, 24"or more flat monitor.

VI MR WORKSTATION

One additional latest advanced post processing workstation of 19 inch LCD/TFT monitor with additional camera. It should be swappable (Interchangeable with main console with full functional capability as the main console) and should have all post processing software's and complete DICOM functionalities.

VII. COMPUTER SYSTEM:

- 1. Host Computer, Processor: intel core i7
- 3. RAM memory capacity at least : >/= 32 GB
- 4. Hard Disk Capacity Not less than 2000GB and Image Storage at least: 500,000 at 512x512 Matrix: uncompressed

- 5. DVD : Re writeable
- 1. Additionally 5000 high storage CD's or 1000 high storage DVD's to be provided.
- 9. The main console should have integrated MR compatible music system for the patient
- 10. Color TFT/LCD Monitor:
- High resolution flat screen monitor horizontally tilt able, forward and backward
- Screen Size(diagonal): 19 inch
- Screen matrix: 1280 x 1024

VIII IMAGE PROCESSOR:

- 1. Image Processor-RAM memory -minimum of: 32 GB
- 2. Image reconstruction time- rectangular matrix 256x256 minimum reconstruction as standard : quote your highest available reconstruction as standard
- 3. Reconstruction Matrix: Range

IX. IMAGING SPECIFICATION:

- 1. Off centre FOV:
- Lateral
- · AP
- 2. Slice orientations- sagittal, Axial, coronal ,single/ double angulations Oblique etc.
- 3. Display no. of slices at the console
- 4. Display SNR of a chosen sequence at the console
- 5. Scan modes:
- · Single slice
- · 2D multiple single slice
- 2D multiple slice
- · 3D volume
- 3D multiple stack
- · Cine acquisition
- · Dynamic pre and post contrast studies
- 6. Maximum intensity projection (MIP)
- 7. Minimum Intensity Projection (Block Blood) in MRA
- 8. Multi planar Reconstruction (MPR)
- · Oblique
- · Orthogonal
- · Curved MPR

- 9. Pre-configured Protocols
- 10. 3D surface rendering software
- 11. Software for CNS imaging with surface coils to scan from head to sacrum. It should be possible to have imaging pasting/composing on the main console and workstation with the output image in DICOM format:
- 12 Software for peripheral angiography with surface coils from renal arteries to the lower limbs upto the feet
- 13. various image viewing parameter in the system
- 14. various image analysis parameters

X. SOFTWARE SEQUENCES BASIC:

- A
- 1. Spin Echo for 256x256 matrix: best TE and TR
- 2. Gradient echo for 256 x 256 matrix: best TE and TR
- 3. Inversion Recovery (at 256 x 256 matrix)

B FAST SEQUENCES:

- 1. Fast spin Echo(at 256 x 256 matrix)
- · Turbo Factor / Echo Train length minimum:
- · Resolution Matrix 512 x 512
- 2. Fast Gradient Echo(at 256 x 256 matrix)

C. ULTRAFAST SEQUENCES:

- 1. EPI
- · Type of EPI
- · Single Shot
- · Multi Shot
- · EPI Factor max.: 256
- · EPI Acquisition Matrix
- · 64 x 64:
- · 128 x 128 :
- · 256 x 256 :

D. These sequences should also include (but not restricted to)

- 1. Cardiac imaging
- 2. Abdominal imaging including MRCP and noncontras angiogram NATIVE & equivalent.
- 3. MR Spectroscopy

XI. Application Software:

A. MR Angio package

- · 2D TOF
- 3D TOF
- · MIP
- Multi slab
- Quantitative flow package 2D/3D steady state sequences for high resolution neuro imaging should be part of the main configuration. The real time FIESTA/Balanced FFE/true FISP should be standard. Non contrast angiography technique for renal and peripheral angio [Inhance, Native, trance etc].

B. Advance Angiography package

Phase contrast angio

- · 2D PC
- 3D PC
- · MTC
- · Contrast Enhanced Angio:

The system should be quoted with time resolved technique for peripheral vessels, aorta, thorax etc

The system should be quoted with 3D volume acquisition sequences/ packages for high resolution liver imaging and also steady state sequences for abdomen imaging should be quoted as standard

The system should have as standard software/technique based on the propeller techniques for motion correction for involuntary head movement of the patient

C. MR cardiac package

ECG Triggered Heart imaging

- · Advanced cardiac applications: Morphology/ wall motion: 2D/3D IR prepared sequences for myocardial evaluation: Cardiac function including EF, ED/ES volume cardiac output, wall thickening and wall thickness;
- 2D/3D steady state sequences for high resolution morphology, real time spiral imaging techniques for coronary artery imaging free breathing sequences/navigators; interactive real time sequences for on the fly change in parameters; all these cardiac related application should be quoted as standard of the main console/workstation

D. MR diffusion weighted and diffusion tensor imaging with maximum b value of 7,000s/mm2with automatic calculation of tensor trace images and ADC maps .The system should be available to perform multi direction diffusion weighted imaging and diffusion tensor imaging and the same should be possible on the main console and workstation. It should be for neuro, muscular and cardiac applications

E. 3D MRCP

- F. Functional imaging brain with EPI bold with color coding and on line calculation of Z score on the main console/workstation: optional. Also give the details about the hardware
- H. Spectroscopy the system should have the hydrogen, single voxel spectroscopy, multivoxel, multislice 2D, 3D spectroscopy, PRESS,STEAM and also the chemical shift imaging in 2d/3d. The complete processing/post-processing software including color metabolite maps should be available on the main console and it should be quoted as standard. The advanced spectroscopy post processing software should allow to process Display, manipulate, analyze and print the spectroscopy data on the main console/workstation. It should be possible to have prostrate spectroscopy in conjunction with the surface coil include any other interface, or hardware and software required for this application
- I. Fat and water excitation please the application package
- J. Single and Multi shot EPI imaging techniques.
- K. Please the motion correction algorithm/package for high-resolution motion free Diffusion weighed imaging with multishot/ segmented EPI techniques. It should be possible to have FLAIR diffusion with generation of corresponding ADC maps.
- L. Perfusion Imaging to enable large anatomy coverage of the brain and in line calculation of the resulting hemodynamic as well as physiological parameters. The perfusion analysis should have capability to calculate color display of rMTT, rCBV, rCBF, corrected CBV, permeability constant and volume leakage.

- M. BOLD(Blood Oxygen Level-Dependent) imaging: BOLD .technique with automated 3D motion correction, z- score, correlation analysis with color overlay on anatomical images. It should be possible to have Real Time Processing of BOLD imaging data on the main console for the complete reconstruction.
- N. The system should have facility for quantification of the CSF flow data on the main console and / or the workstation.
- O. The system should have the Hydrogen, Single Voxel spectroscopy, Multivoxel, multislice 2D, 3D Spectroscopy and also the Chemical shift imaging in 2D/3D. The complete processing / post processing software including color metabolite maps should be available.
- P.The system should have facility to do Head to Toe imaging without shifting the patient at one go for metastases study and without any loss of SNR.
- Q. It should be possible to have the prostate spectroscopy in conjunction with the endorectal Coils.
- R.The system should perform DTI (Diffusion tensor imaging) at least in 21 directions with possibility of processing with depiction of fractional anisotropy, mean diffusivity and other DTI metrics. Provide the fiber tracking software with overlays on various conventional images.
- S. The system quoted should have the software for Whole Body Diffusion weighted imaging.

XII . ARTIFACT REDUCTION TECHNIQUES: - details.

XIII. FAT AND FLUID SUPPRESSION TECHNIQUES: Fat suppressed technique to get fat, water, in Phase out of Phase contrast in a single acquisition essential (Dixon, ideal 3 D Dual Echo)

XIV.DOCUMENTATION:

- 1. DVD with covers-- 100 Nos
- 2. Dry view laser Imager with:
- Resolution: 14 bits/600 DPI or more
- With minimum three port
- DICOM Compatible

XV. A/C AIR CONDITION SYSTEM:

15° C to 24° C Maintenance around the Clock

Installation of Temperature & humidity meter with humidifier

Document: Capital Medical Device Technical Specification

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XVI. POWER REQUIREMENT:

Power input to be 220-240VAC, 50Hz / 3 Phase of appropriate rating

Resettable over current breaker shall be fitted for protection

Environmental factors:

• The unit shall be capable of operating continuously in ambient temperature of 30 deg C and relative humidity of 80%

XVII. TERMS OF INSTALLATION:

The firm shall be responsible for site evaluation and complete installation, full technical cooperation for alteration of existing building Complex etc., if needed.

Accessories

New stereotaxy frame – Leksell microsteroractic system or equivalent complete set for biopsy with all accessories; should include 2 biopsy needles, 2.1 and 2.5 mm diameter; one set of screws of all sizes, – one number

MR compatible anesthesia machine

General feature

Anestheia Machine of closed breathing circuit configuration

Suitable for Adult and pediatric

Anesthesia gas delivery system

Equipped with anesthesia vaporizer, (Sevoflorine & Isoflorine), Anesthesia ventilator

Should have independent attachments for connecting central gas supply and pin indexed cylinders Should have provision for attaching $\frac{1}{2}$ cylinders of (O2 and N2O)

Monitoring system to monitor Anesthetic gases, ECG, Respiration, Pulse Ox meter, NIBP & Temperature.

Should have audio-visual oxygen Failure warning system with nitrous oxide cut off.

Trolley with upper shelf and medical utility rail

can support two 10 L an aesthetic gas bottles (O2-N20)

Flow meter

The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters

For O2: 0.1-10 L/min

For N2O: about 0.1-10 L/min

For Air : 0.1-10 L/min

Color coding

Each connection valves ,gauge, and flow meter is labeled and color-coded for the appropriate gas type

Gas supply pressure

350-500kpa (common to O2:N2O,Air)

Vaporizer

Sevoflorine & Isoflorine both calibrated. Temperature and back pressure compensated type with safety lock button

O2 flash valves

The O2 flash button can be easily pushed for O2 to the patient, flow volume approx. 45-70 l/min

Safety & warning flowing device

Should have automatic cut-off valve with audible alarm when O2 pressure drops and failure below standard

Pop- off

Should prevent over-pressure with surplus gas evacuation adapter and gas open ,close ,semi close circuit selector knob

Features

A flow meter with incorporating safety mechanism

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/ with separable structure to manipulate according to the condition of surgical operation

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Complete patient monitoring capabilities :respiratory gas

Fully autoclavable and latex-free superior ventilation options

Easily adjustable and replaceable flow meter glass tube

Monitor Should provide facility

Monitoring system to monitor Anesthetic gases, ECG, EtCO2, Pulse Oximeter and airway pressure, NIBP, IBP, rectal/&skin temperature and BIS (to measure the effects of anesthetics and sedatives on the state of brain) should be present pressure transducers and necessary accessories as per requirement.

Oxygen and Nitrous oxide anesthetic agent in the inspired mixture

Oxygen situation of the blood with both adult & pediatric probes & sensors

Airway pressure monitoring should be present

Temperature monitoring with 2 probes for rectal and skin

Mounting

Mobile stand mount for the unit

Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes Individual locking front castor Brake

Color Coded Cylinder Yoke

Yokes with sliding clamping bars for easily handling .Extendable rear platform for two cylinder

Accessories

With All other complete standard accessories

Should be supplied with necessary attachments for use of the breathing circuits

Alarm system features

Low O2 concentration alarm sound with indicator light

When O2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

Ventilator

- Modes: Automatic Volumetric and Manual
- Electrically powered compressor, minute volume: 2 to 25 L/min
- Tidal volume: 20 1500 ml
- Respiratory rate: 5 to 70 cycles/min
- I/E ratio: 2/1 to 1/4
- Inspiration pressure: approx. 10 to 65 mbar
- Peak inspiratory flow: 0 to 60 L/min
- Trigger sensitivity: 1 to 10 mbar
- Front panel shows status, errors and sensors failure (low/high pressure, power failure)
- Audio-visual alert on low/high pressure, apnea, power failure
- Display of operational status, with set and measured values

- Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures
- Self diagnosis with each start-up and integrity testing of all system parameters
- With adjustable patient-circuit support arm
- Built-in rechargeable battery, autonomy approx. 45 hrs
- Automatic switch to battery in case of power failure, automatic recharge when connected to mains
- Power requirements: 220 V $\pm 10\%$, 50 Hz and rechargeable battery

Supplied with:

- 2 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)
- 2 x Adult reusable breathing circuits (tubes / balloons / valves / masks)
- 2 x Spare parts/maintenance kit (air filters, tubing, O-rings)
- 2 x Set of spare fuses

MR compatible Multipara monitor (Non Invasive Monitor) with slave monitor in console room

- 1. ECG /Resp: 10 lead ECG cable with clip 2 set per monitor.
- 2. NBP: Adult cuff -2nos per monitor and two sizes of Pediatric Cuffs one per monitor. (Complete sets)
- 3. SpO2: Adult SpO2 sensor with cable two nos per monitor and Pediatric SpO2 Sensors one no per monitor.
- 4. IBP: Include four nos per monitor of reusable pressure transducer with bracket, holder and 100nos disposable domes per monitor.
- 5. Temperature: Central temperature Probe two per monitor and Skin temperature probe one no per monitor
- 6. Airway pressure monitoring should be present

MR Compatible Pressure Injector:

Must have Independent dual Syringe powerhead.

Flow rate: 0.1-10 ml/sec

Volume: 1 ml to syringe capacity

Programmable pressure limit of 325 psi with 200 ml disposable sterile syringe

With minimum of 30 protocols

Syringe heater range 35 deg C+/- 5 deg C.

Should be provided with head mounting device and integral IV pole.

Should be supplied with at least 2000 Syringes and 2000 power injector extension cable.

Unit will be provided with display monitor to provide Pressure Monitor graph, Flow Profile, Stop Watch Feature, Scan Display, multiphase capability and protocol locking capabilities.

MR compatible oxygen cylinder (50 Liter) with oxygen regulator and humidifier

5. System Configuration Accessories, Spares, Consumables and other components:

Main unit

Main Console with 02 monitor

Additional Console (post processing workstation) with 02 monitors

DVD/CD Archieving - 02 (1 ea on all the consoles)

Patient Table

Dry view imager

Non invasive monitor

Laser color printer

Anesthesia machine

Dual head pressure injector (with 2000 syringes)

UPS with servo controlled stabilizer of one hour back up

Oxygen cylinder, 50 L---02

Hand metal detector

Stationary metal detector

Leksell stereotaxy frame with biopsy kit

RF shielding

Air conditioners (AC) with chiller

Non-magnetic dockable trolley

PACS with 06 monitors for six concurrent users with undefined end user license

DVD burning station

Standard Patient positioning acc and restraining devices--02 sets

View Boxes – slim, four in one with fluorescent tubes with shutters and variable luminescence--- 02

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, film, etc..)

All standard accessories, parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirement:

Power input 380 +/- 10% VAC/50Hz

Resettable over current breaker shall be fitted for protection

UPS with servo controlled stabilizer of one hour back up capacity to handle complete MRI, Laser imager, work stations, color printer, anaesthesia delivery system, monitor and defibrillators.

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Mangemnt system (Or Equivalent)

9. Installation, Training and Commissioning:

- 1. The supplier must provide installation, training and commissioning of the device at health Facility
- 2. Application specialist visit at least for six weeks to orient resident technicians / Radiologists
- 3. Train one Radiology Technologist and one maintenance Engineer at the manufacturing site for three weeks (for each MRI equipment)
- 4. Train two Radiologist and two Biomedical Engineer for three weeks at a suitable centre in Ethiopia (for each MRI equipment).
- 5. Date of Commencement of warranty: After Installation, demonstration & proper functioning of equipment and handing over of the installed equipment in the specified site.

Turn key Works

PREMISES:

The interiors of the rooms (Equipment room, Console room, Patient Waiting room, Change room and Reception.) in all respects for successful installation and commissioning of the equipment to the satisfaction of the Purchaser/user department. This shall include everything required for successful commissioning but not limited to the following:

- i. **Civil Works**: Necessary Civil works like Platform, Pedestals, etc., if any, required shall be provided.
- ii. **RF shielding**: a). Radio frequency shielding protection for console and Gantry room to be provided.
- b). R.F. Shielding of room with built in medical Gas Pipe line for patient resuscitation
- c). All necessary shielding should be provided such that the filed strength/RF outside the scanning room is within

acceptable limit and have no effect on nearby equipment.

- iii. **Flooring**: Shall provide and lay Anti-static flooring of 2 mm thick, manufactured by reputed standard manufacturers. Colour as per Standard requirement.
- iv. **False Ceiling**: Shall provide and fix false ceiling of Luxalon make with necessary fixing arrangements as per manufacturers specifications. Colour as per Standard requirement.
- v. **Walls**: Walls upto ceiling shall be provided with vitrified tiles 60cm x 60cm. Colour as per Standard requirement.
- vi. **Electrical**: From the main supply point of the hospital panel board, the supplier shall supply and install the main incoming switch fuse unit, three phase electrical cable, electrical Wiring systems for light and other Electrical fittings, separate power distribution boards and lay distribution lines required for all items installed with the MRI, Console room, Patient waiting room, Change room, etc.
- vii. Plumbing: Required Plumbing work shall be provided.
- viii. **Furniture**: chair, Table, for changing room, console, radiologist's room etc.

ix. Air Conditioners

The supplier shall install AC in Gantry room, UPS room and any other adjacent rooms in order to centrally air conditioned the whole area. The temperature of the gantry room to be maintained at 20 deg C.

10. Warranty and After Sale service:

- 1. A well Experienced service and maintenance Engineer should be provided to attend the equipment with preventive schedule maintenance (Provided by the Local Agent)
- 2. Free comprehensive warranty for one years (including Labor, spare parts, accessories and liquid helium) starting from the date of commissioning.

- 3. The Cost of the extended warranty (Comprehensive Maintenance Contract) from 2nd year to 10th year inclusive of labor, spare parts, accessories and liquid helium should be separately quoted. The CMC should cover all Bidder items and local accessories.
- 4. Up time Guarantee: Minimum 95%
- 5. Upgradability: All software/system upgrade for the entire system on the existing applications must be provided whenever needs by the system free of charge throughout the basic warranty and extended warranty period. This will include any hardware or parts if the software added needs them to enhance the existing capabilities.
- 6. The machine must be fresh product

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

General Hospital Capital Medical Equipment Technical Specification

Base Code	Item Description	Department
Ctsc-90	1. Generic Name: CT Scan Machine - 64 Slice	Imaging
	2. GMDN/UMDN Name:	

Document: Capital Medical Device Technical Specification

Version 1: November, 2019 G.C.

3. Clinical Purpose/Description:

CT (computed tomography), uses special x-ray equipment to obtain image data from different angles around the body and then uses computer processing of the information to show a cross-section of body tissues and organ.

Operational requirements

Multi-Slice (64 Slices) Spiral CT Scanner for High Resolution Whole Body Scanning including Cardiac, Vascular, implants or complicated fracture application. The equipment should be capable of acquiring 64 or more slices per 360 rotation. The system should be capable of doing ultra low dose imaging using model based iterative reconstruction technique.

4. Technical Specifications

Manufacturer

Brand

Model

COUNTRY OF Origin

Gantry

- i) Aperture diameter of 70 cm or more
- ii) Control Panel: Should have control panel on either side for easy positioning
- iii) Positioning Lights: should have 3D laser lights for positioning.
- iv) FOV(Field of View): should have FOV of at least 50 cms or more.
- v) Tilt:- Remote tilt of +/- 30 Degrees or more from console.

X-ray Generator

Manufacturer

Brand

Model

COUNTRY OF Origin

- i)The Generator should be of high frequency type and having adequate output to facilitate spirals of at least 100 sec duration.
- ii)The system X-ray power should be 70kw and above.
- iii)The mA range available should be between 20 to 600 mA with increments in steps of not more than 5 mA.

KV range: 80-140 KV or more

X-Ray Tube

Manufacturer

Brand

Model

Country Of Origin

- 1 Tube current: 20-600mA
- 2 Real Time mA modulation for dose regulation..
- 3 Tube Voltage:80-140 Kv or more.
- 4. Dual focus with Anode Heat Storage Capacity of at least 7MHU
- 5. Anode Temp Monitoring System.
- 6. Heat Dissipation rate: >/= 700KHU/minute
- 7. Filter and beam limiting devices:
- 8. Focal Spot size and number should specify.
- 9. X-ray tube should be Liquid cooled bearing assembly tube

Detectors

Manufacturer

Brand

Model

Country Of Origin

The data acquisition system in spiral and sequence mode should have 64 or more rows of detector electronic channels that can acquire 64 slices for complete 360 degree rotation.

Detector should be Solid state (or better) of latest technology with latest scintillator material free from repeated calibration

The system should have collimation for 64 slices against the thinnest possible slice of the system $64 \times 0.625 \text{mm}$

☐ Slice thickness: 2mm to 6mm

Area of Coverage

High Resolution (0.625 mm or better) coverage along Z axis. should be 38 mm or more per rotation.

Patient table

- 1. Minimum load bearing capacity of at least 200kg with 1 mm positioning accuracy.
- 2. Table speed Horizontal: =>100 mm/sec.
- 3 Vertical Table travel: 40 cm
- 4 Longitudinal Scan Range: 100-1800mm or better
- 5 Facility of positioning aid for horizontal Iso centric positioning of the patient..
- 6. Carbon Fibre Table Top.

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7. Minimum table top height should not be more than 55 cms from the floor level for easy transportation

Helical Application/Acquisition:

i)Scan length of at least 100 cm. in a single gapless Spiral/Helical Scan with a free pitch selection. Types of helicals should be mentioned.

ii)Facility to monitor contrast enhancement & automatically initiate scanning.

iii)Acquisition of Cardiac images with ECG Gating (Prospective & Retrospective Gating) the temporal resolution achieved using 1, 2 or 4 sections of consecutive cardiac cycle to reconstruct each axial image.

iv)Real time X-ray dose reduction which combines both Z axis and angular tube current modulation to adjust the dose to the size and shape of individual. It should be possible to modulate the mA with ECG signals.

V) The Reconstruction Time in Spiral scan should not be less than 15 Images / Sec

Vi) Scan Time

Complete 360 scan should be performed at 0.40 Sec. or less.

Image Resolution

high Contrast: 24 LP/cm or better for complete FOV. (the phantom used, scan time, mA, scan field, dose, slice and MTF).

Main Console:

a) It should have intel core i7 latest version with configuration of minimum 32 GB RAM and 2TG HDD or more

The System shall have all functions menu driven.

All applications like scanning, image reconstruction, filming, MPR, CT Angiography, maximum intensity projection MIP, 3D Volume rendering Technique, Virtual Endoscopy package should be possible from the console.

The image reconstruction time should be 15 images/second or more in 512 x 512 matrix.

b)There should be facility to read and write CD on main console.

Post Processing Workstation

Workstation with intel multi core latest version, 3.6 GHz processor with configuration of minimum 32 GB RAM and 700GB HDD. Satellite console should have all the features as of main console (swappable). Image Evaluation Software and following post Processing facility.

- i) Calcium scoring, cardiac LV, RV analysis, cardiac scoring & reporting, CT coronary analysis software, cardiac comprehensive report.
- ii) Software for brain perfusion and abdominal tumour perfusion studies.
- iii) Complete virtual endoscopy package.
- iv) Software for stenosis analysis.
- v) Software for Dental Planning.
- vi) Facility for direct 3D image formatting in any plane during acquisition as planned on scout images.
- vii) Osteo software or equivalent softwares for complete library of analysis templates for most Bone research
- viii) The system should consists of real time CT fluoroscopy with at least 6 to 8 frames per second with dedicated 21 inch color LCD monitor and standard accessories.

MONITORS: (for both consoles)

1 Resolution: 1280 x 1024 pixels

2. Pixel Size: <0.3 mm

- 3. Flat screen LCD Type of medical grade monitor at least 21" with fast image refresh rate should be fast and preferably instantaneous and flicker free .
- 4. Should be non interlaced and progressive display type & sturdy.

Consoles Common Feature:

- 1 The two sets of workstation should be interconnected by ISDN Lines or other communication standard (to be provided by the vendor) for two way transfer of images and reports.
- 2. Spatial alignment and visualization of two different data sets of one patient generated on different modalities or with different acquisition time..
- 3 Post Processing Software: Perfusion CT, VRT, MIP, SSD, Image Fusion, Vessel segmentation, Virtual Endoscopy software to be provided on both the workstation.
- 4. Cine display should be available ,both interactive and automatic ,and should have a minimum image refresh rates of $8-10/\sec$.

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- 5. Window width and centre should be freely selectable.
- 6. Patient Registration , pre registration facility and transfer of information via DICOM should be possible.

Post processing tools

- 1. 2-D post processing: image zoom and pan; image manipulations including averaging, reversal of grey-scale values, subtraction and mirroring; image filter functions including advanced smoothing algorithm and advanced bone correction.
- 2. Real-time multi-planar reconstruction (MPR) of secondary views, with viewing perspectives in all planes including curved & orthogonal MPR.
- 3.CT angiography, MIP, MinlP, SSD, VRT and other advanced 3D applications and colour coding for different tissues..
- 4 Spatial alignment and visualisation of two different data sets of one patient generated on . different modalities or with different acquisition times.
- 5. Perfusion CT for study of brain. Liver, kidney, pancreas etc.
- 6. Volume measurements.
- 7. Fusion of morphological data obtained on CT, MR

Image Evaluation Tools:

- 1 Parallel evaluation of multiple ROI in circle, irregular and polygonal forms.
- 2. Statistical Evaluation for area/ volume, S.D, Mean value, Min/Max. value and Histograms.
- 3. Advanced cardiac packages with ECG gating for cardiac and vascular evaluation in trauma patients..
- 4. Profile cuts: horizontal, vertical and oblique views.
- 5. Distance & angle measurement, freely selectable positioning of coordinate system, grid and image annotation and labelling.
- 6. Dynamic evaluation of contrast enhancement in organs and tissues, calculation of timedensity curves, peak enhancement images and time-to-peak images.

Image Transfer, archieving & Networking

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined enduser lisence PACS (Picture Archieving and Communication System).

This system should be able to provide on-line accessibility of processed image data in six OT's, ICU, CCU, and radiology conference room at trauma centre etc.

The server hardware should consist of intel core i7 latest version, 32GB RAM, 5000GB HDD, DVD, CD RIW, 28" or more fiat monitor.

Each viewing terminal should have a PC with intel core i7 32GB RAM, 500 GB HDD, CD/DVD, combo drive, 24"or more flat monitor.

Patient communication system:

An integrated intercom and Automated Patient Instruction System (API) or other patient communication system should be provided

CONNECTIVITY AND ARCHIVAL

- 1 DICOM connectivity should be optimized for networking with other imaging systems.
- 2.DICOM converters for linking the camera with other imaging systems of the department/section should be provided, if required separately. It should have sufficient memory to store images from the CT as well as other system connected to it.
- 3. Filming parallel to other activities, including independent scanning, documentation and post-processing and configurable image text..
- 4. **Archiving:** DVD/CD writer should be provided for archival.

Option of viewing these discs on any PC without DICOM viewer should be available.

CT Scan Compatible Non Invasive Monitor

- 1. Portable and Light weight preferably <10kg
- 2. Modular with 15 inch multi colour TFT display
- 3. Monitoring parameters; ECG, respiration, NIBP, SpO2 and temperature
- 4. Digital and 6 waves / traces display
- 5. Trends up to 24 hours
- 6. 60 minutes or more battery back up
- 7. Convenient handle for carrying the same
- 8. Able to fix with bed/trolley

CT Scan Compatible Monitor Defibrillator with recorder

- 1. Biphasic, with auto and manual mode. Manual selection upto approx. $300\,\mathrm{J}$
- 2. Should be mains and battery operated, with charging indicator.
- 3. Should be able to deliver 30 shocks with fully charged battery.

- 4. Should have true 1-2-3 Color-coded operations.
- 5.to have inbuilt Internal Thermal Recorder.
- 6.Should have Automatic lead switching to see patient ECG through paddles or leads. Should measure chest impedance and should be able to compensate.
- 7. Should be provided with Adult and Pediatric external paddles.
- 8. Should have both Synchronous and Asynchronous mode.
- 9. The charging time to highest energy level should be \leq 9 seconds.
- 10.Should have external pacemaker facility.

CT Scan Compatible State of the art general anaesthesia induction system with the following

General feature

Anestheia Machine of closed breathing circuit configuration

Suitable for Adult and pediatric

Anesthesia gas delivery system

Equipped with anesthesia vaporizer, (Sevoflorine & Isoflorine), Anesthesia ventilator

Should have independent attachments for connecting central gas supply and pin indexed cylinders Should have provision for attaching ½ cylinders of (O2 and N2O)

Monitoring system to monitor Anesthetic gases, ECG, Respiration, Pulse Ox meter, NIBP & Temperature.

Should have audio-visual oxygen Failure warning system with nitrous oxide cut off.

Trolley with upper shelf and medical utility rail

can support two 10 L an aesthetic gas bottles (O2-N20)

Flow meter

The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters

For O2: 0.1-10 L/min

For N2O: about 0.1-10 L/min

For Air : 0.1-10 L/min

Color coding

Each connection valves ,gauge, and flow meter is labeled and color-coded for the appropriate gas type

Gas supply pressure

350-500kpa (common to O2:N2O,Air)

<u>Vaporizer</u>

Sevoflorine & Isoflorine both calibrated. Temperature and back pressure compensated type with safety lock button

O2 flash valves

The O2 flash button can be easily pushed for O2 to the patient, flow volume approx. 45-70 l/min

Safety & warning flowing device

Should have automatic cut-off valve with audible alarm when O2 pressure drops and failure below standard

Pop- off

Should prevent over-pressure with surplus gas evacuation adapter and gas open ,close ,semi close circuit selector knob

Features

A flow meter with incorporating safety mechanism

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/ with separable structure to manipulate according to the condition of surgical operation

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Complete patient monitoring capabilities :respiratory gas

Fully autoclavable and latex-free superior ventilation options

Easily adjustable and replaceable flow meter glass tube

Monitor Should provide facility

Monitoring system to monitor Anesthetic gases, ECG, EtCO2, Pulse Oximeter and airway pressure, NIBP, IBP, rectal/&skin temperature and BIS (to measure the effects of anesthetics and sedatives on the state of brain) should be present pressure transducers and necessary accessories as per requirement.

Oxygen and Nitrous oxide anesthetic agent in the inspired mixture

Oxygen situation of the blood with both adult & pediatric probes & sensors

Airway pressure monitoring should be present

Temperature monitoring with 2 probes for rectal and skin

Mounting

Mobile stand mount for the unit

Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes Individual locking front castor Brake

Color Coded Cylinder Yoke

Yokes with sliding clamping bars for easily handling .Extendable rear platform for two cylinder

Accessories

With All other complete standard accessories

Should be supplied with necessary attachments for use of the breathing circuits

Alarm system features

Low O2 concentration alarm sound with indicator light

When O2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system

A N2O safety device which automatically cut off the N2O flow when the O2 supply pressure drops

Ventilator

- Modes: Automatic Volumetric and Manual
- Electrically powered compressor, minute volume: 2 to 25 L/min
- Tidal volume: 20 1500 ml
- Respiratory rate: 5 to 70 cycles/min
- I/E ratio: 2/1 to 1/4
- Inspiration pressure: approx. 10 to 65 mbar
- Peak inspiratory flow: 0 to 60 L/min
- Trigger sensitivity: 1 to 10 mbar
- Front panel shows status, errors and sensors failure (low/high pressure, power failure)
- Audio-visual alert on low/high pressure, apnea, power failure
- Display of operational status, with set and measured values
- Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures
- Self diagnosis with each start-up and integrity testing of all system parameters
- With adjustable patient-circuit support arm
- Built-in rechargeable battery, autonomy approx. 45 hrs
- Automatic switch to battery in case of power failure, automatic recharge when connected to mains

- \bullet Power requirements: 220 V $\pm 10\%,\,50$ Hz and rechargeable battery
- Supplied with:
- 2 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)
- 2 x Adult reusable breathing circuits (tubes / balloons / valves / masks)
- 2 x Spare parts/maintenance kit (air filters, tubing, O-rings)
- 2 x Set of spare fuses

CT Scan compatible Pressure Injector with the following:

Must have Independent dual Syringe powerhead.

Flow rate: 0.1-10 ml/sec

Volume: 1 ml to syringe capacity

Programmable pressure limit of 325 psi with 200 ml disposable sterile syringe

Syringe 200 mL disposable sterile syringe with minimum of 30 protocols

Syringe heater range 35 deg C+/- 5 deg C.

Should be provided with head mounting device and integral IV pole.

Unit will be provided with display monitor to provide Pressure Monitor graph, Flow Profile, Stop Watch Feature, Scan Display, multiphase capability and protocol locking capabilities.

5. System Configuration Accessories, Spares, Consumables and other components:

Main Unit

Main Console with 02 monitor

Additional Console (post processing workstation) with 02 monitors

CT Fluoroscopy with 01 monitor

DVD/CD Archieving - 02 (1 ea on all the consoles)

Patient Table - 01

PACS with 06 monitors for six concurrent users with undefined end user license

DVD burning station

Air conditioners (AC)

Lead Glass window as per room requirement

Lead Door as per room requirement

Anesthesia Induction System with all accessories -01 set

Dual head Automatic Pressure Injector -01(with 2000 syringes and 2000 Extension cable)

Collapsible wheel chair with rubberized swivel wheels. -02

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Standard Patient positioning acc and restraining devices. -02 sets

Good quality Light weight Lead Aprons-10 No's

Gonadal shields – 2 No's

Thyroid shields -3 No's and Lead goggles -2 No's

View Boxes – slim, four in one with fluorescent tubes with shutters and variable luminescence-- 02

Laryngoscopes adult and Pediatric Sizes -- 01 Set

endotrachial tubes of adult and Pediatric Sizes -- 100 each

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, film, etc..)

All standard accessories, parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

Non Invasive Monitor with the following accessories - 01

- 1. ECG /Resp: 5 lead ECG cable with Clip -2 set per monitor. and 10 lead ECG cable with clip -1 set per monitor.
- 2. NIBP: Adult cuff -2nos per monitor and two sizes of Pediatric Cuffs one per monitor. (Complete sets)
- 3. SpO2: Adult SpO2 sensor with cable two nos per monitor and Pediatric SpO2 Sensors one no per monitor.
- 4.IBP: Include four no's per monitor of reusable pressure transducer with bracket, holder and 100nos disposable domes per monitor.
- 5.Temperature: Central temperature Probe two per monitor and Skin temperature probe one no per monitor

Defibrillator Monitor/ Recorder with the following accessories- 01

Adult and pediatric Reusable paddle-1 each

Disposable pads - 100 each

ECG Cable- 5 lead - 1 each

ECG Electrodes - 1000 each

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Uitility Requirement:

Power input 380VAC/50Hz

Resettable over current breaker shall be fitted for protection

UPS with servo controlled stabilizer of one hour back up of suitable capacity of handle complete CT scanner, Laser imager, work stations, color printer, anaesthesia delivery system ,monitor and defibrillators.

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Mangemnt system (Or Equivalent)

System should be DICOM READY

Fire fighting and Security System with inbuilt alarm, smoke detector system, to be connected to main hospital control system.

9. Installation, Training and Commissioning:

The supplier must provide installation, training and commissioning of the device at health Facility

The supplier must provide training two radiology Technologist and two Biomedical Engineer for three weeks at installed site (for each CT Scan equipment).

The supplier must provide application specialist visit at least for four weeks to orient resident technicians/radiologists.

The supplier must provide training for one radiology Technologist and one Biomedical Engineer at the manufacturing site (for each CT Scan equipment).

Turn key Works

(c) Premises:

The interiors of the rooms (Equipment room, Console room, Patient Waiting room, Change room and Reception) in all respects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

- i. Civil Works: Necessary Civil works like Platform, Pedestals, etc., if any, required shall be provided.
- ii. X ray radiation shielding: Proper lead protection lead window as well as lead door for console, patient change room and Gantry room should be provided.
- a) lead thickness b) door frame c) Should be washable, laminate finish with color in harmony with building lead sandwich

iii. Electrical: From the main supply point of the hospital panel board, the supplier shall supply and install the main incoming switch fuse unit, three phase electrical cable, electrical Wiring systems for light and other Electrical fittings, separate power distribution boards and lay distribution lines required for all items installed with the CT, Console room, Patient waiting room, Change room, etc.

- iv. **Plumbing**: Required Plumbing work shall be provided and completed by the Bidder.
- v. Furniture: chair, Table, for changing room, console, radiologist's room etc.

vi. Air Conditioners

The supplier shall install AC in Gantry room, UPS room and any other adjacent rooms in order to centrally air conditioned the whole area. The temperature of the gantry room to be maintained at 20 deg C.

10. Warranty and After Sale service:

- 1. The supplier must be provide minimum of one years warranty for CT scanner system including Labor, X-ray tube and all parts and accessories starting from the date of commissioning.
- 2. The Cost of the extended warranty (Comprehensive Maintenance Contract) from 2nd year to 10th year inclusive of labor, spares and X Ray tube should be separately quoted. The CMC should cover all Bidder items and local accessories.
- 3. All software/system upgrade for the entire system on the existing applications must be provided whenever needs by the system free of charge throughout the basic warranty and extended warranty period. This will include any hardware or parts if the software added needs them to enhance the existing capabilities .
- 4. Up time Guarantee: Minimum 95%
- 5. A well Experienced service and maintenance Engineer (certified by the manufacturer) should be provided to attend the equipment with preventive schedule maintenance (Provided by the Local Agent)
- 6. The machine must be fresh product

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Diam-90	1. Generic Name: Dialysis Machine	Dialysis Unit
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description:	
	A process of purifying the blood of a person whose kidneys are not working normally. Achieves removal of waste products such as potassium, urea and free water from the blood when the kidneys are in a state of kidney failure.	
	4. Technical Specification:	
	Touch screen/button control with digital display	
	Should have inbuilt battery for 30 min	•
	Facility to show trends curve of all parameter	
	Automatic self test facility	
	Extracorporeal circuit	1
	Arterial pressure range: -280 mmHg to + 400 mmHg or wider range, Accuracy: ±10mmHg	
	Venous pressure range: 60 mmHg to + 380 mmHg or wider range, Accuracy: ±10mmHg	
	Trans membrane pressure: -60mmHg to +400 mmHg or wider range, Accuracy: ±10 mmHg	
	Blood pump: Peristaltic pump	
	Blood flow range: 50 to 500 ml/min in 8mm size tube, Accuracy: ±10%	
	Air bubble detector: Ultrasound method, monitor the entire operating phase	
	Alarm Indicator: Traffic light to indicate the status such as bypass, air leak, blood leak, dialysis temperature, etc	
	Dialysis Fluid system	
	Dialysis fluid flow range: 300 - 800ml/min, selectable	
	Dialysis fluid temperature: 35°C to 39°C, Accuracy: ±0.2%	
	Blood leak detector: Optical detector, color specific	
	Ultra filtration rate: 0 to 4.00 L / hr (higher range is acceptable), Accuracy: \pm 3%	
	Dialysis fluid filter system: Endotoxin filter	
	Disinfection and Cleaning program: Rinse, Hot cleaning and Hot disinfection cycles are required.	
	Use recommended chemicals at a temperature of min 84°C.	
	Blood pressure monitor facility	
	Supplied with endotoxin filter	
	Indicating Real time Kt/V measurement	
	System shall have Heparin Module	
	Dialysis chair	
	Multi positioning electro hydraulic operation with stable base	

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Chair height adjustment

Chair back fully reclines to the horizontal position

Chair foot area rises to the Trendelenburg position

Hand held control unit for easy adjustment of chair/recliner two large adjustable arm rests

Large stable vein puncture platform also promotes patient comfort

Cleanable and sanitized

Stainless steel frame

Premium medical grade treated vinyl upholstery

Replaceable clear protective cover foot areas

Securely balanced in all operational position

Both side armrest extension

Arm set fold to allow side entry of the patient

Arm extensions must provide visibility of elbow region, be large enough to securely support when puncture be refracted in case of patient collapse.

Minimal bending for vein puncture

Rapid and Easy adjustment from sitting to relining supine and Trendelenburg position

Easy repositioning and lock to secure safety in operation

Provision for railing

Carrying capacity: 180kg

Seat dimension: 200 x 60 x 60-90 cm (L x W x H)

Trendelenburg position: 12⁰

CPR support

Headrest

Cushioned seat

Cushioned arm rest

Reclined base to floor

Leg support

Water Treatment system

Designed for maximum saving of raw water, with high efficiency

Raw water storage tank that can support 15 dialysis machines

At least 20 x 60 inch Multimedia Filters with automatic control head

At least 20 x 60 inch Water softener, single or duplex with automatic head

Product storage tank that can support 15 dialysis machines

At least 20 x 60 inch Carbon filters with automatic control head

Complete pressure reading, flow, temperature monitoring

Visual and Audible alarms: Conductivity, water quality

Visual and Audible displays of operations status at location and at Nurse Station

Ultraviolet Disinfection

All pretreatment modules programmable backwash and regeneration facility

Compact in sleek cabinet, housing membrane, and high pump and bypass mechanism.

Reverse Osmosis

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Page 333 ISBN No: Double pass or double stage

Produce water 2 times higher than required

Film tech Membranes with housing

With Multi stage vertical pump with back up Distribution system

Stainless Head Pump with back up pump

Motorized ball valve for automatic recirculation system

Made of high medical grade material

Primary loop with minimal number of joints

Disinfection of membrane and distribution loop

Heat resistant for hot disinfection

Smooth interior

Drain piping with air gap

Fully automated control system

Automatic activation of backup system

Output water quality match AAMI (Association for Advancement of Medical Instrumentation) standards for hemodialysis

5. System Configuration Accessories, Spares and Consumables

Venous blood Clamp

Blood tubing compatible for the machines

Dialyzer poly sulphone steam/gamma ray sterilized different sizes

Fistula needle different sizes

Acid concentrate

Bicarbonate cartridge /powder/

Hemodialysis catheter temporary and permanent different size

Semi-automatic renal biopsy needle

Plasma filter gamma ray sterilized

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning should be included.

6. Operating Environment;

Operating Temperature: +10°C to +40°C

Relative Humidity: <85%

7. Utility Requirements:

Power Supply: 110-220VAC, Frequency: 50/60Hz

Electromagnetic compatibility: EN 60601-1-2: (IEC 601-1-2)

UPS with stabilizer for 1hr backup

Inlet water pressure: 1.5 - 6 bar max

Water temperature range: 5°C to 30°C

Concentrate supplies: Canister / Cartridge / Bags

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation/Training/Commissioning:

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Page 334 ISBN No: The supplier must provide Installation, technical and end user training on site.

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
		_
Xfcd-90	1. Generic Name: C-arm fluoroscopy x-ray machine, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	It used for cardiac, orthopedics, vascular, trauma, spine and general surgery	
	procedures.	
	4. Technical Specification:	
	Fully counterbalanced C-arm with compact flat detector.	
	Integrated operator control panel with 12" color LCD/TFT monitor for	
	positioning the system.	
	Hand switch and/or foot switch control.	
	Radiation indicator.	
	system lock for x-ray control	
	C-arm mobile stand	
	Orbital movement:125° (-35° to +90°)	
	Angulations: ±190°	
	Horizontal movement: 20 cm (7.9") or more	
	Swivel range: ±12°	
	Vertical Travel: 40 cm (15.7") or more	
	Source to Image Distance (SID): 86 cm (33.8")	
	Immersion depth: 63.5 cm (25")	
	Lateral movement: steering wheel	
	Integrated laser for radiation free positioning of C-arm	
	X-ray generator	
	High-frequency generator with power output 15kW or more	
	kV range: 40 kV to 120 KVp, with KVp accuracy of $\pm 10\%$	
	mA range: 5mA to 100mA	
	Automatic Exposure Control (AEC)	
	Radiography parameters	
	kV range: 40 kV to 120 kVp	
	mA: 5 mA to 100 mA	
	mAs: max. 300 per exposure	
	Exposure Time: For patient exposure; ≤1s and for tube capacity; up to 5 s	
	Fluoroscopy Parameters	
	Continues fluoroscopy mode	
	kV range: 40 kV to 120 kVp	
	mA range: up to 12mA	
	Pulsed fluoroscopy mode	

Document: Capital Medical Device Technical Specification

kV range: 40 kV to 120 kVp

mA range: up to 30mA

Continues with road map and Pulsed with real time subtraction facility for Digital Subtraction Angiography (DSA) should be provided as standard

X-ray tube

Dual focus rotating anode

Small focus: 0.3mm

Large focus: 0.6mm

Tube voltage: 40-120Kvp

Anode heat capacity: 300KHU Anode cooling rate: 60KHU/min.

Flat Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector size: 26 cm x 26 cm or more.

Pixel size: 155 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero Line pairs or more.

at least three user selectable input fields

Integrated laser localizer

Active matrix size: 1.5k x 1.5k or more.

5.2 Mobile View Work Station

Compact and light weight design with mobile castors for easy maneuverability

Monitors height should be adjust for the convenient of surgeons position: up to $20\ \mathrm{cm}$

Monitors rotate 170° for optimized viewing angle in horizontal and vertical direction

An injection trigger for contrast media

Connectivity:

Digital video output: 2 DVI connectors enables image display on external monitors

Video input: displays external video signals like ultrasound images on the right monitor.

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.

Storage of 30,000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

Document: Capital Medical Device Technical Specification

Version 1: November, 2019 G.C.

Page 337 ISBN No:

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

Monitor:

Two 19" high brightness LCD/TFT color monitors for live image display, Last Image Hold and stored memory display.

Resolution: 1280 x 1024 pixels

Touch screen system control and with external keyboard should be supplied

Anti-glare

Image acquisition and image processing

The digital workstation should be based on the latest high speed processors of at least 64 bit.

Patient data management; Electronic record with name, date, anatomy, etc.

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold Video invert

Annotation (text, trace ,arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc..

5. System Configuration Accessories, Spares, Consumables and other components:

C-arm Fluoroscopy unit with x-ray generator, x-ray tube ----1

Flat panel detector---1

Mobile view workstation with two monitors---1

All software packages for cardiac, trauma, vascular, orthopedics, spine, general and other procedures should be provided as standard

A CD-R/W based long term archiving with envelope----1000

External key board----1

UPS for mobile view workstation and C-arm----1

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid guard--3

Gonad shield with small, medium, large size---2 of each

Eye Goggle---3

Lead Glove—3 pair

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment,

Document: Capital Medical Device Technical Specification

including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media)

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Electrical Requirements of Safety ${\bf E}$

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

The machine should be fresh product

The machine should compliant with IAEA safety standards

9. Installation/Training/Commissioning

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty/ After sales service:

The supplier must be provided minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Departmen
Xrrd 90	1. Generic Name: X Ray - Radiography, Digital with fluoroscopy	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:]
	Digital Radiography Machine used for imaging of internal structures of the body	
	4. Technical Specifications:	
	A fully digital radiography system capable of detector exposure in vertical, horizontal and oblique positions to perform general radiography	
	Completely integrated (integrated Generator and Image Acquisition) and auto quality control features incorporated	
	Automatic brightness control (ABC) function	
	System must have a method of measuring and recording patient absorbed dose (Dose Area measurement system)	
	System should have Anatomical programming radiography (APR)	
	System should have over load protection feature	
	System should have switch on x ray indicator	
	Generator:	
	Generator should be of high frequency inverter technology for constant output and lowest radiation doses.	
	KV range: 40 – 150KVp, with KVp accuracy of ±10%	
	Protection level against electric shocks: type B	
	mA range: 10 to 1000 mA (with 16 values of high voltage current adjustment)	1
	Power: 65 - 85KW	
	mAS maximum: 600 per exposure	
	The X-ray exposure time (radiography time) should be automatically adjusted	
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	-
	System should have Automatic Exposure Control (AEC)	
	Digital Fluoroscopy:	
	Real-time optimization techniques to maintain constant brightness at the lowest allowable dose to the patient.	
	Continues with road map and Pulsed with real time subtraction facility for Digital Subtraction Angiography (DSA) should be provided as standard	
	Direct digital imaging system for fluoroscopy	
	Last image hold facility during fluoroscopy	
	The standard continuous fluoroscopic operating mode from single image display to serial exposures with varying frame rates up to 15 fps	
	Foot switch for fluoroscopy and acquisition. Having independent fluoro KVP and mA selector	-
		_

Continuous fluoroscopy mode

mA range: up to 12mA

kV range: 40 kV to 120 kVp

Pulsed fluoroscopy mode

kV range: 40 kV to 120 kVp

mA range: up to 30mA

X-Ray tube and collimator:

X ray tube should be floor mounted for fluoroscopy and ceiling mounted for radiography purpose

Floor mounted, with longitudinal movement not less than 140cm and lateral movement not less than 24cm

Tube rotation vertical and horizontal angle: 270° (+180°/-90°)

X-ray tube anode heat monitoring with thermal switch control

Multi leaf collimator having halogen/bright light source with auto shut provision for the light

High speed rotating anode compatible with the generator

Over loading protection feature

Dual focus rotating anode with spot sizes less than 1.3mm

Anode heat capacity: 300KHU or more

Auto-tracking with detectors and collision protection sensors

All movements electromagnetic brakes with fully counter balanced mechanism

Provision for auto positioning, auto synchronization and auto centering with vertical Bucky and table

Adjustable multi leaf collimation system with SID laser localizer

Automatic shut-off timer to preserve the collimator field lamp.

Has a rectangular light field with cross hair markings and lamp/timer feature

With cross hair centering and pre-indication of field sizes at certain source to image distance (SID)

Radiographic Table:

Integrated Bucky unit for flat panel detector

Grid ratio: 10/1

Film to Focal Distance (FFD): 100cm

Balanced at counter weight

Table movement: 4 ways with breaks

The table must have easy access from both sides (for patient transfer purposes and cross table imaging)

The table Bucky must include automatic exposure control

The table must have foot activated locks for hands free position

The table should be mounted on high quality fiber wheels with brakes

Horizontal table with carbon fiber table top of minimum 210cmx80cm

The tabletop move in the lateral direction and the imaging system move in the longitudinal direction.

The table tilts from the upright vertical position (+90°) to the horizontal

Document: Capital Medical Device Technical Specification

position (0°) to the head-down-tilt position (-15°)

Allowable patient weight: Min. 200kg

Facility for tracking with X-Ray tube.

Provision for collision protection.

Flat panel Detector System:

Separate detector for table and Bucky

Flat panel wireless detector solid state technology or latest with cesium iodide scintillator

Detector size: 43 cm x 43 cm or more

The detector should be movable to the entire length of the table

Pixel size: 148 um or less.

Facility of tracking with X-Ray tube

Detector Quantum Efficiency (D.Q.E) 65% or more @ Zero Line pairs

Active matrix size: Approx. 2.8k x 2.8k

Minimum image depth of 16 bit

The machine a detector storage compartment

Vertical Bucky Stand

Grid ratio: 10/1

Film to Focal Distance: 140cm

Balanced at counter weight

The unit should be provided with vertical Bucky having tilting facility across +90 degrees

A detector capable to take digital images in horizontal, vertical and oblique positions

Provision to do chest radiography without grid

Control Console

With technique selector and digital display for KV, mAs and/or mA and exposure time

Auto Bucky Selection switch

Auto tube focal spot selection switch

Audiovisual indication of the x-ray exposure

Provided with hand switch for control of radiographic exposure.

Tube readiness for exposure

Self diagnostic Programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc..

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6

Document: Capital Medical Device Technical Specification

GHz processor, 32GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Image acquisition and image processing workstation:

A separate workstation for image positioning and patient demographic data

The digital workstation should be based on the latest high speed processors of at least 64 bit.

The processing station must have 8 GB RAM, Intel multi core latest generation, at least 1TB, HDD and 19 inch or higher medical grade high definition color display TFT/LED touch screen monitor with external keyboard and all necessary software package

The machine an integrated workstation with a color display TFT touch screen monitor.

Real-time image processing: Digital Compensation Filter and Super Noise Reduction Filter

The server provide full amount of post processing features viz. geometric corrections, window level algorithms, annotation like markers, predefined text, drawing lines and geometrical shapes, multi-scale image processing, measuring distance and angles, shuttering, histograms, zoom, grey scale reversal, edge enhancement, noise reduction, indication of gray scale saturation level, latitude reduction.

The post processing features should also include contrast and brightness adjustment, storage of image with a memory of at least 200,000 images.

The machine should be fully network ready and it should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless connectivity

Read and Write in CD/DVD for data Storage and review

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, spares and consumables

X-ray generator -----1

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Page 343 ISBN No: X-ray tube one for floor mounted and one for ceiling mount

Bucky stand ----1

Radiographic table---- 1

Flat panel detector----2 (One for the Bucky stand and one for the radiographic table)

UPS with stabilizer for complete system---1

Image acquisition Workstation ---- One main and one additional fully networked workstation with high resolution

Archiving System (PACS) with four monitors ----1

CD-R/W based long term archiving with envelope-----10,000

Exposure switch----2

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Lead glass of 2mm lead thickness (or equivalent) with frame -----1

Lead Glove----3

Lead door as per room requirement

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (like contrast media, etc...)

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: +10°C to +40°C

Relative Humidity: <85%

7. Utility Requirements:

Suitable Power input to be 380VAC, 50Hz

Suitable UPS with stabilizer for 30 minutes backup

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General electrical safety Requirements

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation, Training and Commissioning

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training.

Document: Capital Medical Device Technical Specification

Turnkey works

The Supplier is responsible to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include but not limited to the following:

a). Radiation safety:

Proper X-Ray shielding lead lined door of 2mm thickness (or equivalent) should provide for the main equipment.

Proper lead glass window of 2mm lead thickness (or equivalent)

Red Warning Light 220V Above Exposure Room Door

b). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (grounding should be included)

Three phase breaker with size as per manufacturer recommendation

c). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

d). Network:

Network Outlet provided on the control and 4 doctors room and connected and working

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Xrad -90	1. Generic Name: X Ray - Radiography, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Digital Radiography Machine used for imaging of internal structures of the	
	body made by electromagnetic radiation passing through the body.	
	4. Technical Specifications:	
	A fully digital radiography system capable of detector exposure in vertical, horizontal and oblique positions to perform general radiography	
	Completely integrated (integrated Generator and Image Acquisition) and auto quality control features incorporated	
	System must have a method of measuring and recording patient absorbed dose (Dose Area measurement system)	
	System should have Anatomical programming radiography (APR)	
	System should have over load protection feature	
	System should have switch on x ray indicator]
	Generator	1
	Latest high frequency inverter technology for constant output and lowest radiation doses.	
	KVp: 40 – 150, with 1KV increment, and KVp accuracy of ±10%	
	Protection level against electric shocks: type B	1
	mA range: 10 to 1000 mA (with 16 values of high voltage current adjustment)	1
	Power: 65-85KW	-
	mAS maximum: 600 per exposure	1
	The X-ray exposure time (radiography time) should be automatically adjusted	-
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	
	System should have Automatic Exposure Control (AEC)	1
	Over load protection feature	1
	X-Ray tube and collimator	1
	Floor mounted, with longitudinal not less than 210cm and lateral movement	1
	not less than 24cm	
	Dual Focal spot sizes of 1.3mm sq. or less	1
	Tube stand vertical movement is 120 to 180cm	1
	Tube rotation angle: $\geq \pm 120^{\circ}$	1
	X-ray tube anode heat monitoring with thermal switch control	1
	High speed rotating anode and dual focus tube compatible with the generator	1
	Over loading protection feature	1
	High speed rotating anode dual focus tube compatible with the generator	1
	Anode heat capacity: 300KHU or more.	-
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Housing Material: built in material resistant to blows and falls

Multi leaf collimator having halogen/bright light source with auto shut provision for the light

Adjustable multi leaf collimation system with SID laser localizer

Automatic shut-off timer to preserve the collimator field lamp.

Has a rectangular light field with cross hair markings and lamp/timer feature

With cross hair centering and pre-indication of field sizes at certain source to image distance (SID)

Radiographic table:

Integrated Bucky unit for flat panel detector

Grid rate: 10/1

Film to Focal distance (FFD): 100cm

Balanced at counter weight

Table movement: 4 ways with breaks

The table must have easy access from both sides (for patient transfer purposes and cross table imaging)

The table must have foot activated locks for hands free position

The table should be mounted on high quality fiber wheels with brakes

Horizontal table with carbon fiber table top of minimum 210cmx80cm

The tabletop move in the lateral direction and the imaging system move in the longitudinal direction.

Allowable patient weight: Min. 200kg

Flat panel detector

Flat panel wireless detector solid state technology or latest with cesium iodide scintillator

Separate detector for table and Bucky

Detector size: 43 cm x 43 cm or more

The detector should be movable to the entire length of the table

Pixel size: 148 um or less

Facility for tracking with X-Ray tube

Detector Quantum Efficiency (D.Q.E) 65% or more @ Zero Line pairs

Active matrix size: approx. 2.8k x 2.8k

Minimum image depth of 16 bit

The machine a detector storage compartment

Vertical Bucky Stand

Grid ratio: 10/1

Film to Focal distance (FFD): 140cm

Balanced at counter weight

The unit should be provided with vertical Bucky having tilting facility across +90 degrees

Control Console:

With technique selector and digital display for KV, mAs and/or mA and exposure time

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switch on indicators

Auto Bucky Selection switch

Auto tube focal spot selection switch

Audiovisual indication of the x-ray exposure

Provided with hand switch for control of radiographic exposure.

Tube readiness for exposure

Self diagnostic Programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc...

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6 GHz processor, 32GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Image acquisition and image processing workstation:

A separate workstation for image positioning and patient demographic data

The digital workstation should be based on the latest high speed processors of at least 64 bit.

The processing station must have 8 GB RAM, Intel core i7 latest generation, at least 1TB, HDD and 21 inch or higher medical grade high definition color display TFT/LED touch screen monitor with external keyboard and all necessary software package

The machine an integrated workstation with a color display TFT touch screen monitor.

Real-time image processing: Digital Compensation Filter and Super Noise Reduction Filter

The server provide full amount of post processing features viz. geometric corrections, window level algorithms, annotation like markers, predefined text, drawing lines and geometrical shapes, multi-scale image processing, measuring distance and angles, shuttering, histograms, zoom, grey scale reversal, edge enhancement, noise reduction, indication of gray scale saturation level, latitude reduction.

The post processing features should also include contrast and brightness adjustment, storage of image with a memory of at least 200,000 images.

The machine should be fully network ready and it should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless connectivity

Read and Write in CD/DVD for data Storage and review

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DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, spares and consumables

X-ray unit with x-ray generator, x-ray tube -----1

Bucky stand ----1

Radiographic table---- 1

Flat panel detector----2 (One for the Bucky stand and one for the radiographic table)

UPS with stabilizer with 30 minutes backup---1

Image acquisition Workstation ---- One main and one additional fully networked workstation with high resolution

Archiving System (PACS) with four monitors----1

CD-R/W based long term archiving with envelope-----10,000

Exposure switch----2

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Lead glass with frame -----1

Lead door as per room requirement

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (if any)

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}$ C to $+40^{\circ}$ C

Relative Humidity: <85%

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7. Utility Requirements:

Suitable Power input to be 380VAC, 50Hz

8. Standards & Safety Requirements:

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation, Training and Commissioning

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training.

Turnkey works

The Supplier is responsible to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include but not limited to the following:

a). Radiation safety:

Proper X-Ray shielding lead lined door of 2mm thickness (or equivalent) should provided for the main equipment.

Proper lead glass window of 2mm lead thickness (or equivalent)

Red Warning Light 220V Above Exposure Room Door

b). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (grounding should be included)

Three phase breaker with size as per manufacturer recommendation

c). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

d). Network:

Network Outlet provided on the control and 4 doctors room and connected and working

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Document: Capital Medical Device Technical Specification

Tender and Purchase Order No.
Name and Model of the product
PO Box 25-11-276-32-66
Tel: +251-11-276-32-66
Fax: +251-11-275-25-56
Addis Ababa

Base Code	Item Detail	Department
Xrmd-91	1. Generic Name: X Ray - Mobile, Digital	Imaging
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description	
	Clinical Purpose/Description: A compact, light weight device used in emergency, trauma and ICU departments as well as operating theaters for conventional radiography	
	4. Technical Specification:	
	Mobile stand	
	Compact and light weight design with mobile castors for easy maneuverability	
	Fully counterbalanced with compact flat detector	
	Backup battery with continues operating time of 2hrs/100 exposures	
	Dose area measurement system	
	Automatic exposure control	
	KV, mA increase & decrease	
	Effective braking system for parking, transport and emergency.	
	Articulated arm for maximum positioning flexibility in any patient position.	
	Emergency stop button	
	Standby and exposure release switch	
	Ready and X-Ray on switch with Indicators	
	All cables shall be concealed in the arm system	
	Storage facility for flat panel detector and other supplies	
	Digital display of kV, mAS and/or mA and time	
	X-ray generator:	
	High Frequency generator without put power 25Kw	
	kV range: 40-125Kvp	
	mA: 20 mA to 320 mA	
	mAs: max. 280 per exposure	
	Exposure time: for patient exposure ≤1s and for tube capacity should be up to 5s	
	Self diagnostic programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc	
	X-ray tube and collimator:	
	Output should match the output of the generator	
	Dual focus rotating anode with spot size less than 1.3mm	
	Tube focal spot selection Switch	
	Total filtration: minimum 2 mm Al	
		•

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Tube voltage: 40-125Kvp

Anode heat capacity: 300KHU

Anode cooling rate: 40KHU/min.

Tube horizontal movement: 45 cm or more

Tube vertical movement: 100 cm or more

Adjustable multi leaf collimator with SID laser localizer

Collimator lamp on switch

Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector active size: 35cm x 43cm or more.

Pixel size: 148 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero LP/mm or more.

With at least two user selectable input fields

Active matrix size: 2.8k x 2.3k

Image acquisition and image processing:

Shall have integrated 17" high brightness LCD/TFT color button/touch screen monitor.

The digital workstation should be based on the latest high speed processors of at least 32 bit.

Patient data management- Electronic record with name, date, anatomy, etc..

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold

Annotation (text, trace, arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc..

Connectivity:

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.

Storage of 3000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Work list Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Document: Capital Medical Device Technical Specification

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, Spares, Consumables and other components:

Main unit with x-ray generator, x-ray tube----1

Flat panel detector----1

All software packages shall be provided as standard

A CD-R/W based long term archiving with envelope----10,000

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ---2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}$ C to $+40^{\circ}$ C

Relative Humidity: <85%

7. Utility Requirements:

Power input: 220V/50Hz

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device

The supplier must provide sufficient technical and end user training on site.

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including Labor, X-ray tube, detectors and spare parts and accessories from the date of installation as well as after sale services.

The supplier must provide extended warranty from 3rd year to 5th year inclusive of labor, spare parts, accessories, detector and X Ray tube.

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Xrmd-90	1. Generic Name:	Imaging
	2. GMDN/UMDN Name, Code: X ray – Mammography, Digital	
	3. Clinical Purpose/Description:	
	Digital Mammography machine is used as screening tool to detect and diagnosis early breast cancer in women experiencing no symptoms with	
	facility for stereotactic biopsy and 3D tomosynthesis.	
	4. Technical Specification:	
	Full Digital Mammography System consisting of exposure stand with attached swivel system, separate console with radiation shield, automatic exposure control and mammography X-Ray Tube which allows fast, low-dose, high-quality imaging of the breast and Upgradable system with latest technology available in future.	
	Full Digital Mammography System consisting of exposure stand with attached swivel system, separate console with radiation shield, automatic exposure control and mammography X-Ray Tube which allows fast, low-dose, high-quality imaging of the breast and Upgradable system with latest technology available in future.	
	System should have Automatic Exposure Control (AEC)]
	Should be able to upgrade with contrast enhanced mammography techniques.	
	System should be upgradable with latest technology available in future.	
	Gantry assembly:	_
	Isocentric system	
	Collimator: Fully Automated adjustment for different paddles, sizes and magnification	
	Movement: Motorized vertical and rotating movement	
	Arm locking system: Electromechanical brakes or equivalent	
	Arm moving system: Motorized	
	Control buttons for vertical and rotational movement on both sides of C-arm]
	Focal spot to image detector distance (SID): >65cm]
	Patient face shield for 2D imaging]
	Breast Compression:	
	Manual and automated breast compression	
	Max. force for automated: ≥150N and ≤200N	
	Emergency release Automatic decompression after exposure	
	Digital numerical both sides indicator: for C-arm rotation angle and	-
	compression force	
	Memorizable MLO angle: C-arm shall be able to stop automatically at contra lateral angle	
	Scatter rejection: Antiscatter grid (or equivalent technology)	
		=

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Magnification views: at least one magnification view, magnification ratio shall be provided

Antiscatter grid removal: Automatic, motorized for magnification views

Shifting paddle: should be available

Maximum compression thickness: 15 cm or more.

The compression extremely smooth and there be automatic decompression at the end of each exposure.

Safety mechanism for compression with respect to power failure.

Large paddle, Regular sliding paddle, Round spot and square spot compression paddles and Special paddles

Highly effective computer aided detection (CAD) digital mammography solution for early detection of cancer.

Latest advanced technology for identification of micro classification and suspicious lesions

X-Ray Generator:

The X-ray generator be high frequency with the following parameters:

Power output : ≥7kw

KV range: at least 25-35 kV in steps of 1 kV

mAS range max.: 5-500 mAS

Exposure time: for Patient exposure; 25ms-700ms and for tube capacity; up to 4.5s

Maximum mA: 180mA

X-Ray tube unit:

Dual focus rotating anode tube with the following parameters:

Nominal focal spot size: large and small: 0.3mm and 0.1mm

Anode heat storage: 200 KHU or more

Anode material: Tungsten

Flat Panel Detector:

Flat panel wireless detector solid state technology or latest with CsI Scintillator

Detector size: 24 x 26cm or more with two image formats

pixel size: 85 um or less

Detector Quantum Efficiency (D.Q.E): 65% @ Zero Line pairs or more

Image matrix size in pixels: approx 2.8 Kx 3K or more

Machine with detector storage compartment

Stereo tactic biopsy system

Fully compatible with Full Field Digital detector

Facility to do stereotactic biopsy automated on the entire three axis.

Facility for needle core biopsy, Fine needle aspiration and wire localization.

Compatible to use with vacuum assisted biopsy.

Transparent lead radiation shield, face shield, remote service modem, quality control tool kit

ACR phantom, phantom for calibration of AEC, phantom for calibration of image detector.

Document: Capital Medical Device Technical Specification

The system should have capability of 3D Tomosynthesis and vacuum assisted biopsy system.

Facility to place the Patient for stereotactic biopsy on a couch for patient comfort.-(supine, lateral or prone position).

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Acquisition Workstation/Operator console:

A separate workstation for image positioning and patient demographic data is required.

Both detector and generator controls integrated in the same console

Dose index shall be displayed for each exposure and recorded

Computer system: System of latest technology (processor generation/type/speed, RAM, HDD, Storage systems, etc...)

Storage capacity: for 5000 patients

High Contrast 3Kx 3K 21inch TFT/LCD medical grade monitor be provided with workstation.

Double hand switch for the exposure and double foot switch for breast compression/arm movements shall be available

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

The following image processing should available on the workstation:

Freely selectable screen layout

Windowing, Contrast and Brightness setting/adjustment

Magnification, panning and zooming

Image inversion (black/white and possibly color)

Contrast enhancement (with table)

Display of histogram

Before /after comparison

Filter

Annotation:

Left/right marking

Text additions

Lines

Rectangles and circles

Measurements:

Distance

Angle

Density

Biopsy:

Stereo tactic biopsy system which is fully compatible with FFDM (Fully Field Digital Mammography).

A high resolution image of 20 1p/mm possible with the stereo tactic biopsy system.

5. System Configuration Accessories

Mainframe System----01

X-Ray tube Unit & tube----01

Flat Panel Detector---01

Image acquisition Workstation---01

Stereotactic Biopsy System----01

Archiving System (PACS) with four monitors---01

All software packages should be supplied

A CD-R/W based long term archiving with envelope----10,000

Compression paddle: Standard, High edge, Small, Medium, and Spot

Mammography Lead guard with frame----01

UPS with stabilizer for one hour backup----01

Patient comfort couch for stereotactic biopsy in supine, lateral or prone position---01

Phantoms and meters for the quality control and calibration of the various components (mammography, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

6. Operating Environment;

Operating Temperature:+10 °C to + 40 °C

Relative humidity: < 85%

Document: Capital Medical Device Technical Specification

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General electrical safety Requirements

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

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Addis Ababa

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Base Code	Item Detail	Department
Ultec-90	1. Generic Name: Therapy - Electro and Combination, Ultrasound	Physiotherapy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	- TENS: A medical device use electric current to stimulate the nerve for therapeutic purpose and to reduce acute and chronic musculoskeletal	
	pain. - Ultrasound therapy: The use of high frequency vibration sound wave that can breakup stony deposits or tissues, accelerate the effect of drugs in targeted area and assist in the measurement of the elastic properties of tissue.	
	4. Technical Specification:	
	Adjustable digital timer, auto shut off buzzer	
	The unit should be user friendly and ergonomically designed	
	The unit Shall have LED color screen to display all parameters	
	The unit Shall have contact treatment control	
	The unit should be portable/ mobile on trolley, operated by mains power supply	
	The unit Shall have on/off switch	
	Ultrasound therapy:	
	The use of high frequency vibration sound wave that can breakup stony deposits or tissues, accelerate the effect of drugs in targeted area and assist in the measurement of the elastic properties of tissue.	
	Ultrasound modes: pulsed and continues	1
	Ultrasound frequency: 1 and 3 MHz	-
	Pulse frequency: approx. 10Hz to 100 Hz	1
	Intensity: 1 – 3 w/cm ²	1
	Duty cycle: 5, 10, 20, 50, and 80%	1
	two water proof treatment head	
	Number of connections: one]
	TENS	
	TENS is a medical device use electric current to stimulate the nerve for therapeutic purpose and to reduce acute and chronic musculoskeletal	
	pain. Shall have four independent current channels.	1
	Shall have approx. 50 treatment suggestions	1
	Shall have approx. 60 current forms per channels.	1
	Combination therapy:	1
	Adjustable intensity per channel	1
	Comprises of TENS and ultrasound therapy which used for nerve	1
	Comprises of 121 to and arrabound morapy which used for herve	_

stimulation, pain relief and to treat tendon and ligaments.

Shall have dual treatment suggestions

5. System Configuration Accessories, Spares, Consumables and other components :

Power cable

Trolley for mounting purpose

Ultrasound multi frequency treatment head with holder---02

Ultrasound gel 450ml---20

Velcro straps (small and large size)---10m of each

Rubber electrodes (Different size of rectangle, Different size of butter fly, Different size of long strips, Different size of round)-- 300 of each

Moist pads -- 300 of each

Patient cables, plugs

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment:

Operating Temperature: +10°C to +30°C

Relative Humidity: <85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility /NA/

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Document: Capital Medical Device Technical Specification

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Name and Model of the product
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Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Detail	Department
Octm - 90	1. Generic Name: Optical Coherence Tomography	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	1
	Optical coherence tomography (OCT) is an interferometry, non-invasive optical	1
	tomography imaging technique offering millimeter penetration with micrometer	
	scale axial and lateral resolution.	4
	4. Technical Specification:	_
	Tomography imaging	_
	Signal type: CCD image	
	Signal source: Super luminescent Diode, 840 nm	
	Longitude/Axial resolution: ≤ 5 um in tissue	
	Methodology :spectral Domain	
	Transverse resolution :<20um	
	Longitudinal (depth) range: 2mm in tissue	
	Scan speed :> 26000A scan per second	
	Normative database: RNFL(retina nerve fiber layer) GCC(ganglion cell complex) and macular thickness,.	
	Fundus Alignment, Documentation	
	Signal type: CCD image	1
	Field of view: 36 degree w * 22degree h or more	_
	Viewing method: Flat panel display	_
	Illumination: Near IR/Red free	1
	Internal fixation: 32 x 16 LED dot matrix	1
	External fixation: Slit lamp type adjustable blinking LED	1
	Minimum pupil diameter: 2.5 -3mm	-
	PC workstation with Core i7 CPU with laser printer (color),1T HDD, DVD	1
	Read/Write, Image capture card and software loaded for digitization of imagesRAM	
	16 GB and interfaces to RVG and Intraoral digitization.	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	
	- Ups with stabilizer (30min)	
	- Motorized table that accommodate main unit with all accessories.	
	All standard accessories, consumables and parts required to operate the equipment,	
	including all standard tools and cleaning and lubrication materials including items not specified above.	

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

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		1 =
Base Code	Item detail	Department
Ulto-90	1. Generic Name: Ultrasound – Ophthalmic	Ophthalmic
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A-Scan can be used for biometric calculation and quantifying the	
	reflectivity of lesions in the eye and orbit where as B-Scan is used for	
	imaging the anatomy.	
	4. Technical Specification:	
	A-scan and B-scan mode	
	A scan probe frequency: not less than 10MHz	
	B scan probe frequency: not less than 10MHz	
	facility for IOL power calculations (all formulas)	
	auto & manual measurement function.	
	distance & area measurement on B-scan images	
	vector A-scan measurement	
	simultaneous B-scan with vector A-scan measurement	
	A-scan dynamic recording with gain adjustments	
	video CD recording facility	
	dynamic movie archiving	
	integrated or external compatible printer	
	5. System Configuration Accessories, Spares, Consumables and other componenets:	
	A scan probe1	
	B scan probe1	
	Printer and CD recorder	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical	
	Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent)	4
	9. Installation, Training and Commissioning:	4
	The supplier must provide installation, and commissioning of the device at	

health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

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Base Code	Item Detail	Departmen
Yagl-90	1. Generic Name: YAG Laser	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:]
	Neodymium-doped Yttrium Aluminum Garnet (Nd: YAG) laser is Fully	1
	integrated laser workstation used in Ophthalmic surgery.	
	4.Technical Specification:	
	Motorized table and chair	
	Continuously adjustable brightness	
	Adjustable slit height]
	Vertically-adjustable instrument table is also suitable for patients in wheelchairs.	
	Continuously adjustable slit width	
	Straight binocular tube with eyepieces	
	LASER delivery system:	1
	Combined Argon/YAG Laser for ophthalmological procedures that deliver	
	laser treatment for dual Anterior segment and posterior segment conditions	
	Medical grade Monitor: 21-inch LED with a minimum 1920 x 1080 resolution	1
	High-intensity light source that can be focused to shine a thin sheet of light into the eye with a conjunction biomicroscope	
	Straight binocular tube with eyepieces	1
	Tower illumination system and incorporated filters.	1
	The image on the monitor screen is equal to the image	1
	Seen through the oculars of the slit lamp	-
	Blue, Red-Free, Amber filter which improves	
	Contrast and color of retinal images	
	Heat insulation and Exciter / Barrier filter	1
	Zoom magnification changer, which provides continuous observation through the magnification range	1
	USB interface	1
	Joystick, quick action brake and easy grip controls for precise slit adjustments	
	Choice of ≥5 magnification steps for observation from overview to detail	1
	Width of slit image: Continuous from 0 to 10 mm	1
	Rotation of slit image: Continuous ±90°	-
	Travel of instrument base: vertical, lateral and axial	-
	Continuously adjustable brightness	-
	Vertically-adjustable instrument table is also suitable for patients in wheelchairs.	-

Adjustable slit height

Continuously adjustable slit width

Possibility of providing patients with immediate diagnostic

Image which verifies diagnosis and can be used for legal cover

Horizontal movement range

Wheel for vertical movement

Short frontal distance to the patient's eye

Internal fixation mechanism

Minimal pupil measurement: 4 mm

Joystick command of movement

Special optic system for low exposure of the eye to the light

Safety stop when light intensity more than limit value

Optimized illuminated area on the eye, for safety

UPS system with minimum30 minute back-up

Voltage stabilizer of appropriate rating

Nd:YAG laser:

Super Gaussian mode

Wavelength: 1064 nm

Attenuation level >10

Four-point He-Ne aiming beam, coaxial to Nd: YAG beam

Maximum energy in single pulse: 10 mJ

Maximum energy in double pulse: 25 mJ

Maximum energy in triple pulse: 40 mJ

Argon laser:

Run on self-contained air cooling

Wavelengths: 488/514/529 nm

Power total spectrum: 50 mW to 2.5 W

Power green spectrum: 50 mW to 1.1 W

Red diode aiming beam with adjustable setting

Modes of operation:

Single pulse with adjustable power and duration

Auto repeat in steps up to maximum of 6 Hz

Continuous wave

Safety goggles for Nd:YAG

Elbow rest (handcrafted wood)

Chinrest paper (Box of 1000)

UPS system with minimum 30 minute back-up

Voltage stabilizer of appropriate rating

5. Accessories/Consumables/Spare part and other component

With all standard and complete accessories safety eyeglasses for YAG , contact lenses, (optional) laser indirect ophthalmoscope and endo probe

Document: Capital Medical Device Technical Specification

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Refa -90	1.Generic Name : Refractometer – Automated	Ophthalmic
	2.GMDN/UMDN Name/Code:	
	3.Clinical Purpose/Description:	
	Auto Ref-Keratometer is computerized vision testing machine used obtain and	
	objective measure the eye's refractive error. This measurement provides the most	
	accurate prescription for corrective lenses. It should be with full auto mode and	
	complete unit with all standard accessories.	
	4.Technical Specifications automatic radius measurement.	
	automatic peripheral measurement.	
	It must have adjustable tilt color LCD monitor at least 5inch	
	active accommodation relaxation.	
	IOL measuring mode	
	reliable PD measurement.	
	large cylinder measuring range up to 10 D.	
	Measurement as from 2.3mm pupillary diameter	
	In-built printer with paper cutter function.	
	Refractometer:	
	• Sphere (SPH): -30 to + 22D in steps of 0.12/0.25D	
	• Cylinder (CYL): 0 to +/- 10D in steps of 0.12/0.25D	
	• Axis (AX): 1 to 180° in 1 deg steps	
	Measurable pupil diameter: min 2.0mm diameter	
	Automatic measurement (release) in the case of correct centering.	
	• 1 to 10 automatic measurements possible.	
	Radius Measurement:	
	• Surface refraction power 33.75D-67.5D in 0.01/0.12/0.25D steps.	
	• Radius 5.0-10.0mm in 0.01mm steps.	
	• Cylinder size 0-10D (Axis 0-180° in 1° steps).	
	Cornea vertex distance: 0, 10, 12, 13.5, 15mm.	
	Minimum pupillary diameter: 2.3mm.	
	Pupillary distance up to 85mm in 1mm steps.	
	an inbuilt thermal printer.	
	RS232C and video NTSC.	
	5.System Configuration Accessories, Spares, Consumables and other	
	components:	
	Trolley: 01 no. All standard accessories, consumables and parts required to	
	operate the equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer (including items not specified above	

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Department
Octm - 90	1. Generic Name: Optical Coherence Tomography	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Optical coherence tomography (OCT) is an interferometry, non-invasive optical tomography imaging technique offering millimeter penetration with micrometer scale axial and lateral resolution.	
	4. Technical Specification:	
	Tomography imaging	
	Signal type: CCD image	_
	Signal source: Super luminescent Diode, 840 nm	
	Longitude/Axial resolution: ≤ 5 um in tissue	_
	_	
	Methodology :spectral Domain	
	Transverse resolution :<20um	
	Longitudinal (depth) range: 2mm in tissue	
	Scan speed :> 26000A scan per second	
	Normative database: RNFL(retina nerve fiber layer) GCC(ganglion cell complex) and macular thickness,.	
	Fundus Alignment, Documentation	
	Signal type: CCD image	
	Field of view: 36 degree w * 22degree h or more	
	Viewing method: Flat panel display	
	Illumination: Near IR/Red free	
	Internal fixation: 32 x 16 LED dot matrix	1
	External fixation: Slit lamp type adjustable blinking LED	1
	Minimum pupil diameter: 2.5 -3mm	1
	PC workstation with Core i7 CPU with laser printer (color),1T HDD, DVD	1
	Read/Write, Image capture card and software loaded for digitization of imagesRAM	
	16 GB and interfaces to RVG and Intraoral digitization.	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	

- Ups with stabilizer (30min)
- Motorized table that accommodate main unit with all accessories.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

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Addis Ababa

Base Code	Item Detail	Department
Arga-90	1. Generic Name: Argon laser	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	=
	It is a laser system that uses noble gas as the active medium and used in many	
	applications such as forensic medicine, general surgery, ophthalmic surgery, and holography and as an optical pumping source.	
	4. Technical Specification:	
	Selectable Argon Wavelengths 457.9nm, 488nm, 514.5nm and Multi-Line Maximum. Output Power 16mW at 457.9nm, 80mW at 488nm, 100mW at 514.5nm and 300mW Multi-Line.	
	Beam Diameter 1/e^2 0.75mm Beam. Divergence 0.95mrad.	_
	Beam Pointing Stability <30urad. Output Power Drift (after warm-up) < +/- 1%.	
	Beam Amplitude Noise < 1% RMS Polarization Ratio > 250:1	
	Warm-up Time 10 Minutes Dimensions (LxWxH – inches) 19.2" x 7.6" x 5.4" Weight (lbs/Kg) 22lbs / 10Kg	
	Cooling method:laser cooled	
	Output power stability (over 2 hour period after warm up): $< +/- 1\%$. Beam pointing stability (over 2 hour period after warm up, ± 2 °C): <30 µrad	_
	Manufacturer, Country of Origin and Model of Equipment Part which is	
	Manufactured by other Company Must be Clearly indicate The standard length of the cooling hose is 6	
	5. System Configuration Accessories, Spares, Consumables and other	
	components: Power supply, cooling system, Wavelength Select Modules, Safety Interlock Accessories, Safety Eyewear minimum 100 quantity and all the necessary accessories	
	6. Operating Environment;	=
	Operating Temperature:+10 °C to + 30°C	=
	Relative humidity: < 85%	=
	7. Utility Requirements:	=
	Electrical Power Supply: 220VAC <u>+</u> 10%	=
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
	10. Warranty and After Sale service:	
	The supplier must be provide minimum of Two years warranty including labor and	

spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

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Base Code	Item Detail	Department
Func-90	1. Generic Name:Fundus Camera	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	A Fundus camera or retinal camera is a specialized low power microscope with	
	an attached camera designed to photograph the interior surface of the eye,	
	including the retina, optic disc, macula, and posterior pole i.e. the Fundus. A	
	digital camera converts these images into digital images.	_
	4. Technical Specification:	4
	Digital Fundus Camera provides color and Fundus auto fluorescence (FAF) imaging within a small compact design.	
	Field angles 30-60 deg.	1
	Image captures (Color, Fluoresce in Angiography, Green, Blue and Red).	-
	Capture: 1 chip sensor color 1 chip sensor black & white	_
	Monitor 15 inches LCD for direct display.	-
	Fixation light: internal and external fixation lights both.	-
	Exposure interval 0.5 - 1 sec.	+
	Facility for data storage, data transfer, image archiving, image analysis.	-
	Instrument table: asymmetrical motorized suitable for patients in wheel chair.	-
	Supporting latest computer hardware & software.	-
	5. System Configuration Accessories, Spares, Consumables and other	+
	components:	
	Suitable UPS with maintenance free batteries, voltage regulation and spike	1
	protection for minimum 30 min. back-up supplied with the system.	
	Digital Fundus Camera, complete with compatible printer for reporting and all	
	standard accessories.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent)	_
	9. Installation, Training and Commissioning:	_
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
	10. Warranty and After Sale service:	

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

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FAX: 251-11-275-25-55

Base Code	Item Detail	Department
Peri-90	1. Generic Name: Perimetry/ Automated Visual Field Analyzer	Ophthalmic
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A device provides visual field assessment for glaucoma detection as well as	
	numerous other eye conditions.	
	4. Technical Specification:	
	ergonomically designed and easily use with button/touch screen digital display color LCD/TFT monitor	
	integrated/external compatible printer	
	automatic chin rest operation	
	source to image distance of approx. 0.30 m	
	full threshold mode test comprises of Peripheral, macular and central coverage up to 70°	
	quick mode test for shortening test times in both screening and threshold modes.	
	supra threshold mode for fast screening	
	projection type of stimulus method	
	stimulus time of 0.1-1s	
	stimulus time interval approx. 0.8s to 2.8s	
	stimulus color: green, red, white and blue	
	stimulus size: Goldman I, II, III, IV, V	
	automatic background light intensity adjustment	
	a complete package of visual field analysis software including normal eye database	
	patient information entry; Name, ID, Sex, Birth date, Visual acuity, Diagnosis, Correction, etc	
	storage of approx. 15,000 images on hard disc	
	Connectivity:	
	Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.	
	Integrated facility documentation with DVD/CD or USB	
	a capability of link Fundus images from other devices like OCT, Fundus	
	camera, etc.	
	5. System Configuration Accessories, Spares, Consumables and other	
	components: Ups with stablizer	-
	^	4
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication	
	materials, to be included in the offer.	
	6. Operating Environment;	

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Department
Cryo-90	1. Generic Name: Ophthalmic Cryo unit	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Used most often to treat retinal tears, is a procedure that uses intense cold to	
	induce a chorio retinal scar and to destroy retinal or choroidal tissue.	
	4. Technical Specification:	
	Digital temperature display	
	Safe and effective low pressure freeze and defrost	
	Complete gas scavenging	
	Wide array of interchangeable probes	
	Freezing temperatures -89 degrees	
	Curved glaucoma type probe necessary and retinal probe	
	Probe specs-completely non electric and autoclavable	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	with all standard and complete accessories	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC <u>+</u> 10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
	10. Warranty and After Sale service:	
	The supplier must be provide minimum of Two years warranty including	
	labor and spare part from the date of commissioning.	
	After basic warranty the supplier must agree for after sales service	
	11. Documentation:	
	User and service manual in English	
	12. Packaging and Labeling;	
	Packing of all the goods clearly marked and securely packed.	
	Each goods will be further packed in separate package with all its standard	

accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base Code	Item Detail	Department
Seal-90	1. Generic Name: Tube Sealer	Laboratory
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	Tube Sealer is used in sealing of blood bag tube without causing hemolysis and leakage of blood.	
	4. Technical Specification:	
	Bench-top use	
	Digital temperature display	
	Compatible with Polyvinyl chloride (PVC) tube with different type and size tube	
	Radiofrequency sealing with no risk of hemolysis of blood in tube segment	
	Radiofrequency wave only heat the tube not the liquid inside	
	No warm-up time	
	The sealing time ≤ 2 seconds.	
	Automated tube detection	
	Automatic Sealing	
	Anti-spark and overheat protection system to avoid damage to system & tubing	
	Tear seal feature to make segments Easily separate the tube segment after sealing	
	Splash guard to protect phlebotomist from any risk of contamination.	
	Easily accessible tube sealer electrode for disinfection and cleaning	
	Well Electrodes protected by a cover to prevent blood splutter.	
	Audio Visual Indication for ready to seal, seal process and detailing the functional status of sealer.	
	Number of sealing: simultaneous multiple tube sealing not less than 4/time	1
	No. of seals per charge more than 1,000 continuous seals from a fully charged battery.	
	Provided with sensors which adapt with sealing time Automatic protection system for over temperature welding fully automated	
	Automatic adjustment for RF power and sealing type	1
	Easy to clean; stainless steel External feature	1
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1x Main Unit	1
		_1

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1x Battery Charger

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

With all standard and complete accessories

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Sla-90	1. Generic Name: Slit Lamp	Ophthalmic
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Complete eye exam to get a better look of structures eyes]
	4. Technical Specification:	
	4.1 Microscopic Units	
	Should be Galilean-type converging binocular microscope type	-
	It 5 steps magnifications of 6/10/16/25/40x	-
	It overall visual field ø35.1mm, ø22.5mm, ø14.1mm, ø8.8mm, ø5.6mm	-
	4.2 Eyepiece lens	
	It the magnification 12.5x	-
	Diopter adjustment range -5D to +5D	-
	Binocular tubes inter pupillary distance 55 – 75 mm	-
	4.3 Illumination unit	-
	It the Slit width 0 to 14mm, Slit length 14 to 1mm and aperture diameter ø14, 10, 5, 2, 1, 0.2 mm	
	4.5 Slit direction	-
	It Vertical to horizontal inclination: 5°/10°/15°/20° for the Side swing	-
	Filters Blue, red-free (green), grey (10 %)	-
	4.6 Chinrest unit	1
	a longitudinal movement of at least 90mm	1
	a lateral movement of at least 95mm.	1
	a chin rest vertical movement of at least 80mm.	1
	4.7 slit lamp stand	1
	Should be supplied with motorized table.	1
	It move all direction movements and with automatic and manual]

operations

5. System Configuration Accessories, Spares, Consumables and other components:

with all standard and complete accessories

Eyepiece lens 4 pairs

LED 10 pieces

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety $\,$

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Addis Ababa

Base Code	Item Detail	Department
Pham-90	1. Generic Name: Phaco + Vitrectomy Machine	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Phaco + Vitrectomy Machines are used to break up and remove	
	cataractous lenses and to performs anterior and posterior microsurgical	
	procedure in which to repair retinal disorders of the eye. It possess	
	irrigation, irrigation, aspiration and ultrasound, diathermy, and vitrectomy operational modes	
	4. Technical Specification:	-
	The units should possess irrigation, irrigation, aspiration, ultrasound,	-
	diathermy, and vitrectomy operational modes.	
	Phaco power 0-100%	1
	Phaco Vacuum Level: 0-500mmHg	1
	Pump Flow Rate 10 to 40 cc per min	1
	Ultrasound delivery mode: continuous, micro pulse and burst mode -	
	without generating significant heat.	
	The units should possess irrigation, irrigation/aspiration, ultrasound,	
	diathermy, and vitrectomy operational modes.	
	For effective cold Phaco it software for adjustable duty cycle.	-
	Advanced fluidics with sensor system for vacuum and irrigation.	-
	Digital pulse pump with vertically designed fluitics panel, vacuum	
	sensitive proportional fluid venting.	<u> </u>
	Facilities for Bipolar Coagulation, Phaco emulsification, ultrasound Aspiration and Anterior Vitrectomy	
	Machine good panel display with digital control good audio, memory set	-
	up for surgical parameters	
	Digital LCD color display screen 15"	
	Computer microprocessors - Intel chipset for medical applications.	
	Simple to service and upgrade, customized surgeons programs,	1
	programmable power pole with automatic programmed adjustment of	
	bottle height during each procedurals phase.	
	Constant anterior chamber volume by means of micro-processor controlled	
	venting-pressure equalization system	-
	Advanced technology multifunctional foot switch,	-
	Vitrectomy attachment should be available upto 600 cuts/minute.	-
	Machine with good track record will be preferred.	-
	Two IA straight hand pieces with 4 piezo electric crystals.	-
	Display for relative and absolute ultrasonic time and dose	-
	Bipolar Coagulation: 2 to 6 watts; Foot controlled	-
	Phaco emulsification:	1

- a) Ultrasonic tip frequency: 29-60 KHz
- b) Phaco power in both linear and pulse mode
- c) Ultrasound pulse rate 1-14 pulses/sec
- d) Micro flow tip
- e) Auto priming, auto fluidic and auto tuning

Aspiration: 0-500 mmHg linear vacuum

Anterior Vitrectomy: 30-600 cuts/min

Multifunctional foot pedal with a reflux switch

Machine stainless steel trolley with 4 lockable wheels

5. System Configuration Accessories, spares, Consumables and other consumables:

Aspiration/irrigation unit: 5 hand pieces

Re-usable silicone hose system: 10 hand pieces

Foot switch

Irrigation cannula: 10 pieces

Infusion stand.

Hand piece: 5 pieces

Titanium tips: 30 degree US tips: 30

Pars-plana titanium tips

Pneumatic vitrectomy 20 G

Electromagnetic vitrectomy

Phaco-keratome

Diathermy cord: 1

Tubing: 6

Silicon Sleeves: 5

Test chambers: 5

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85% 75

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of three years warranty spare part from the date of commissioning.

Document: Capital Medical Device Technical Specification

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Meto-90	1. Generic Name: Microscope - Operating, Ophthalmic	Ophthalmic
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Operating microscope which is primarily used for ophthalmology and	
	ophthalmic eye surgery.	
	4. Technical Specification:	-
	Full motorization of the controls and the zoom magnification.	
	Handling and versatility in ophthalmic surgery	
	Head: Zoom optical head	
	Magnification: 5x – 32x continuous zoom(electronic/hand controlled)	
	Magnification of assistance microscope: 6x, 10x, 16x	
	Eye pieces: 10x paired wide field, dioptric setting + 5D to - 5D	
	Variable working distance from 200 mm to 500 mm through motorized multi focal lens.	
	Adjustable range for Pupil Distance: 50mm to 75mm	
	Light source: LED illumination]
	Illumination: Coaxial through the lens with fiber optic cable]
	Illumination type: 6 + 0 deg. coaxial illumination, 26 deg. Oblique illumination	
	Coaxial illumination: ≥60,000 Lx	
	Oblique illumination: ≥60,000 Lx	
	Inclinable binocular tube, inclinable over range of minimum 0- 180Deg.	
	Arm: counter balanced pantographic arm with 3200 rotation	
	Stand: Mobile floor stand on four castor wheels for easy handling and absolute stability	
	Ergonomic handles with buttons for motorized control of focus and zoom both hand & foot.	
	Graphic display LCD with background illumination	
	Camera should be independent of microscope.	
	Essential Accessories: o Stereoscopic co observation attachment for second observer with tilt able eyepieces, minimum 0-160 Deg.	
	Integrated Beam Splitter	
	3-Chip CCD HD (high definition) output camera with c-mount for connecting with the microscope & recording on a hard drive on mini DV disks.	
	Digital video recording facility with appropriate video editing software.	1
	Accessories: Diploscope (face to face attachment)	1
	Function footswitch: 12 up to 14	1
	Digital still camera for attachment with microscope System]

5. System Configuration Accessories, Spares, Consumables and other components:

Supplied with extra LED spare x2

Appropriate Eye piece a pair of 6x, 10x, 16x

Power cord x1

Fiber optic cable x1&Power board x1

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Frev-90	1. Generic Name: Freezer - Vaccine, 500 L/ 700 L	Pharmacy
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Freezer is an horizontal Pharmaceutical Freezers for storage of vaccines and other sensitive materials under stable temperature conditions @-15°C to -50°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	The Chamber is Double Walled with PUF Insulation, inside 304 Stainless Steel, CFC Free (eco-friendly)	
	Lockable door, solid	
	Freezer must have battery back-up and PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure, battery low etc.	
	Freezer ≥3 Compartment.	
	Freezers with heated air vent and front panel air filter.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	
	Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.	
	Heavy duty hinge for closure and un-interruptive service.	
	Informative display and control screen with history tracking	
	Easy data transportation through USB port and it must also have on board diagnostic software.	
	Attachable external remote alarm system	
	Independent Dual Compressor System	
	Electronic temperature control: -15°C to -50°C with 1°C Increment	
	Accuracy, whatever the load: +/- 1°C	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device, with connection/interface for external read-out	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording device	
	Integrated four castors with break	

Minimum compressor starting voltage: 22% below nominal voltage

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \, ^{\circ}\text{C}$ to + $30 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Refg-90	1. Generic Name: Refrigerator - General purpose 300L/500L/700L	Pharmacy
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	General purpose Refrigerator is an Upright refrigerator for storage and conservation of vaccine, chemicals and reagents in clinical laboratory and	
	pharmacy @ 0°C to 10°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	Internal net volume: 300L/500L/700L	
	Easily adjustable ≥ 3 shelves	
	Insulation material: polyurethane, CFC-free	
	Lockable door, solid	
	Electronic temperature control: 0°C to 10°C.	
	Accuracy, whatever the load: +/- 1°C	
	Lighting System: Top LED	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording device	
	Integrated four castors with break	
	Minimum compressor starting voltage: 22% below nominal voltage	
	Microprocessor controlled spike and surge protection, and protection against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status, voltage fluctuation and load as % of nominal current	
	Electronic fuse disconnects and reconnects automatically	
	KVA rating matches power consumption of the refrigerator	
	PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure, battery low, Door Ajar etc.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	

Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.

Heavy duty hinge for closure and un-interruptive service.

Informative <7" display and control screen with history tracking

Easy data transportation through USB port and it must also have on board diagnostic software.

Adjustable LED lighting for efficient energy

Illumination with auto-on feature and ON/OFF switch

Forced-air circulation maintains chamber uniformity and provides

Quick recovery after door openings

Bacteria-resistant interior, exterior, and door handle

Voltage stabilizer of appropriate rating

Keeping inside temperature for 8Hr during power failure

Accepted input range: -20 % to +20 %

Response time: <15 ms

Power consumption: 500 W

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +43°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Document: Capital Medical Device Technical Specification

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Uran-90	1. Generic Name: Analyzer - Urine	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: -Qualitative and/or quantitative in vitro	
	determination of various chemical and cellular constituents of a clinical	
	urine specimen	
	4. Technical Specification:	
	* Tests to include: color, turbidity, , creatinine, ascorbic acid, bilirubin,	
	glucose, hemoglobin, ketones, nitrites, pH, protein, urobilinogen, specific	
	gravity, blood, red cells, white cells, casts, crystals, sperm, and	
	microorganisms.	
	* Internal memory capacity for >2,000 samples.	
	* Quality control routines to be user friendly with results recorded internally	
	* Bar code reader facility required for automated registering of samples	
	* must support calibration	
	* LCD display for testing parameters visualization.	
	* Micro pipes maximum accepted volume not less than 1.5 ml. /automated and manual mode	
	* Capability to use reagents of most common brands without exclusive use	
	of reagents produced by a single supplier for at least 85% of all possible	
	equipment tests and analysis and reagents available, and for placement	
	closed system otherwise open system	
	5. System Configuration Accessories, Spares, Consumables and other	
	components: Complete spare is need	
	* *	
	All necessary reagents for at least 5,000 samples testing	
	Complete set of calibration / test samples for all tests (50 sets if not reusable) UPS and stabilizer with one unit	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication	
	materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30 °C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code		Department
	Item Detail	
Ccan-91	1. Generic Name: Analyzer - Clinical Chemistry,	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: Chemistry Analyzer is required for the detection and quantification of blood chemistry and othe body fluids.	
	4. Technical Specification:	
	The Operational Requirements: should be with programmable memory -	
	The Processing mode: - patient by patient , Test by test and STAT mode	_
	Operating Mode: End point, Kinetic, initial rate, monochromatic, bichromatic, turbid metric, serum blank (differential), fixed time, optics and wavelength range.	
	System: open system-able to work with reagents and supplies from other manufacturers	_
	Automatic Wavelength selection by multi-position filter wheel – selection from wavelength of 340 – 800 nm.	
	- Throughput: more than or equal to 200 tests/hr under speed optimized conditions	_
	- Assay: End point, rate assay, fixed point assay	
	- Calibration: Linear, non-linear, with possibility of two and multi point calibration; multi point calibration for kinetic and fixed type modes.	
	- Light Source: long life halogen or equivalent lamp.	
	- resolution : 0.0001 Abs	
	Temperature control: cuvette heating (electrical) in caruousel and reading path: 37 0C	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1- main unit	_

2- Graphic printer- for printout of parameters, results, calibration curves,

kinetic and statistics, facility to store data in PC through connecting data

cable and related software must be provided along with quotation.

3- Desktop PC (microprocessor with speed not less than 3.00 GHz, 512MB

RAM, 80 GB HDD, 105 keys Board, scroll mouse,

multimedia kit, 56 kbps modem 32 MB AGP Card, 52xCD CD-RW Drive,

with 17" TFT Digital Color Monitor) with compatible Operating system

must be provided along with quotation

4-Complete Start up kits consumables (reagents, kits, controls...),

accessories, and spares required for installation and standardization of the

system to be provided.

5- Reusable: cuvette block for 4 tests Each

: Reagent bottles

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

Document: Capital Medical Device Technical Specification

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

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User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Mibl-90	1. Generic Name: Microscope - Binocular, LED	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: To magnify and study specimens and small]
	objects by transmitted visible light	
	4. Technical Specification:	
	Microscope frame with revolving, 30 degree inclined binocular tube 360 degree	
	rotatable head illuminator LED light source with white light intensity control and LED light life more than 10,000 Hrs.	
	Fixed graduated mechanical stage approx. 200 x 150 mm, travelling approx. 80 x 50 mm	-
	Double slide holder	1
	Coarse focusing: approx. 3 mm per rotation	1
	Fine focusing: approx. 0.3 mm per rotation	1
	Range of magnification: 40 to 1000x	1
	Reverse angle quadruple revolving nose-piece, with distinct click-stop, with rubber	1
	grip for easy handling	1
	Objectives, full plan achromatic: 4x (0.10 NA), 10x (0.25 NA), 40x (0.65 NA), 100x	1
	(1.25 NA, oil) and 100X oil immersion	
	Condenser: Abbe with iris diaphragm aperture, 1.25 NA]
	Eyepieces: Focusable pair, 10x (FN 20), with inter-pupillary distance- and dioptre]
	adjustment	
	Retractable eye guards	
	Filter: blue	
	All optics anti-fungus treated	
	Brightness control: 0 to 100 % (linear)	
	Detachable plano-concave mirror unit with adjustable convex and concave mirror on alternate side	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	_
	Ø 1 x Pair eye shades	_
	Ø 1 x Pair of tube caps	_
	Ø 1 x Oil, immersion	_
	Ø 1 x Lens cleaning kit consisting of lens cleaning tissue, 100 ml cleaning	
	solution, dust blower	-
	2 x Fuse	-
	1 x Power cord	-
		-
	dust cove and storage box	

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Hema-91	1. Generic Name: Analyzer-Hematology, 5 Differential	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	Automated differential blood count: Automated hematology instruments using multiple parameters and methods (such as fluorescence, flow cytometry and impedance) are used to count and identify the 5 major white blood cell types in blood (so-called 5-part differential count): neutrophils, lymphocytes, monocytes, eosinophils and basophils.	
	4. Technical Specification:	1
	Principles:]
	Electrical impedance method with advanced SRV technology for accurate & precise total count	
	Diode based LASER Technology for 5 part differential	
	Photometry – LED based technology for hemoglobin	
	Parameters: Not less than 24 parameters (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM#, MON#, NEU#, EOS#, BAS#, LYM%, MON%, NEU%, EOS%, BAS%, RDW-SD, RDW-CV, PDW-SD, PDW-CV, MPV,PCT)	
	Plus: 2 scatter-grams, – WBC 5 part differential & WBC/Baso and 3 histograms –RBC, WBC & PLT	
	Throughput: 60 tests / hour	
	Sample mode: whole blood in open & closed mode with pre-dilution capability	
	Chambers: Dual chamber advanced system	_
	Auto Clean Modes: Available	
	Quality control : 3 levels, average, + (-) range SD and CV for all measured and calculated parameters, Levey Jennings Chart, Separate QC database	_
	Quality control results must be viewable by operator, stored, readily retrievable.	
	Sample volume: 110µl of whole blood in open & closed mode	

Fault statistics: RBC and WBC clogging < 3% of measurement (normal use)

Calibration: - Automatic (by calibrator) with 1-, 2-, or 3 measurement, or factorial (manual) calibration of WBC, HGB, PLT, MCV, RDW, MPV, PDW.

Automatic sampler with rack for 50 samples

Preferable, if it measures also body fluids like CSF, pleural

Data capacity: 100 000 results with all scatter-grams & histograms

Peripheral ports: USB interface (4), Support for host computer, Support for external printers, Support for hand-held barcode reader

- Display: LCD screen
- Indication of self-test failures and assistance messages
- Sample ID, date and time are reported with test results
- Supplied complete with dedicated data analysis and data management software
- Results are reported on external inkjet printer
- Casing, corrosion proof material such as plastic or epoxy coated steel

Data back-up method: USB mass storage device

Software upgrades method: Via USB port

5. System Configuration Accessories, Spares, Consumables and other components:

UPS and stabilizer as one unit, with maintenance free batteries for minimum one-hour back-up

Supplied with external printer with local market available cartilage

continues supply of reagents controls and calibrators

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment:

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including

labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Refb 90	1. Generic Name: Refrigerator- Blood bank, 300L/500L/700L	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Upright refrigerator for storing whole blood or red blood cell packs in a blood bank.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant	
	Storage capacity: 300L/500L/700L	
	Easily adjustable ≥ 3 shelves	
	Fan-cooled for even distribution of air in the cabinet.	
	Roll out drawers easily height adjustable.	
	Material, internal: , Drawer made of stainless steel .	
	Material, external: stainless steel or epoxy coated steel.	
	Insulation material: polyurethane, CFC-free	
	Lockable door, glass	
	Electronic temperature control: 2°C to 6°C.	
	Accuracy, whatever the load: +/- 1 C	
	Hold-over time: min 6 hrs (full load at 4 °C (+/- 1 C) takes at least 6 hrs to	
	reach 10°C, at ambient 32°C)	
	Cooling-down time: max 8 hrs (full load at 37 °C (+/- 1 °C) takes max 8 hrs for all packs to reach 6°C)	
	External digital display with actual interior temperature, minimal graduation 0.1 C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures, sensor fail	
	Battery back-up for audio and visual alarm system, and temperature recording device Fit with remote alarm connection and interface	
	Fitted with integrated castors	
	Minimum compressor starting voltage: 22 % below nominal voltage	
	Supplied with automatic voltage regulator:	
	Microprocessor controlled spike and surge protection, and protection	
	against disturbances	
	Accepted input range: -20 % to +20 %	
	Response time: <15 ms	
	Multiple LED bar-graphs display: connected/disconnected status,	
	voltage fluctuation and load as % of nominal current	1

Electronic fuse disconnects and reconnects automatically

KVA rating matches power consumption of the refrigerator

Nominal output voltage: 110-240 V / 50 Hz, single phase

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Frep-90	1. Generic Name: Freezer - Plasma, 300L/500L/700L 2. GMDN/UMDN Code/Name: 3. Clinical Purpose/Description: Blood plasma freezers are used for plasma storage.	Laboratory
	3. Clinical Purpose/Description:	
		I
	Blood plasma freezers are used for plasma storage.]
	I I I I I I I I I I I I I I I I I I I]
	4. Technical Specification:]
	Hold over time during: power cut: Greater or equal to 6Hr]
	Ice pack freezing capacity: At least 30 Kg/24 hour]
	Features: Temperature range: down to -40 C. Hot zone appliance]
	compression type	
	Refrigerant CFC free	_
	Automatic defrost.	
	Fan-cooled for even distribution of air in the cabinet	
	Easily adjustable shelves	
	Easily adjustable ≥ 3 drawers]
	Lockable door, solid]
	Electronic temperature control: up to -50°C]
	Accuracy, whatever the load: +/- 1 C]
	Temperature monitoring:	1
	External digital display with actual interior temperature, minimal graduation $0.1~^{0}\mathrm{C}$	
	Electronic temperature recording device]
	Audio and visual alarm system indicates unsafe temperatures	1
	Battery back-up for audio and visual alarm system, and temperature recording device Fitted with integrated castors	
	Minimum compressor starting voltage: 22 % below nominal voltage	
	Supplied with automatic voltage regulator:]
	Microprocessor controlled spike and surge protection, and protection against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status, voltage fluctuation And load as % of nominal current	
	Electronic fuse disconnects and reconnects automatically	_
	KVA rating matches power consumption of the freezer	
	Power requirements: 220V / 50/60 Hz	1
	Fower requirements. 220 V / 30/00 Hz	
	Accepted input range: -20 % to +20 %	1

5. System Configuration Accessories, Spares, Consumables and other components:

Spare parts to be included for each freezer

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

		I _
Base Code	Item Detail	Department
Anbg -90	1. Generic Name: Analyzer - Blood Gas	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Blood gas analyzers are used to measure blood gases, electrolytes, Ph values, concentrations of lactate, hemoglobin, several electrolytes, oxyhemoglobin, carboxyhemoglobin, and methemoglobin and other biochemical parameters of the blood 4. Technical Specification:	
	Compact design, light weight	-
	Fully automatic, upgradeable, fast electrolyte analyzer	-
	Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric Pressure, Na+, K+, Ca++, Cl-, Bl urea and Sr Creatanine & Blood sugar. All these parameters should be measured simultaneously	
	Calculated parameters should include BE, BE ecf, HCO3, Lactate, Anion Gap, SaO2 etc	
	Sample volume: <100ul.	-
	Result should be available: < 45 sec	-
	Maintenance free electrodes with individual electrodes ON/OFF facility Fully automatic liquid calibration of all parameters at user-defined intervals without the use of Gas calibrated reagents, external gases, tanks or regulators Continuous reagent level monitoring with graphic display.	
	Storage of data of 1000 procedures	-
	Rinse procedures and reference measurements performed with each sample	-
	Automatic zero calibration within each cycle	1
	Patient results, calibration, maintenance schedule and quality control data are displayed on well-illuminated, adequate size LCD color touch screen display. Noise level: <60dB	
	pH Analyte	-
	Measuring Range: 6.8 - 7.8pH	-
	PO2 Analyte	-
	Measuring Range: 0 - 760mm Hg	-
	pCO2 Analyte	
	Measuring Range: 5-100 mm Hg	
	Na+ Analyte]
	Measuring Range: 100-180mmol/L	
	K+ Analyte	
	Measuring Range: 1-10mmol/l	
	Ca++ Analyte	
	Measuring Range: 0.25-5.00mmol/l;]

Hct Analyte

Measuring Range: 15-70%

tHb Analyte

Measuring Range: 3.0 -23g/dL;

Heat disbursed through a exhaust fan

Easy and safe transport stable when tabletop mounted.

Different report lay-outs are selectable

Data print out on built in graphic printer.

Built in auto quality control facility

Automatic result processing, test ordering and transmission to Hospital Information System

Automatic data archiving and customizable layout.

Data backup with read/write CD-ROM drive

USB ports for easy connection of e.g. flash drives, keyboards, etc.

5. System Configuration Accessories, spares, Consumables and other consumables:

Blood Gas Analyzer -01

Reagents for one year 20 samples/day or as per requirement should be provided along with the machine.

Electrodes for all the parameters specified -01 set

Quality control tools/reagents for one year 20 samples a day-01 set or as per requirement.

Two sets of spare/replaceable fuses, reagents and capillary tubes sufficient for 100 tests;

Cartridges-combination of various tests;

External source of gas (if applicable);

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Mcil-90	1. Generic Name: Microscope - Inverted	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	An inverted microscope is a microscope with its light source and condenser on the top above the stage pointing down, and the objectives and turret are below the stage pointing up.	
	For analysis of cell tissue culture and CPE in culture vessels, micro test and microtitration plates using bright field and phase contract with transmitted light	
	4. Technical Specification:	_
	A 4x, A Ph 10x (phase contrast) and SPL pH Ox (phase contrast) with large working distance.	-
	Objectives for bright field and phase contrast with 40xmagnification and Height adjustable 30W high light density halogen lamps	
	Illumination unit swivels for contrast adjustment and Large specimen surface (max 220 mm).	-
	5. System Configuration Accessories, spares, Consumables and other consumables:	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment:	_
	Operating Temperature: +10°C to +43°C	
	Relative Humidity: <85%	
	7. Utility Requirement:	
	Power: 220V / 50Hz	
	Compatible UPS with maintenance free battery and Resettable over current breaker (voltage regulator)	
	Resettable over-current mains fuse to be incorporated	
	Electrical protection by resettable over-current breakers or replaceable fuses fitted in both live and neutral lines	
	8. Standards & safety Requirements:	

Document: Capital Medical Device Technical Specification Version 1: November, 2019 G.C.

Page 416 ISBN No: Shall meet IEC-60601-1-2:2001(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Should comply with quality system- Medical device applicable to manufacturers and service providers that perform their own design activities

Should comply with electrical safety requirements for electrical equipment for measurement control and laboratory use

9. Installation/Training Commissioning:

The supplier must be provide installation, and commissioning of the device

The supplier must be provide technical and end user training for two weeks on site.

10. Warranty/After sale Service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of installation.

After basic warranty the supplier must be provide Five years maintenance contract period with price break down.

11. Documentation:

User, technical and maintenance manual must be supplied in English

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods must be clearly marked and securely packed. Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively

Additional packing and labeling requirements should bear in each package

Federal Democratic Republic of Ethiopia Pharmaceuticals Fund and Supply Agency (EPSA)

Tender and Purchase Order No.

UMDNS Name and Model of the product

P.O. Box 25-11-276 32 65	
TEL: 251-11-276-32-65	
FAX: 251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Departmen
Dase Coue	Item Detan	Departmen
Inst-90	1. Generic Name: Inspissator -TB Culture Preparatory	Laboratory
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	7
	Used for preparation batches of uniform TB culture medium in clinical	7
	research laboratory	
	4. Technical Specification:	
	Ergonomically designed with a digital display which is easily read from a distance.	
	The unit consists of tank, vessel/tray and outer case which are made of stainless steel	
	digital temperature control	
	Incubation temperature: 80°C	
	Temperature uniformity: ±0.9°C	
	Inspissations time: 47 minutes	
	a facility to maintain constant liquid level and temperature	
	capacity of 150 test tubes or 160 universal containers	
	5. System Configuration Accessories, Spares, Consumables and other	
	componenets:	
	Insect resistant blanket and quilt replacement for Inspissator	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication	
	materials including items not specified above	_
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	
	10. Warranty and After Sale service:	
	The supplier must be provide minimum of Two years warranty including	
	labor and spare part from the date of commissioning.	

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Mira-90	1.Generic Name: Microtome - Rotary, Fully Automated	Laboratory
	2.GMDN/UMDN Code/ Name:	
	3.Clinical Purpose/Description:	
	Fully motorized heavy duty automated microtome: Rotary microtome is precision instruments designed to cut uniformly thin sections of a variety of materials for detailed microscopic examination.	
	4.Technical Specification	
	Section thickness range should be between 0.25 to 100μm with increments in the range of 0.5μm, 1μm, 5μm with LED display.	
	Trim thickness range should be 1-600μm with 1μm, 2μm, 5μm and 10μm increments, respectively with LED display.	
	Vertical stroke 70-80mm. Specimen advance 30-35mm.	
	Section counter, knife angle position locator and specimen orientation light facility should be there.	
	Emergency stopping facility and lockable hand wheel should be present.	
	It option of foot pedal operation and emergency stop button in automated mode.	
	Automatic object return to starting point and connection for backlighting with cold light source.	
	Directional specimen holder fixture with quick clamping system, standard clamp and universal cassette clamp.	
	Round specimen holder with all accessories.	
	spacious, removable section waste tray with integrated armrest.	
	5.System Configuration Accessories, Spares, Consumables and other components:	
	Fully Automated Rotary Microtome with accessories	
	Universal knife holder base, disposable blade holder, disposable blades,	
	Stereo zoom microscope attachment for glass knife sectioning with cold light source using gooseneck.	
	Glass knife maker, Glass knife holder. Glass knife box, high quality glass strips for making glass knife (~30 pcs).	
	Glass knife maker and its accessories should complete the whole system from breaking to making of glass knife ready to use.	
	The specimen holder of microtome should be capable of holding resin blocks for sectioning.	
	Instrument should be capable of making semi-thin section of resin embedded sections with the help of glass knife.	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication	

materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Mirm-90	1.Generic Name -Microtome - Rotary, Manual	Laboratory
	2.GMDN/UMDN Code/ Name:	
	3.Clinical Purpose/Description:	
	Rotary microtome is precision instruments designed to cut uniformly thin sections of a variety of materials for detailed microscopic examination. The microtome operation is based upon the rotary action of a hand wheel activating the advancement of a block towards a rigidly held knife.	
	4.Technical Specification	 -
	Microtome with accessories	
	• 1 universal knife holder base	
	• 1 disp. blade holder	 -
	• disposable blades 75 x 8 mm.	 -
	• 1 standard knife holder N, w/o base	
	• 1 Knife, 16 cm, profile c, steel	
	• 1 knife, 22 cm., profile d. steel	
	• 1 specimen orientation device	
	• 1 stand spec. clamp, orient	
	• 1 cooling stage, 40 mm. diam. w/CO2 hose, 150 cm.	
	• 1 trolley stand, CO2 bottle	
	• 1 quick-freezing nozzle with hose for CO2 freezing	
	5.System Configuration Accessories, Spares, Consumables and other components:	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	=
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	1
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	
	Equivalent)	4
	9. Installation, Training and Commissioning:	-
	The supplier must provide installation, and commissioning of the device at health Facility	_
	The supplier must provide onsite technical and end user training]

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Aeli-90	1. Generic Name: Analyzer – Elisa	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	ELISA (enzyme-linked immuno sorbent assay) is a plate-based assay technique designed for detecting and quantifying substances such as peptides, proteins, antibodies and hormones.	
	Micro plate ELISA Reader with printer	1
	Description: Reader with 8 channel and 12 channel modes	1
	Micro plate reader and evaluation unit for ELISA evaluation	1
	Multi channel auto reader with on-board data reduction and reporting.	1
	• For kinetics, endpoint and scanning read modes. Shaking mode.	
	Technical features:	
	• Wavelength range: 300-900 nm.	
	Absorbency ranges 0.000-4.000 O.D.	
	Serial and parallel interfaces.	
	Accommodates all 96-well micro plates.	
	• Six filter capacity. Filters supplied: 405nm, 450nm, 490nm, 630 nm.	
	Soft ware but not limited to the following	
	Point to point curve fit	
	Polynomial regression, linear & sigmoid regression, log &linear	
	User programmable open system	
	Selective plate formatting	
	Alphanumeric test name	
	Duplicate well options	
	Curve plotting and editing	
	Flags and error massage	
	Built in printer	
	ELISA, incubator,	
	Description: Oven with 4 plates	
	Technical Specifications	
	• Micro plate shaker / incubator suitable for all standard depth 96-well plates	
	Heated lid and base cover the plate entirely	
	Positions to accommodate 4 plates	
	• Continuous or timed operation, with alarm buzzer and automatic switch-off	_
	Temperature range: ambient plus 5 C to 60 C	
	• Temperature stability: approx. 0.1 C, uniformity approx. 0.2 C	

- Shaking speed: 250 to 1800 rpm, adjustable in steps of 10 rpm
- Orbit, approx. 2 mm
- LCD displays time set and elapsed, temperature set and actual
- Power requirements: 220 V / 50 Hz, with voltage surge protection
- Supplied with: UPS of sufficient capacity to ensure uninterrupted finalizing of ongoing testing, in case of power variations or power interruption

Micro plate ELISA Washer,

Description: Washer with 8 channel

Technical Specifications

- 8-channel strip manifold
- Open system, automatic
- Automatic rinse & prime programme
- 75 user-definable protocols
- Wash parameters include: 16-character assay name, number of cycles, wash volume, flow rate and variable soak times
- Dispense only and aspirate only modes for reagent addition and removal
- Built-in multi-speed shaker for improved CVs and reduced assay backgrounds
- Crosswise aspiration/double aspiration of flat bottom micro-plates for reduced residual liquid
- Bottom wash mode for rapid dilution of reagent
- Built-in vacuum & pressure pump assembly
- Bottles for waste rinse and wash
- Accommodates flat, U or V-shaped bottom plates
- Between 1 10 wash cycles
- Dispensing volumes from 25 to 3000 ul
- Soak time: 1-600 seconds
- Fluid flow rate in 150 to 1000 ul / well / sec to accommodate cellular assays
- Spill-over protection & electronics isolated from fluidics
- Optional automatic buffer switching
- Flip out aerosol cover or similar

5. System Configuration Accessories, Spares, Consumables and other components:

• Supplied with: UPS of sufficient capacity to ensure uninterrupted finalizing of ongoing testing, in case of power variations or power interruption

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base Code	Item Detail	Department
		-
Afcc-90	1. Generic Name: Analyzer – CD4	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	CD4 [abs] counter, provide absolute and percentage results of CD4 T	
	lymphocytes) concentration in whole blood samples.	
	4. Technical Specification:	
	Output: Quantitative CD4 Absolute count, CD4 %	
	Sample type: Capillary or venous whole blood	
	Sample volume: 20 - 25 μL	
	Reading time to results: 20 - 22 min for first sample. Then 4 minutes per]
	sample	
	Throughput (per 8 hrs working day/operator):90 - 110 tests	_
	System Batching capabilities	
	System Built-in printer and optional external printer ,USB, RS232	
	connectivity	_
	Number of tests results printed with 1 paper roll: 100 - 120	
	Data storage: Approx. 10,000 test results	
	Connectivity	
	System Built-in voltage surge protection	
	Capacity battery life (in hours and test runs): 8 hours	
	System Factory calibrated	
	System Internal quality control (IQC)	
	System Compatible with external quality control scheme(s)	
	5. System Configuration Accessories, Consumables and other	
	components: probes, different types of tubes, with all standard accessories and	_
	consumables must be provided.	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	1
	Operating Temperature:+10 °C to + 30 °C	1
	Relative humidity: < 85%	1
	7. Utility Requirements:	1
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for	1
	Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or	1

Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

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Base Code	Item Detail	Department
Pcrm-90	1. Generic Name: Thermocycler, PCR machine or DNA amplifier	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	It is a laboratory apparatus which most commonly used in genotyping, cloning, mutation detection, sequencing, microarrays, forensics, and paternity testing to amplify segments of DNA via the polymerase chain reaction and to facilitate other temperature-sensitive reactions,	
	4. Technical Specification:	
	Running facility of different temperature in the same plate with user defined time determines the optimal annealing temperatures. Fits all standard Thermocycler, real time PCR systems and DNA sequencers Individually wrapped sterile, RNase and DNase free Well edges slightly raised facilitates plate sealing Thin walls for optimal thermal transfer On board calculating facility to approximate the optimal annealing temperature.	
	The system support PCR volumes. Choice of saving the methods to USB	
	memory stick. Programmable heat lid cover for efficient PCR optimization. The system allows easy product updates via USB port.	
	Peltier based heating and cooling.	
	Thermo block made of silver. Capable of testing temperatures at Denaturation, Annealing & Extension steps Gradient technology ensure identical ramp rates in both gradient and normal operations.	
	Inbuilt advance scheduling feature for users convenience will be a preference Programmed templates and protocols. Auto Restart facility with user defined time interval when power fails and resumes. Email notification to the logged-in user whenever certain errors, warnings, and	
	system events occur. Temperature control modes providing flexibility for different applications Adjustable user defined ramp rate to meet sensitive experimental conditions. Advanced security features.	
	Monitor indicates the step, cycle and remaining runtime. Minimum two USB ports. Ethernet port. Log book function for error messages and new calibration.	
	Automated for both real-time PCR and post-PCR (end point). Analysis using in-built Peltier based PCR machine. Excitation source LED light source. System flexible to	
	support 96 well plates. Easy door design for loading and unloading 96-well plates. The instrument have display with an TFT touch screen about 8.5 in. ±0.1°C temperature uniformity across the whole block instantly after	

every temperature change means that any well, in any instrument Record every well, with every filter, in every cycle.

Record every well, with every filter, in every cycle. 96-well format with 0.2 ml supported by 96 well plates and strips Well edges slightly raised facilitate plate sealing

Thin walls

for optimal thermal transfer Well shape:U-bottom

Laser Printer Type

Paper Size A4 Automatic 2–sided (Duplex) Print Resolution: 2400×600 dpi Print Speed: Up to 40 ppm single side print and 20ppm duplex side print

PC with at minimum: 3GHz CPU Quad Core i7, 64-bit operating system Medical Grade 21-inch LCD monitor with a minimum 1920 x 1080 resolution 8 GB RAM

500-GB hard drive 1000x sheet of paper UPS system with minimum 2Hr back-up Voltage stabilizer of appropriate rating

5. System Configuration Accessories, Spares, Consumables and other components:

High-Power USB Wi-Fi Module x (1set)

Temperature Verification Kit x (1set) Thermal Cycler Power Cord x (1set) Thermal Isolation Frame x (1set)

Complete Reagent startup kit

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit

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Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Departme
Staa -90	1. Generic Name: Auto Histology/cytology slide stainer	Laborato
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Slide stainer automates the staining of prepared cytology and/or histology	
	tissue specimens by diffusing dyes into the specimens through surface	
	adsorption, direct staining, indirect staining, or mordant staining.	
	4. Technical Specification:	
	Automatic Slide Staining Machine ,One touch, walkway automation – from	
	drying to glass cover slipping to ensure high levels of laboratory efficiency user	
	Menu-driven Safe and homogeneous Slide staining mechanism.	
	Fully automatic and programmable reagent management system.	-
	Flexible transmission mechanism & Precise positioning system ensure	-
	stable staining, and with two water station and 24 work stations with timing	
	in minutes and seconds, facility for single and double load.	
	Self-contained bench-top unit that is menu-driven, microprocessor	
	controlled, and fully programmable and whether it is bench top or not	
	necessary if it is fulfills the other features user:	
	Windows in closed fume hood that allow easy loading and unloading	
	without opening the entire hood.	_
	Automatic Slide Staining Machine equipped with slide washing and	
	charcoal filtering system	1
	Staining capacity > 60 is more than enough in our testing capacity user:	_
	With rinsing station, heating station and heating station for drying.	
	Easy refilling of reagent troughs by simple removal from instrument.	
	Adjustable agitation of the slide basket	
	Compatible with all standard slide baskets	
	Processing parameters printed using a printer.	
	All process parameters displayed by TFT Touch screen display with touch	1
	controls and menu.	
	Infiltration time separately programmable for each station	
	Easy editing and changing of programs, even during processing	
	Audiovisual alarms, error messages and warning codes	
	Fume Extraction Active carbon filter	1
	UPS system with minimum 8Hr back-up	1
	Voltage stabilizer of appropriate rating	1
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	
	Tank covering lid x (1set)	
	Charcoal filter x (1set)	

Water tank x (1set)

Hose for water fill x (1set)

Tank holder basket x (1set)

Slide holder basket x (1set)

Reagent tank x (1set)

With all standard and complete accessories /Consumable startup kit

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Cenb-90	1. Generic Name: Centrifuge – Refrigerated, Blood Bank	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	It used for separating blood and blood components from whole blood like platelet, plasma, RBC and Cryoprecipitate and Functions as a centrifuge and cell washer specifically for blood banking procedures.	-
	4. Technical Specification: Microprocessor control, operated by touch panel, LED or LCD display, operated data can be saved automatically, RCF value can be set directly for working, easy to use.	-
	Rotor identification system, over speed, over temperature, door interlock, unbalanced protection	
	Display: RPM, RCF, Time, Temperature, Program, Accel/Decel, Rotor Number, Rotor Radius	
	Capacity:12x6000ml(12 blood bags) Speed Accuracy:±20rpm Time Range:0-99H59min59s	
	Dimension :aprox830×720×1250(mm) Net Weight :Greater than 260kg	
	Noise Level ≤ 60 dB(A) Acceleration/ Deceleration :0~9. The shortest Acceleration time : Speed 0~6000rpm)	
	5. System Configuration Accessories, Spares, Consumables and other components:	-
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85% 7. Utility Requirements:	+
	Electrical Power Supply: 220VAC ±10%/50HZ	_
	8. Standards and Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning: The supplier must provide installation, and commissioning of the device at	-
	health Facility	

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package Each item with all accessories /spare part configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Mif-90	1. Generic Name: Microscope - Fluorescence	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Fluorescence microscope observation visualizes intracellular structures, particularly protein and molecular structures, using fluorescent proteins or dyes, Using the phenomena of fluorescence and phosphorescence	
	4. Technical Specification:	
	Fixed Kohler with reflected and Fluorescent illumination	
	Objectives	
	Plan-APOCHROMAT with magnifications of $10x \text{ NA } 0.25 \text{ WD } 10.6 \text{ mm}$, $20 \times \text{NA } 0.40 \text{ WD } 1.2 \text{ mm}$, $40 \times \text{NA } 0.75 \text{ WD } 0.51 \text{mm}$ and $100 \times \text{NA } 1.30 \text{ WD } 0.13 - 0.2 \text{ mm}$ optimized for specimens without cover slip (D = 0),Illumination	
	Fluorescent microscope with digital camera(optional)	
	Transmitted light	
	*LED Reflected light and Fluorescence module with 455 nm LED and light source and Halogen Lamp: 6 V/12V, 30 W/100W with Light source adjustment range: Fully adjustable between 1.5 V and 6 V DC(100W mercury, 75W xenon, and 150W metal halide arc lamps are commonly used)	
	Color temperature at 6 V:2,800 K and Luminous power:280 lumens	
	Average life: 1,000 hours ,and Illuminated area: 1.5×3 mm	
	LED Module: Max. 40 mW, 365 – 625 nm; LED hazard group 2 according to DIN EN 62471	
	Switching objectives: Manually using four-way objective revolver	
	Objectives: Range of infinite focus objectives with W 0.8 screw thread	
	Eyepieces:30 mm diameter, With visual field number 18: PL $10 \times / 18$ Br. foc.	
	With visual field number 20:PL 10× / 20 Br. foc.	
	Object stage:XY stage, 75×30 right/left, and Dimensions (width × depth) :140 × 135 mm	
	Range of adjustment (width \times depth):75 \times 30 mm	
	Coaxial drive: Optionally right or left	
	Verniers:Can be read off from left	
	Object holder: With spring lever left	
	Abbe condenser 0.9/1.25; fixed Kohler For Vobj 4× to 100×	
	Abbe condenser 0.9/1.25; full Kohler For Vobj 4× to 100×	
	Binocular Tube 30°/20	

Maximum field of view:20

Eyepiece distance (pupil distance): Adjustable from 48 to 75 mm

Viewing angle:30°

Viewing height:380 to 415 mm

Visual output: Tube factor 1×

5. System Configuration Accessories, Spares, Consumables and other components:

Transport case

*Rechargeable battery pack

*Illuminating mirror

rechargeable battery: Fuses according to IEC 127 T4.0 A/H

Halogen Lamp

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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PO Box 25-11-276-32-65
Tel: +251-11-276-32-65
Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Name	Department
Eegm-90	1.Generic Name: EEG Machine	Neurology
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	An electroencephalograph have electrodes placed on a patient's scalp to measure, amplify, display in graphic form, and record the weak electrical signals generated by the brain.	
	4. Technical Specification:	1
	Number of EEG Channels should be 32 with color coding, and another eight channels for Polygraph. Also any two channels can be configured as Bipolar, AC or DC through software	
	Facility for simultaneous sampling of all EEG channels and multiple sampling rates.	
	Phonics Stimulator with software programmable for manual or automatic sequences.	
	Networking facility	
	DICOM compatible	
	32 Channel Amplifiers needed.	
	CMRR≥ 110 dB or better	
	Noise $\leq 2uV$ peak to peak	
	Input Impedance≥ 100 Mohm	
	16 bit ADC resolution voltage of 0.15 uV	
	Low filter adjustable between 0.16 to 5 Hz.	
	High Filter Adjustable between 50 to 100Hz.	
	Notch Filter Adjustable to software.	
	Acquisition Sensitivity from 1 microvolt per mm to 2000 microvolt per mm.	
	Networking facility	
	Acquisition Software:	
	Facility to combine all user defined settings into templates or protocol, for use in different applications.	
	Facility for Individual Channel Control, Customization of Montages, along with Remontage Capabilities.	
	Graphical view of the current montage during the EEG recording.]
	Facility to define New Sensors should be possible as standard i.e. assign to amplifier inputs, define traces in a mintage, define calculated channels (Average, Source/Laplacian)	
	Facility to click any point to display corresponding traces & Slide pointer to change displayed duration of the Overview.	-
	Facility for sortable list of all events placed in the recording, both automatically and manually.	

Facility to review and add events to recorded traces.

Facility for automatic time counters and event insertion during Hyperventilation.

Facility to controlled display Sensitivity for User defined value.

Facility to choose Low & High Cut Filters along with facility to enter any user defined value.

Facility to file zip

Facility of configurable Time Base

Spike & Seizure software

1Trend Analysis software

Review Software:

Paging facility as Automatic Paging, Mouse controlled Paging and/ or Keyboard Paging.

Playback of EEG for more channels.

Facility for Zoom/ Magnify EEG trace

Facility for Copy & Paste of EEG or Trends to reports and presentations

Facility for Automatic generation of reports.

Facility for viewing several recordings in tiled or cascading windows

Patient Administration Software:

Network supported patient and test management software, archive to CD or DVD, powerful search, patient folder, workspaces

Upgrading the digital EEG to Video EEG with day/night camera using MPEG-2 latest a generation technology

Video camera to control patient movement

all components for video EEG up gradation

Resettable over current breaker shall be fitted for protection

5. System Configuration Accessories, Spares, Consumables and other components:

Compatible Laser Printer with 600 DPI Resolution and A4 Size printing facility – 01

Patient cable and connectors with electrodes and electrodes with head cape, Papers for at least 1000 EEG Exams and all the necessary power cables and other interfaces.

Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications.

Suitable UPS with maintenance free batteries for minimum three-hour back-up should be supplied with the system.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

•			
2. GMDN/UMDN Code/Name:: 3. Clinical Purpose/Description: Infant radiant warmer used for the treatment of hypothermia on infants and it consists of a biocompatible bed, overhead heater with suction unit. 4. Technical Specification: Mobile, mounted on 4 double swiveling castors wheels, all 4 with brakes. Antistatic castors, with breaks Table surface with conductive mattress with infant head/shoulder support Mattress-padding: foam density approx 25 kg/m3. Mattress cover: Memory Foam Mattress, waterproof, washable. resistant to cleaning with chlorine based solution and flame retardant Side boards transparent acryl, drop down and lockable Bassinet trolley; bed should be tilt able and have provision for X-Ray cassette holder. Markings on the bassinet and X-Ray cassette holder are mandatory to enable proper positioning of the baby while doing the X-Ray. Integrated T-piece resuscitator with adjustable controls of PIP and PEEP. Integrated Balance Scale. With built-in blender for controlling levels of Oxygen concentration from 21% to at least 60% With Built in Medical air compressor. Under table 2 storage drawers. Side rails allow for mounting of accessories. Hood suspended above the table integrates heating element and overhead light. Overhead light: LED Base should be height adjustable with electrical foot switches on both sides. Integrated support for two not less than 10L oxygen cylinder. Display with LED screen full color for displaying graphics and trends of air temperature, Skin temperature (main temperature and peripheral temperature,) Oxygen concentration in the environment, newborn's weight, Respiration, heart pulse and newborn data. Feather touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection	Base Code	Item Detail	Department
3. Clinical Purpose/Description: Infant radiant warmer used for the treatment of hypothermia on infants and it consists of a biocompatible bed, overhead heater with suction unit. 4. Technical Specification: Mobile, mounted on 4 double swiveling castors wheels, all 4 with brakes. Antistatic castors, with breaks Table surface with conductive mattress with infant head/shoulder support Mattress-padding; foam density approx 25 kg/m3. Mattress cover: Memory Foam Mattress, waterproof, washable. resistant to cleaning with chlorine based solution and flame retardant Side boards transparent acryl, drop down and lockable Bassinet trolley; bed should be tilt able and have provision for X-Ray cassette holder. Markings on the bassinet and X-Ray cassette holder are mandatory to enable proper positioning of the baby while doing the X-Ray. Integrated T-piece resuscitator with adjustable controls of PIP and PEEP. Integrated Balance Scale. With built-in blender for controlling levels of Oxygen concentration from 21% to at least 60% With Built in Medical air compressor. Under table 2 storage drawers. Side rails allow for mounting of accessories. Hood suspended above the table integrates heating element and overhead light. Overhead light: LED Base should be height adjustable with electrical foot switches on both sides. Integrated support for two not less than 10L oxygen cylinder. Display with LED screen full color for displaying graphics and trends of air temperature, skin temperature (main temperature and peripheral temperature, Noxygen concentration in the environment, newborn's weight, Respiration, heart pulse and newborn data. Feather touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection	Wari-90	1. Generic Name: Warmer - Radiant, Infant	NICU
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disinfection		Feather touch operation with large digital display and comprehensive	
Control unit has flow meter and displays pressure.			
YY . 1		A V A	
Heating element: emitter with parabolic reflector and protected by metal grid			
Control unit allows air and skin temperature preset (LED indicator) and drives radiant heater Output (servo and manual)			
Equipped with Oxygen analyzer module to monitor O2 levels at the ambient.			

Combined with an acrylic helmet, can be used to administer a closed environment with higher concentrations of O₂

Integrated timer: 1 to 59 min, with count-up and count-down feature

Temperature range, skin: 34 to 38 deg C (user pre-settable)

Bed can tilt continuously up to \pm 12° for Trendelenburg proclive & declive positions, through electric command buttons.

Monitoring of skin temperature by means of sensor, range: 30°C to 42°C

Heater Type: Stainless steel or equivalent

Heater output: 0 to 100% in increments of 5%

Built-in SpO_2 module to measure O_2 saturation and heart pulse with information to be displayed on the control panel LED screen.

Audio and visual alarms for: Power failure, Probe failure or disconnected, Heater failure, Temperature higher or lower than set temperature, Oxygen concentration higher or lower than set, SpO₂ probe failure or disconnected.

Display reports systems errors, sensor failure.

Control unit: audiovisual alarms according to timer and temperature presets avoiding overheating

Protection: OVP, earth leakage protection.

5. System Configuration Accessories, Spares, Consumables and other components:

- 1 x Memory Foam Mattress
- 3 x skin temperature probe (including connection cable)
- 3 x spare skin temperature probe (including connection cable)
- 1 x spare heating element
- 2 x empty 10L and Medical oxygen cylinders

Skin adhesive for fixing probe – 100 units

Acrylic helmet – 1 set of 3 sizes

5 x spare 0f set fuses

Eye pads for use during phototherapy -50 units

IV pole

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

n ~ -		-
Base Code	Item Detail	Department
Incn-90	1. Generic Name: Incubator - New born	NICU
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/ Description:	
	Used to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns that cannot effectively regulate their body temperature.	
	4. Technical Specification:	
	Electronic control of humidity, air temperature and infant skin temperature.	
	Clear, hard cabinet for infant viewing.	
	Double wall with air circulation.	
	Easy access control panel, with light touch operation switches.	
	Facility to elevate base, adjustable range.	
	Self-test functions are performed.	
	Controlled by microprocessor or microcontroller.	
	Servo controlled mode to adjust patient's skin temperature not lower than 34°C up to 38°C. Can be operate on the range from 36°C to 38°C.	
	Servo controlled mode to adjust compartment air temperature from 23°C or less to 37°C or more. Can be raised on the range from 37°C to 39°C.	
	Air filter	
	Minimal resolution of 0.1 °C.	
	Monitored parameters: air temperature, patient's skin temperature, oxygen concentration and humidity	
	Micro controlled humidifier with range 40 to 90%	
	Oxygen input flow rate 1 to 10 litres/min or oxygen concentration range 21 to 95%.	
	Maximum CO2 concentration inside incubator 0.2%.	
	Noise level in the interior of the hood less than 60 dBA.	
	Head end raise facility with auto lock.	
	Capable of use in X-ray without removing baby	
	Trendelenburg and inverse Trendelenburg positions.	
	Auto-calibration of measurement circuits.	
	Displayed parameters	
	Patient skin temperature	
	Compartment air Temperature and	
	Humidity	
	Oxygen saturation	
	Visual and audible alarms for:	
	Patient skin high/low temperature alarm.	

Air circulation / probe / system / power failure alarm.

Humidity alarm.

Temporal alarm silencer.

Heater power indicator

User Adjustable Parameters

Air temperature control from 23°C/73.4°F to 37°C/98.6°F

Patient temperature control from 34°C/93.2°F to 38°C/98.6°F

Humidity control from 40 to 90%

Oxygen input flow rate from 1 to 10 lpm

Components:

Transparent cabinet.

Double-wall with air circulation between the hood and the double wall.

One door with air curtain.

Mattress with washable and water proof cover; removable and not smaller than 55 cm (length) x 34 cm (wide).

Accommodates shelves and I/V poles.

Mounted on stationary table, base of which is at least 80 cm high

At least four ports for tubes access to the interior of the hood.

At least four ports to access the patient.

At least one door or drawer or accessories base

Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes. Mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium.

Humidifier Water tank capacity not less than 1 liter.

Mobility:

Cylinder Mounted on mobile, wheeled base, with breaks at least in two wheels.

5. System Configuration Accessories, spares, Consumables and other consumables:

One extra mattresses

3 extra sets of skin temp. sensors

3 extra sets of air temp sensors

Two extra sets of air filters

Sticky reflective patches.

Sleeves

oxygen analyzer (sensors)

Two extra sets of fuses

Mattress with washable and waterproof cover.

• Internal Quality control and calibration system and control material

6. Operating Environment;

Operating Temperature:+5 °C to + 45 °C

Relative humidity: < 85%

Document: Capital Medical Device Technical Specification

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601-2-19 (Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

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Addis Ababa

Base code	Item detail	Department
BiP-90	1. Generic Name: BiPAP	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway pressure (CPAP) that	
	gives a constant flow of oxygen/air to the patient at a preselected pressure, thereby	
	imposing a small overpressure within the lungs that assists the gas exchange	
	4. Technical specification	
	The system should meet all the numerical values given in the technical specifications	
	within a tolerance of +/- 10 %	
	IPAP 4 to 30 cmH2O	
	EPAP 4 to 25 cmH2O	
	Breath rate 0 to 30 BPM with spontaneous for time mode	
	Timed inspiration: 0.5 to 3.0 sec	
	Rise Time: 100 to 600 m-sec	
	Machine should be based on the solenoid valve technology and should offer preferably auto track sensitivity and adjustable risetime.	
	Filter: foam and ultrafine	
	LCD digital control	
	Altitude compensation: auto	
	Light weight, portable hand	
	Limiting the delivered pressure in the event of an occlusion	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 db at mid pressure range	
	User adjustable settings	
	Patient alarms	
	Equipment alarms to alert user to power failure,	
	low battery,	
	overheating,	
	mask / tube fault Inlet air filter to be fitted.	
	5. System Configuration Accessories, Spares, Consumables and other Components:	
	Five of each size of reusable, sterilizable masks and tubes (adult, pediatric, neonatal)	
	Two sets of fuses, if replaceable type used	
	Five replacement inlet air filters Supplier to specify if the following are available as options:	
	flow meter, humidifier, oxygen analyzer	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 45°C	
	Relative humidity: < 85%	
	·	
	7. utility requirement	
	Electrical Power Supply: 220VAC +/-10%, 50Hz	
	UPS of suitable rating with voltage regulation, spike protection and	
	maintenance free inbuilt batteries for 2hrsback up	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for	
	Electromagnetic compatibility. Or should comply with 89/366/EEC; EMC-directive.	
	Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	

Shall meet medical device quality assurance 93/42/EEC

CE marked

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

b). Drain Connection:

Drain outlet via either drilled floor or any other for drainage purpose

Connection: Ø 50 / 45 mm or copper Ø 35 / 30 mm

Capacity: ≥10 L/min

c). Electrical Connection:

Single phase electrical line from hospital MDB/Generator near to the machine (with grounding)

Single phase breaker with size as per manufacturer recommendation near to the machine.

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User/operating and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Base code	Item detail	Department
CP-90	5. Generic Name: CPAP	ICU
C1 70	6. GMDN/UMDN Code/Name:	100
	7. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway pressure (CPAP)	
	that gives a constant flow of oxygen/air to the patient at a preselected pressure,	
	thereby imposing a small overpressure within the lungs that assists the gas	
	exchange	
	8. Technical specification	
	Pressure range to be user settable and to include the range 4 to 20 mbar.	
	Controls to be easy to operate, numbers and displays to be clearly visible.	
	Pressure support: 0 - 45 cm H2O	
	Pressure ramp function required to assist falling asleep	
	Manual breath button	
	Feedback control of the warming.	
	Digital display of temperature.	
	Humidity compensation system.	
	Working flow range between 4 and 40 l/m.	
	Alarms at least for: lack of water; sensor failure; high, low temperature.	
	Monitoring of the air temperature: precision \pm 1° C.	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 db at mid pressure range	
	Displayed parameters	
	Tidal volume,	
	Inspiratory pressure, Inspiratory time,	
	- *	
	expiratory time, IE ratio,	
	FiO2	
	User adjustable settings	
	Patient alarms	
	Equipment alarms to alert user to power failure,	
	low battery,	
	overheating,	
	mask / tube fault Inlet air filter to be fitted.	
	5. System Configuration Accessories, Spares, Consumables and other	
	Components:	
	Five of each size of reusable, sterilizable masks and tubes (adult, pediatric,	
	neonatal) Two sets of fuses, if replaces his type used	
	Two sets of fuses, if replaceable type used	
	Five replacement inlet air filters Symplicate energify if the following are evallable as entires:	
	Supplier to specify if the following are available as options:	
	flow meter, humidifier, oxygen analyzer	
	Bubble CPAP ventilator:	
	1) 400 to 700 ml container.	

- 2) Mean positive pressure provided between 2 and 12 cm of H2O.
- 3) Single use entry and exit connectors.
- 4) Patient circuits for adult, pediatric or neonatal patients.

AirO2 mixer

- 5) Oxygen regulation scale between 21% and 100%.
- 6) Stainless steel or metallic antioxidant material.
- 7) Different connectors for Air and O2.
- 8) Flow meter for low flow values from 0 to 1 lt/min.

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+45 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. utility requirement

Electrical Power Supply: 220VAC +/-10%, 50Hz

UPS of suitable rating with voltage regulation, spike protection and maintenance free batteries for 2hrs back up

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

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Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

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Drain outlet via either drilled floor or any other for drainage purpose

Connection: Ø 50 / 45 mm or copper Ø 35 / 30 mm

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Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Venm-90 1. Generic Name: Ventilator - ICU, Mechanical 2. GMDN/UMDN Code/Name: 3. Clinical Purpose/Description: Mechanical Ventilator used for patients to breathe by assisting inhalation of oxygen into lungs and exhalation of carbon dioxide. 4. Technical Specification Display ≥10" LED/TFT touch screen Resolution of 1280 X 1024 Menu of functions appear on the screen. User interface with controls and display Pneumatic with electronic control and alarm Patient category: Adult, Pediatric and Neonate Mounting Trolley/Cast mounting for easy transportation: 4 Castor Dia. 10cm with brakes Integrated printer Ventilation parameters: Tidal volume: 10 - 2000 mL Respiratory rate: 5 - 80 BPM. Pressure: 0 - 100 cm H2O. Inspiratory Peak Flow: 4 - 100 1/min. Minute volume: 1 - 30 1/min. Oxygen Concentration: 21 - 100 % Inspiratory pause: 0.1 - 5.5 sec. PEEP/CPAP: 0-30 cm H2O. I:E ratio: 1:2 - 1:6 / 2:1 Graphical Display of flow(t), TV(t) Pneumatic Gas Sources: Gas delivery system by sound less in built compressor / external integrated compressor with the unit. In case of compressor failure also be operable with compressed air / oxygen supply of 45 to 60 psi. Automatic gas switch over if O2 supply fails Enables spontaneous breathing with filtered ambient air if air and O2 supply failed Digital output and input via interface Internal battery (maintenance free) with 4 hour minimum operating time for	D C 1	Tr. D. 4 T	D t
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Gas delivery system by sound less in built compressor / external integrated compressor with the unit. In case of compressor failure also be operable with compressed air / oxygen supply of 45 to 60 psi. Automatic gas switch over if O2 supply fails Enables spontaneous breathing with filtered ambient air if air and O2 supply failed Digital output and input via interface Internal battery (maintenance free) with 4 hour minimum operating time for		Graphical Display of flow(t), TV(t)	
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Enables spontaneous breathing with filtered ambient air if air and O2 supply failed Digital output and input via interface Internal battery (maintenance free) with 4 hour minimum operating time for			-
Digital output and input via interface Internal battery (maintenance free) with 4 hour minimum operating time for		Enables spontaneous breathing with filtered ambient air if air and O2 supply	
Internal battery (maintenance free) with 4 hour minimum operating time for			1
I the ventilator			
Direct access to vital settings			1
Transducer Sterilizable and reusable			1

PEEP valve built in Patient circuit separate inspiratory and expiratory limb Back up mode for apnea Full alarm system for all ventilator settings and monitored values Time simultaneous display of two waveforms. Display minimum 3 graphs and 2 loops Automatic leakage compensation Adjustable resistance compensation for endotracheal tubes Trans pulmonary pressure monitoring via esophageal catheter Automatic maneuver for static compliance assessment and lung recruitment including trans pulmonary pressure Mainstream (volumetric) or side stream Co2 sensor Integrated continuous cuff pressure controller With independent oxygen supply Inspiration time 0.1 to 10sec Nebulizer: Integrated pneumatic nebulizer Humidifier control Ventilation modes Therapy mode: High flow oxygen therapy Ventilation modes Adaptive Support Ventilation. Guaranteed minute volume and respiratory rate Fully closed loop ventilation and oxygenation **Ventilation Mode:** A/C VC A/C PC A/C PR VC SIMV VC SIMV PC **CPAP** NIV **PSV** SIMV/PSV Pressure support ventilation with bidirectional backup Dual positive airway pressure (biphasic positive airway pressure) Airway pressure release ventilation Synchronized controlled mandatory ventilation Synchronized intermittent mandatory ventilation Volume support, tidal volume guaranteed with bidirectional backup Noninvasive ventilation with bidirectional backup Noninvasive ventilation with mandatory rate

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Monitoring parameter:

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Synchronized nasal CPAP
High flow oxygen therapy
Real-time airway pressure
Real-time auxiliary pressure
Peak airway pressure
Mean airway pressure
Minimum airway pressure
Plateau airway pressure
Positive-end expiratory pressure / cont. positive
Airway pressure
Inspiratory pressure
Cuff pressure
Trans pulmonary pressure at the end of inspiration
Trans pulmonary pressure at the end of expiration
Real time trans pulmonary pressure
Real-time inspiratory / expiratory flow
Peak inspiratory flow
Peak expiratory flow
Real-time tidal volume
Expiratory tidal volume / Inspiratory
Tidal volume
Expiratory minute volume / Spont minute volume
Leakage volume at the airway
Avoid excessive VT
Temperature Y-piece
Chamber outlet temperature
Temperature difference between humidifier chamber and Y-piece
Inspiratory / expiratory ratio
Total breathing frequency
Spontaneous breathing frequency
Inspiratory time
Expiratory time
Index of spontaneous respiratory rate variability
Percentage of spontaneous breathing rate
Static compliance
Airway occlusion pressure
Auto PEEP
Pressure-time product
Expiratory time constant
Inspiratory time constant
Expiratory flow resistance

Γ
Inspiratory flow resistance
Rapid shallow breathing index
Imposed work of breathing
Airway oxygen concentration (FiO2)
Fractional end-tidal Co2 concentration
End-tidal Co2 partial pressure
V/Q status of the lung
Alveolar tidal ventilation
Alveolar minute ventilation
Elimination of Co2
Airway dead space
Dead space fraction measured at the airway opening
Exhaled volume of Co2
Inspired volume of Co2
Real-time plethysmogram
Saturation (pulse oximetry)
Heart Lung Interaction Index
Pulse rate
Carbon monoxide concentration
Methaemoglobin concentration
Total oxygen content
Total hemoglobin
Alarm Audio Visual with Silent Feature
5. Accessories/Consumables/Spare parts/Other component:
1x AC Power Cord
1x spare Backup Battery
1x Humidifier Bracket Kit
1x Humidifier Mounting Adapter
1x O2 Cylinder Holder Kit
1x O2 High Pressure Hose
1x O2 Manifold
1x O2 Sensor Kit
3x RS-232 serial communications cable
10x roll of paper
Adult, Ped. And Neonate Test Lung
3x Adult, Ped. and Neonatal Reusable Patient Circuit/Each
5x Reusable Inspiratory Bacteria Filter
5x Reusable Exhalation Bacteria Filter
2x Water Traps
2x Coupling, Straight Silicone
1x Water Collection

1x Reusable Exhalation Bacteria Filter

1x Reusable Inspiratory Bacteria Filter

2x humidifier bottle

Full software package for all ventilation mode indicated above

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65 Fax: +251-11-275-25-55

Addis Ababa

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Base Code	Item Detail	Department
Femo-90	1. Generic Name: Monitor-Fetal	NICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Electronic fetal monitoring (EFM) provides graphic and numeric information	1
	on fetal heart rate (FHR) and maternal uterine activity (UA) to assess fetal	
	well-being before and during labor.	
	4. Technical Specification:	
	Measure, record, and display FHR, uterine contractions, and maternal blood pressure, heart rate before and during childbirth.	
	Sense FHR and uterine contraction indirectly through the mother's abdomen	1
	and/or directly by placing an electrode on the fetal scalp (or exposed skin	
	surface) and by Measuring the change in pressure within the uterus.	
	Ultrasound working frequency in the range 2MHz -10% to 3MHz +10%.	
	Heart rate measurement range not smaller than 50-210 bpm with resolution	
	not higher than 2 bpm.	_
	Record fetal and maternal ECG recording.	
	Integrated monitoring of fetus and mother.	
	Twins monitoring capability	
	Thermal printer or inkjet printer	
	Support external thermal printer or inkjet printer	
	Built-in rechargeable battery, DC/AC power supply	
	Built-in network capability	
	15"Color TFT screen display waveforms and digitals	
	Maternal Parameters: ECG, SPO2, NIBP, RESP, TEMP	
	Automatic Fetal Movement Detection, AFM waveform display	
	24 hours monitoring data storage and reload	
	Acceleration and Deceleration measurement ability	1
	Baseline, acceleration and deceleration analysis capability	1
	Easy operation by with shortcut key and rotary knob	1
	Super printing functions	1
	Automatic monitoring mode, parameters configurable	1
	At least two high sensitivity equipment compatible probes provided: 2 and 3 MHz	-
	Sensitivity to detect fetal heart beats of at least a 10-12 weeks fetus.	1
	Clinical data management, can be reload, reanalysis, reprint	1
	Visual and audio alarm, comply with international standard	1
	2 MHz pulse wave	1
	Precision: ±1-2 bpm	1

Record differentiated: 30bpm/cm

Temperature: 5°C-40°C

Brightness LED power supply indicator light

audible and visual alarm

Alarm: upper and lower limit alarm

5. System Configuration Accessories, Spares, Consumables and other Components:

At least 1 of system compatible headphones provided.

At least one integrated serial port for PC connection and data transmission.

Memory storage capacity of at least 4 hours of working data.

Cable for data transmission.

1 pair of spare system compatible headphones.

At least 1 bottle of gel for patient application.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency

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(EPSA)
Tender and Purchase Order No.
Name and Model of the product
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Addis Ababa

Base Code	Item Detail	Department
Pamo-90	1.Generic Name: Monitor - Patient	ICU
	2. GMDN/UMDN Name /Code:	
	3. Clinical Purpose/Description: A device used to measureand display	
	physiological signal of patient.	
	4. Technical Specification	
	Adult, pediatric and neonate patient monitoring	
	17" TFT color display with 12 waveforms	
	Measuring Parameters: ECG, EEG, Respiration Rate, NIBP, SpO2, Temperature, IBP,EtCO2 capnography and with all its measuring accessories and spares.	
	SPO2 Range 0 – 100%	
	10-lead: I; II; III; avR; avL; avF; V1-V6	
	Automatic Sweep Speeds 12, 25, 50 mm/s	
	Heart Rate Range Adult: 15 – 300 bpm Neonate/Pediatric: 15 – 350 bpm	
	RESPIRATION	
	Method: Thoracic Impedance	
	Modes: Automatic / Manual	
	Range: Adult: 0 – 120 BrPM Neonate/Pediatric: 0 – 150 BrPM	
	with Apnea and Audio Visual Alarm recallable Alarm Events	
	NIBP	
	Method: Automatic Oscillometric	
	Modes: Manual / Automatic / Continuous	
	Types :Systolic, Diastolic, Mean	
	Measurement Range	
	Range of Systolic Pressure	
	Adult Mode: $40 - 270 \text{ mmHg}$	
	Pediatric Mode: 40 – 200 mmHg	
	Neonate Mode: 40 – 130 mmHg Range of Diastolic Pressure	
	Adult Mode: 10 – 210 mmHg	
	Pediatric Mode: 10 – 150 mmHg	
	Neonate Mode: 10 – 90 mmHg	
	Range of Mean Pressure	
	Adult Mode: 20 – 230 mmHg	
	Pediatric Mode: 20 – 160 mmHg	
	Neonate Mode: 20 – 110 mmHg	_
	Accuracy of Blood Pressure Measurement The Mean green less than 12 mmHg	_
	The Mean error less than ±3 mmHg. The Standard deviation less than 5 mmHg.	
	The Standard deviation less than 5 mmHg	

Over-Pressure Protection: Double safety protection

Alarm Systolic, Diastolic, Mean

CO₂

Range 0 - 99 mmHg

Temperature

Range $0 - 50^{\circ}$ C

Resolution 0.1°C

Accuracy ±0.1°C

Channel: Dual channel

12-lead ECG with 10 hour data storage, ST Segment and Arrhythmia Analysis

Micro stream ETCO2 disposable kit for adult- 50 nos, pediatric & Neonatal – 4 nos, each

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

Should provide hemodynamic, oxygenation, Ventilation calculation package.

- Should have drug calculation package.

Audiovisual alarm in case of Apnea and physiological measurements are outside preset range

Automatic Zoom In Facility in the monitor display.

Silencing feature for audio alarms

Trend display of 48hours

Data interface (for ECG): RS232, BNC or equivalent

Defibrillator sync and protection during defibrillation

Pacemaker detection/rejection

Display reports system errors, leads and sensors failure and built-in battery status

Automatic switch to batteries in case of power failure

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

Should provide hemodynamic, oxygenation, Ventilation calculation package.

- Should have drug calculation package.

Audiovisual alarm in case of Apnea and physiological measurements are outside preset range

Automatic Zoom In Facility in the monitor display.

Silencing feature for audio alarms

Trend display of 48hours

Data interface (for ECG): RS232, BNC or equivalent

Defibrillator sync and protection during defibrillation

Pacemaker detection/rejection

Display reports system errors, leads and sensors failure and built-in battery status

Automatic switch to batteries in case of power failure

Thermal recorder and printer (4Roll)

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- 1 x Spare rechargeable battery pack
- 1 x Set of spare fuses

NIBP accessories:

- 3 x NIBP hose (1 x neonate, 1 pediatric, 1 x adult)
- 3 x Blood pressure cuff (1 x neonate, 1 x pediatric, 1 x adult, 1 obese adult)
- 20 Nos of Disposable IBP transducers with all standard accessories & 6 nos of reusable adapter cable.

ECG accessories:

- 5 x Patient cable extremities (1x neonate/pediatric, 1 x adult)
- 5 x Set of electrodes (1x neonate/pediatric, 1 x adult)
- 1 x Electrode gel, 350 ml

Temperature accessories:

2 x Skin temperature probes and rectal probe (including connection cable)

Pulse Oximetry (SpO2) sensors with cable and plug:

- 5 x Adult size, reusable clip-on type
- 5 x Infant size, reusable clip-on type
- 6 x Newborn size, reusable clip-on type
- 10 x Newborn size, single use wrap-around type

Disposable SpO2 probes for neonatal use - 50 nos.

IBP accessories:

4 x Reusable pressure transducer with bracket, holder

100 x Disposable domes

EtCO2 module with all accessories:

In case of side stream EtCO2-10 sets of sampling tubes for each module to be included.

Micro stream ETCO2 disposable kit for adult- 50 nos, pediatric & Neonatal – 4 nos.

5. System Configuration Accessories, Spares, Consumables and other components:

Reusable adult, neonate and pediatric SpO2 finger probes – 2 each

Disposable SpO2 probes for neonatal use- 50 nos.

NIBP cuffs for standard Adult, Obese Adult, Child and infant – all 1 each

 $20\ \text{Nos}$ of Disposable IBP transducers with all standard accessories & 3 nos of reusable adapter cable.

Rechargeable Li-ion battery with a capacity of 6hr

wireless and cable networking

Prompt knob and touch screen control

Intelligent cooling system keeps the unit running quietly during use

Separate indicator lights for technical and physiological alarms

memory card for increased data storage

Rolling stand trolley, carrying handle with bed-hooks

Thermal recorder and printer (4Roll)

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

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Addis Ababa

Base Code	Item Detail	Departmen		
Mopc-90	1. Generic Name:Monitor - Patient, Central	ICU		
	2. GMDN/UMDN Name Code:			
	3. Clinical Purpose/Description:			
	Central Patient Monitoring System is a full-featured system that can monitor SPO2, ECG, NIBP, TEMP, RESP, CO, Temp, IBP, PR, ETCo2 and other comprehensive patient data centrally.			
	4. Technical Specification:	1		
	Suitable for performing continuous monitoring of several patients in CCU and ICU wards simultaneously.	-		
	21" color TFT, dual screen display	1		
	Waveform: 32@ a time	1		
	Each of the channels shall be user selectable to display any selected parameter from any bed in the system.	-		
	Trend information from the bedside monitor shall be available at the central station in the same format as the bedside monitor.	-		
	Support more than 15 patient monitors centrally			
	The system central station monitor that displays the information	1		
	ECG channel with interpretation with a facility to operate on ECG mode			
	The central station shall permit automatic display and control of any alarm parameter waveform from any bedside in the system.	-		
	This display shall not interrupt the viewing of any normal parameter display on the central monitor if necessary.	-		
	Bed specific audio visual alarms to indicate electrodes misuse, physiologic	1		
	parameters error (high/low pressure, high/medium/low temperature,			
	high/medium/low SpO2, high/low HR, loose electrode, sensor disconnection, pulsation undetected, interference, high/low S-T segment etc)			
	Integrated package of software for Interpretation, analysis, measurement and visualization of S-T segment as well as other parameters	-		
	Provide the service of radio transmitters, receiver and telemetry systems]		
	Wi-Fi enabled workstation for continual capture and broadcasts patient data at remote place of patient with daily activity			
	Central monitor shall have the capability to act as a bedside monitor]		
	Protection against defibrillation shocks and high frequency current	1		
	Perform hemodynamic, ventilator, oxygenation and renal assessment computations	-		
	Audible and visual alarm for technical and physiological parameters error	1		
	Display real time waveforms, readings, emergency status and personal profile of the patient specific to the bed	-		
	integrated With advanced pc work station, with necessary network device	1		
	The processing station must have 8 GB RAM higher, intel core i7 latest			

generation, at least 1TB HDD and 21 inch or higher medical grade high

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definition color display TFT/LED touch screen dual displays with external keyboard, mouse and all necessary software package with LAN, and USB ports

Built in speaker

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included (including items not specified above).

5. System Configuration Accessories, Spares, Consumables and other components:

Recording device with printer print out values and uninterrupted power supply (UPS \geq 2Hr)

3 x Box thermal paper

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

UPS with 4hr capacity

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

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Addis Ababa	Addis Ababa

Base Code	Item detail	Department
Laum-90	1. Generic Name: Laundry Machine	Hospital Equp.
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Used to receive contaminated items for cleaning and to provide an	
	adequate	
	efficient ,economic, continuous quality supply of clean disinfected linen	
	to all patient care services in the hospital.	
	4. Technical Specification:	
	Washer Extractor machine:	
	Both hot and cold water washing Horizontal drum type made of	
	non-magnetic stainless steel, Front loading type,	
	Method of washing should be tumble wash.	
	Machine should be made of 304 grade of stainless steel (Inner cage	-
	should have die-sunk perforations on adequate area and thickness	
	should be of 14 SWG S.S and outer body thickness	
	16 SWG 304 stailess steel).	
	Machine should have large stainless steel front door with toughened glass.	
	Large loading and unloading doors with up to 180 degree opening	_
	angle for easy access	
	Machine should have automatic door locking system while machine	_
	is in operation.	
	Machine should have auto-reverse / open pocket with low spin	
	extract.	_
	Machine should have level indicator. Capacity of 50 kg to 65 kg dry linen.	-
		_
	Nose lebel (dB) <70 Wash speed / Spin speed r.p.m Not less than 34	_
	Extracting speed r.p.m, Not less than 735	_
	Extracting spectr 1.p.m, Not less than 755	_

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Page 470 ISBN No: Machine should have heavy duty Motor Power more than 5.5 Kwt

Machine should have Dual operating system options i.e. both electrical

and steam heating provisions.

Steam pressure :-0.2to o.6 MPa

Air pressure :-0.4 to o.6 MPa

Drum volume :- Not less than 530 Liter

Heating power :- 18-27 kw

Rotation direction: forward/reverse/stop, one way drive With

Electrical water heater, adjustable rotation speed of greater than

1000rpm (max).

With operating valves Material: stainless steel

Automatic stop alarming mechanism

With washing options for dirty and colored clothes

Automatic stopping and stop signaling when finishing With braking system.

. The machine shall have features like wash timer, automatic forward/reverse cyclic timer. Sensor to detect level in soap tank and easy refilling system.

Sensor for water in chamber to avoid dry run.

Built in steam condenser for washing and drain.

Single phase motor invertor

Freely programable control with advanced 7 " colour display for easy operation

Programmeble water temprature for each bath

Programmable overnight bath soak

Long, short and extra short programm

Temprature adjustment

Fresh water flashing chemical mainfold

Shock absorbing system

Two way circulation pump

hose with flat inner surface

Autowash feature

Dirt resistant drain hose

Emergency stop switch

Connections:

voltage inlet: 380V frequency of 50Hz

Hot and Cold Water connections: Machine should have adequate water inlet and drain outlet size with appropriate connection, pressure and satisfactory flow rate.

Dryer:

Tumble dryers are used, machines in which textiles are dried by tumbling in a rotating drum through which heated air is passed.

Capacity 55 to 70 kg of wet linen

Dryer/tumbler should be ,Electrically Heated, Heavy duty, Front Loading, Cool down Feature, Auto-timed, Auto-reversible, Auto digital temperature control, Dual Motor drive, Open Pocket & Front display

Programmable microprocessor controlled with touch panel, color screen LCD/TFT display for working parameters and multi-level interface

Heating Power: Not more than 32kW

Motor power:0.75kwt to 1.10 kwt

Electric, steam heating type

Steam pressure: 0.3-0.5mpa

Equipped with removable lint screen

Automatic signal display when finishing

Tumble dryers with stainless steel drum

Alarms and free display of operating parameters

Auto adjustible vacuum power to the existing condition

Professional brushless motor

Bi-directional drum movement, with auto reversing and exhaust sytem

Perfect tumble dry system

Tumble dryers with humidity sensor and display

Large wide opening door, with semi-perforated inner drum for easy removal of hot air

Easy water empiting to accessible drain out

Noise < 50dB

Adjustible drum speed and rotation

Trap system to remove fine particles

Exact dry moisture sensor

Door minimal heat loss

Less steam consumption but quick dry time

Stainless steel dryer drum

Outer chamber dryer should be made of stainless steel 304 sheet

Inner chamber dryer should be made of stainless steel 316

Heating and time control should be done digital temperature, time controller

Trays should be made from SS 316 sheets

Racks and trolleys racks should be provided for trays inside the dryer

Racks should be provided with wheels to slide them in and out of the dryer

Machine should be fitted with anchor bolt with vibration damper

Safety microswitches on door, depression and filter check

Self-diagnostic fault alarm systems, safety protection system

Power supply: 380v +-10%, 50hz

With all standard accessories

Equipped with removable lint screen Automatic and gives signal when finishing

Stainless steel drum Safety microswitches on door, Electrical heating system,

Air particle filter to ensure the drying air is free from particles.

Tumbler drier of solid steel construction

machine should have thermal overload protection system

cycle programing should be by varying temp or time

Ironing machine

Roller type

Electrical heating system Heating range: (10-200 dgree C)

Heater temperature adjustment for various types of clothes/garments Having maximum and minimum speeds and reversing Roller lenngth. used to dry ironing. Water spray. Variable thermostat control. Roller length: 2.5 meter Roller diameter:=not less than 500mm Ironing speed (Rotation speed:)m/minit - 0 -8 Motor power (KW):- 1.1 to 1.5 Electic heating power (KW) 28 to 30 Roller type, stainless steel body Electrical heating system Heating range: max 200degC Heater temperature adjustment for various types of garments Having maximum and minimum adjustible speed Noise level <65dB Automatic control of overheating Built in electric heating system with temperature setting unit Having driving and exhaust motors with brake system Indication of ironing speed and temperature Separate delivering and receiving table for dirty and clean linen Variable setups for folding Built-in feeding and length folding system Frequency controlled motor Automatic cool down Power supply: three phase, 380v,+-10% 50hz an ironer with exhaust fan for the removal of vapours produced while ironning is preferable the roller padding should ensure uniform pressure through out its

final cover of the roller should be made with NOMEX which is high

length

temp. resistant

The machine must have Emergency stop button

Ironing speed must be adjustable

Laundry trolley for wet clothes:

Material: chrome plated steel/polymers Capacity of not less than 50kg Built on heavy duty castors Mobile box of non-rust polymer construction for solidity and durability.

dimensions: approx. $736 \times 660 \times 965 \text{ mm}$ (h x w x l). With 2 rigid and 2 swivel castors. With outlet tap.

.

Laundry trolley for dry clothes:

Material: chrome plated steel Capacity of not less than 40kg about 55kg

Built on heavy duty castors Material: chrome plated steel/polymers

Capacity of not less than 40kg Built on heavy duty castors. Mobile box of non-rust polymer construction for solidity and durability.

dimensions: approx. 736 x 660 x 965 mm (h x w x l).

With 2 rigid and 2 swivel castors.

Gloves:

Heavy duty type Rubber Gloves laundry For purpose

5. System Configuration Accessories, Spares, Consumables and

other componenets:

washerextractor, drayer and ironor should provide With all standard and complete accessories

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power supply: Three phase, 380VAC ±10%, 50hz

The system must be inclusive of water supply with proper pressure

Should have proper drainage system

Should have heat ventilation and air cerculation system

8. Standards & Safety Requirements:

Shall meet, ISO, and CE, Certification, This shall include standard

and safety requirement and also meet the following:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements

of Safety for Electromagnetic Compatibility

Shall meet ISO 1042 ,safety requirments for hospital laundery machine

machine should have thermal overload protection system

Overall Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the Laundry machine. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

b). Drain Connection:

Bidder shall do drain outlet via either drilled floor or any other for drainage purpose

c). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (Proper grounding should be included)

Three phase breaker with size as per manufacturer recommendation near to the machine.

d). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

e). Evacuation system:

To allow dryer, ironer to work at its best, air inlet passes through an opening outside

Air inlet opening should be standard and placed behind the machine

Exhaust duct is made from galvanized steel not be from plastic ducting

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsight technical and end user training

10. Warranty/ Aftersales service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

10. Documentation:

The supplier must provide user manuals/operation manuals and Services manuals in English.

11. Packaging and Labelling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product :-

PO Box 21904

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Carg-90	1. Generic Name: ECG Machine	Emergency
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	ECG Machine is primary equipment to record ECG Signal in various configurations. With 12 channels with interpretation are required for recording and analyzing the waveforms with a special software.	
	4. Technical Specification:	1
	LCD/TFT color monitor display of at least 7 inches	
	Resolution should be Not less than 800 x 480 dots	
	Display should include ,12 lead ECG waveform, patient information, recording settings, operation mode, heart rate, QRS sync mark, error message, electrode detachment, noise Real time display of ECG waveforms with signal quality indication for each	
	lead	
	Artifact, AC, low and high pass frequency filters.	
	Acquisition mode: simultaneous 12-lead acquisition (10-24s adjustable)	
	Sampling rate: 10KHZ for pacemaker detection	
	CMRR: >105dB	
	Sensitivity:5, 10, 20mm/mV	
	Noise Level:<15uVp-p	
	The machine should have the following filters: EMG interference filter, Anti-baseline drift, High and Low-pass Filter:	
	AC Filter: 50Hz	
	Input Impedance: $\geq 50M\Omega$	
	Patient leak current: <10µA	
	Input Voltage Range:± 5mVpp	
	Input Circuit Current:<10nA	
	Visual alarm for open lead	
	Modes of operation – Automatic, Manual & Rhythm (Not Arrhythmia)	
	Compact and portable, and should have carry handle for portability.	
	Should have defibrillation protection	
	Frequency response 0.05 Hz to 150 Hz with digital filter for AC and EMG Should have full screen preview of ECG report for quality assessment checks prior to print. 12-lead ECG waveform view to be seen on one screen.	
	Interpretation facility of the amplitudes, durations and morphologies of ECG waveforms and associated rhythm for pediatric and neonatal patients. (For all patients)	

Alphanumeric keyboard for patient data Entry. (virtual or hard keys) and one touch operation

Integrated thermal Printer: High resolution (200 dpix500dpi on 25 mm/sec speed) digital array A4 size

Recording speed should be 5, 10, 12.5, 25, 50 mm/s

Recording paper should be 110 mm width, 30 m long Z fold.

It should show the following recording data, ECG waveform, heart rate, lead name, version, date and time, paper speed, sensitivity, filter setting, patient information, measured information, marks

Report formats of 3 x4; 6 x2, Rhythm for up to 12 selected leads; 12 Lead. Extended measurements, 1 minute of continuous waveform data for 1 selected lead.

Should be supplied with built in rechargeable battery with capability of minimum of one hour power backup

It should have features with the capability to transfer the ECG data to a PC using USB/ HIS /LAN/Wireless LAN system.

USB Support for Storage on external portable memories.

At least 4GB internal memory for ECG data storage

Trolley:

Trolley should be made of Stainless Steel

Shelf with a drawer for storing the accessories and consumables.

Four superior castors (two with brakes)

Trolley should have a suitable cable arm firmly affixed having holder for ECG cables while not in use

5. System Configuration Accessories, Spares, Consumables and other components:

1x ECG Machine 12 Leads with Interpretation – 01

2x Lead ECG Patient Cable -02

4 set of chest electrodes adult size-(each set of six electrodes), reusable

4 set of chest electrodes pediatric size-(each set of six electrodes), reusable

4 set of color coded clip clamp limb electrodes adult size (each set of four electrodes), reusable

4 set of color coded clip clamp limb electrodes pediatric size (each set of four electrodes), reusable

5x Standard thermal paper(Roll)

5x Gel of 300mL

All standard accessories, consumables and spare parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%,50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601-General Requirements of electrical safety

Shall meet IEC 60601-2-51-Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

ISO 14971: Medical devices -- Application of risk management to medical devices

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User, technical and maintenance manual in English. Certification of calibration and inspection should be provided.

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare parts shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 21904

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Defi-90	Defibrillator	Emergency
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description:	_
	Fully automated external defibrillators (AEDs) deliver a high amplitude current impulse to the heart in order to restore normal rhythm and contractile function in patients who are experiencing ventricular fibrillation (VF) or ventricular tachycardia (VT) that is not accompanied by a palpable pulse.	
	4. Technical Specification	
	High-resolution TFT color LCD display not less than 5.8 inches for showing 12 lead ECG, pulse, selected energy and delivered energy charge, mains, battery charge ,led indicator	
	Defibrillator with ECG. DC defibrillator for short time depolarization, impulse energy adjustable for extra- and intracranial defibrillation with 2 electrodes (anterior/ posterior).	
	Defibrillator with pediatric and adult paddles and cardioverter	_
	The machine should be compact, portable with built in rechargeable battery & light weight.	
	Operation Modes: synchrony defibrillation and extrathoracical stimulation	
	Defibrillator with pediatric and adult paddles minimum of 4.5cm and 8cm respectively	
	The instruments with a bi-phasic wave form Defibrillation	
	Monitor vital parameters and display them (ECG, SpO2, NIBP, and temperature)	
	Able to print the ECG on thermal recorders	
	Output energy ranges across 50Ω: 2J-360 J	
	Able to work on manual and automated external defibrillation (AED)	
	Charging time:-	
	Manual mode_ Charging time should be less than 5 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)	

AED mode: Charging time should be from 8-15 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)

Should have rechargeable battery (Lithium-ion battery) that is capable of monitoring for minimum of 180 minutes

Thermal array ECG Recorder for Lead selection, II, III aVR, aVL, V, paddles

Heart frequency monitoring with alarms for exceeding or falling below set limits.

A low energy biphasic defibrillator monitor with recorder, having capability to arrest all arrhythmia within a maximum energy of 360 Joules

Monitor ECG through paddles, pads and monitoring electrodes and defibrillate through pads and paddles.

Should have automatic lead switching to see patient ECG through paddles or leads

Able to measure and compensate for chest impedance for a range of 25 to 150 ohms

The machine should have inbuilt auto & manual thermal recorder for printing ECG trace & stored information.

Charge indicator: audible and graphic.

Facility for self-test/check before usage.

The machine should have AED feature as inbuilt with manual override for manual operations.

SPO2 and NIBP integrated facility

5. System Configuration Accessories, Spares, Consumables and other components:

Paddles Adult (pair)-01

Paddles pediatrics (pair)-01

Patient cable-02

Compatible thermal paper for printer - 20 roll

Compatible Gel; 300mL

Disposable pads -20

NIBP Cuff Adult – 02

NIBP Cuff Pediatrics- 02

NIBP Cuff Infants-02

SPO2 Finger Probe - pediatric 01

SPO2 probe Adult -01

Ear Probe – 02

Complete set of ECG Leads – 02

Carrying case-01

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

ISO 14971:Medical devices -- Application of risk management to medical devices

IEC 60601-2-4: Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Document: Capital Medical Device Technical Specification

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare parts shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

General Hospital Capital Medical Device Technical Specification

Base Code	Item Detail	Department
Ultg-90	1. Generic Name: Ultrasound- Ob/Gyn	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Used for obstetrics, gynecology, Abdomen, Urology and Emergency Medicine Packages scanning	
	4. Technical Specification:	
	The system with one active probe ports for easy use and convenient operation.	
	Controls for depth, gain compensation preferably automatic gain and depth control	
	The system have dedicated calculation software package including Obstetrics, Gynecology, Abdomen, Urology and Emergency Medicine Packages)	
	The system have image storage and archiving with CD, USB flash and DICOM	
	System with 15 inch LCD monitor and also can connect to external display	
	Probe: Convex (2-5MHz)	
	Number of elements:192	•
	FOV:58	
	Physical foot print:55x18 mm	
	Convex radius:60mmR	
	with battery support to operate the machine in case of power failure	
	5. System Configuration Accessories and Consumables]
	System with main unit and mobile cart (trolley)	
	Laser Printer for direct image and report print out1pcs	
	Convex probe1pcs	
	Ultrasound paper100 rolls]
	Gel: 250 ml 2pcs	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C]
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards & Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation/Training/Commissioning	1

Document: Capital Medical Device Technical Specification

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Ugcd-90	1. Generic Name: Ultrasound-General Purpose, Color Doppler, Mobile	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A robust state of art fully digital high end latest color Doppler ultrasound system under current production capable of performing imaging applications in abdominal Ob/Gyn, musculoskeletal, cardiovascular, small parts, Urology, Cardiology, Real time 4D, Tissue elastography contrast and Rectum.	
	4. Technical Specification:	
	System broad band beam former capable of processing signals from 2-15 MHZ	
	should incorporate facility for high resolution 2D, M-mode, color M-mode, THI mode, PW, CW mode, Color Flow imaging, Color power Angio imaging, Directional Color Power Angio imaging modes, live real time 3D/4D.	
	full spectrum imaging, Speckle Reduction Filter, Spatial Compound imaging, Pulse Inversion Harmonic Imaging, Trapezoidal Imaging & Contrast Enhanced Imaging (Low –MI)	
	Row data management.	
	Post processing technology.	
	Tissue harmonic imaging.	
	The capability of analyzing 3D data set.	
	Real time triplex mode facility in 2D, color and Doppler modes.	
	Dynamic range of 250 db or higher.	
	High pulse repetition frequency (PRF)	
	256 shades of gray display	
	Minimum 1000 frames per second or more.	
	Facility for real time and frozen, pan or point zooms.	
	Cine loop review minimum 4000 frames/sec	
	Panoramic extended field of view.	
	Independent steering of B mode and color on linear probe.	
	Advanced real time 4D capabilities	
	Advanced tissue elastography	
	Extensive software and automatic and user programmable calculation package for gray scale, color Doppler, 3D and 4D applications.	
	Minimum 19" high resolution medical grade TFT/LCD screen monitor display	
	Should be provided with following transducers:	
	a) Curved (Convex) Probe (2-5 MHz) for Abdomen and OB/GYN, etc (Specify	
	model/cat no) Number of elements:192	
	FOV: 65 deg	
	Physical foot print: 61 x 17	
	Convex diameter:55 mmR	
	Convex diameter.33 min	

b) Micro-curved Probe (4-9MHz) for neonatal and pediatrics, etc.. (Specify model/cat no)

Number of elements:128

FOV:134 deg

Physical foot print: 22 x 6mm

c) Linear probe (5-12 MHz) with 4D capability for small parts, vascular, musculoskeletal, etc.. (Specify model/cat no)

Number of elements:192

FOV:40 deg

Physical foot print:42 x 6 mm

d) Phased Array Probe (2-6 MHz) with 4D capability for Cardiology (Specify model/cat no)

Number of elements: 64

FOV: 128 deg

e) Endo cavity probe (Trans-vaginal + Trans rectal) (4-9MHz) applicable for examining internal organs such as vagina, cervix, uterus, fallopian, ovaries, rectum, etc... (Specify model/cat no)

Number of elements: 128

FOV:150 deg

Physical foot print:25 x 5 mm

Number of elements: 128

Capable of supporting at least four or more transducers ports with switching form console.

Built in image Management software, for off line application when patient has gone after examination, such as image manipulation, Multi Planner reformatting, surface & volume rendering etc.

Skin line scaling markers, curved distance measurement tool and zoom, pan, rotate and trim facility to trim panoramic images from start or end of the panoramic capture.

Hard disk memory of 500 GB or more with built in CD/DVD read write.

Capable to do Elastography with convex probe and compression / strain or better technology based elastography in TV and linear probes.

Should be capable to do Contrast Enhanced Ultra sonography

Should be DICOM Compatible, RIS/HIS

Shall have push handle for pushing.

Trolley on four Double Castors with Brake.

Upgradeable to Fusion / navigation to allow fusing real time ultrasound images with images acquired from other imaging modalities such as eg. CT and MRI.

Should be seamlessly upgradeable on site to automated whole breast 3D functionality

5. System Configuration Accessories, Consumables and other componenets:

- a) On line UPS with 60 minutes backup
- b) Color Laser Printer for direct image and report print out
- c) For parallel processing of Imaging Data, System should be provided with a External latest configuration 1 Tera Byte Hard Disk based work station with USB and serial port with 19" TFT/LCD monitor with very high quality image Management Software (with proper license) with same capabilities as main machine such as retrieving data along Zoom, Pan, Volume Rendering, Multi-planar Reformatting, MIP, retrieving information from CD/DVD with reporting and software exporting

Document: Capital Medical Device Technical Specification

JPG & AVI file format to ink other stations in the hospital.

- d) Ultrasound paper---- at least100 rolls
- e) Gel 250 ml ---- 2
- f) Curved (Convex) Probe ---1
- g) Micro-curved Probe ---1
- h) Linear probe ---1
- i) Phased Array Probe with 4D capability ----1
- j) Endo cavity probe (Trans-vaginal + Trans rectal) ----1

All standard accessories and parts required to operate the equipment, cleaning and lubrication materials with their quantity to be included in the offer.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Trea-90	1. Generic Name: Treadmill	Physiotherapy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	Treadmill provide safe and effective walking and running exercise, also provide partial weight bearing by support of portion of body weight under the supervision of therapists in the physical therapy gymnasium 4. Technical Specification:	-
	Maintenance free brushless motor AC motor	<u> </u>
	Motor: 2.0 CHP	
		<u> </u>
	Bi directional speeding system Treadmill with providing and (0.5, 1.6 km/km are dusting 0.1 km/km)	
	Treadmill with variable speed (0.5 - 16 km/hr, graduation 0.1km/hr)	
	Reverse speed: up to 3.0 Km/hr	
	Positive slope angle: 0% to +15%	
	Negative slope angle: 0% to -10%, graduation 0.5%	
	Patient carrying capacity: not less than 180Kg	
	Treadmill belt run across deck providing low friction and noise when in use.	
	Digital display of speed elevation	
	Reduced shock and non-slip belt surface	
	Automatic center tracking	
	Feature for speed control from high to zero level	
	Display of stage no., stage time, distance covered, pace, calories/minute METS and others	
	Heart rate control and monitoring should be possible with polar transmitter and receiver wireless system	
	The patient heart rate should be seen on the screen	
	An emergency stop button should be mounted on the control panel, it should be visible and easy to reach	
	The treadmill shall be provided with electrically adjustable side bars and step up aid	
	Hip belt with safety switch for automatic stop while the client cannot maintain the running speed of the belt	
	Treadmill running surface (lxw), m:1.5x0.5	
	Overall dimension (lxdxh), m:1.8x0.8x0.9	
	Material: stainless steel	
	The system must have an integrated monitoring system with a display of parameters	
	5. System Configuration Accessories, spares, Consumables and other consumables:	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.	
	6. Operating Environment;	

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Ugcd-90	1. Generic Name: Ultrasound - General Purpose, Color Doppler, portable	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	A portable laptop type and detachable diagnostic imaging ultrasound with mobile cart used to see internal body structures in Abdomen, Obstetrics, Gynecological, Vascular, Urology, Musculoskeletal, Small Parts, pediatrics and neonatal.	
	4. Technical Specification:	
	With internal battery capable of operation 60 minutes	
	System broad band beam former capable of processing signals from 2-13 MHZ	
	Should incorporate facility for high resolution 2D, M-mode, color M-mode, THI mode, PW, CW mode, Color Flow imaging, Duplex mode, triplex mode etc. Full spectrum imaging, Speckle Reduction Filter, Spatial Compound imaging, Beam steering Imaging.	
	steering Imaging, Post processing technology	
	Tissue harmonic imaging	
	Capability of analyzing 3D data set.	
	Real time triplex mode facility in 2D, color and Doppler modes.	
	Dynamic range of 150 dB or higher High Pulse repetition frequency (PRF)	
	Minimum 254 gray shades	_
	1000 frames per second or more.	
	Panoramic extended field of view.	
	Software packages: Abdomen, Obs/Gyn, Vascular, Musculoskeletal, Urological, Small Parts, pediatrics and neonatal	
	Skin line scaling markers, curved distance measurement tool and zoom, pan, rotate and trim facility to trim panoramic images from start or end of the panoramic capture.	
	Independent steering of B mode and color/PW/CW mode in linear probe.	
	Minimum 15" high resolution medical grade TFT/LCD screen monitor display	
	Should be provided with following transducers	
	a) Curved (Convex) Probe (2-5 MHz) applicable for Abdomen and OB/GYN, etc (Specify model/cat no) Number of elements:192	-
	FOV: 65 deg	1
	Physical foot print: 61 x 17	1
	Convex diameter:55 mmR	1
	b) Micro-curved Probe (4-9MHz) applicable for neonatal and pediatrics, etc (Specify model/cat no)	- -
	Number of elements: 128]
	FOV:134 deg	

Document: Capital Medical Device Technical Specification

Physical foot print: 22 x 6mm

Number of elements:128

c) Linear probe (5-12 MHz) applicable for small parts, vascular, peripheral, musculoskeletal, etc.. (Specify model/cat no)

Number of elements: 64

FOV: 128 deg

Number of elements: 64

d) Endo cavity Probe (4-9MHz) applicable for examining internal organs such as vagina, cervix, uterus, fallopian, ovaries, etc... (Specify model/cat no)

Number of elements: 128

FOV:150 deg

Physical foot print: 25 x 5 mm

Capable of supporting at least three or more transducers ports with switching form console.

System built in image Management software, such as image manipulation, Multi Planner reformatting, surface & volume rendering

Hard disk memory of 400 GB or more with built in CD/DVD read write.

System Should be DICOM Compatible, RIS/HIS

Shall have push handle for pushing

Trolley on four Double Castors with Brake

5. System Configuration Accessories, Consumables and other componenets:

Color Laser Printer----1

Ultrasound paper---100 rolls

Gel 250 ml ---- 2

Curved (Convex) Probe---1

Linear probe---1 and Convex probe---1

Trans-vaginal probe---1

Micro-convex probe ----1

All standard accessories, consumables and parts required to operate the equipment, cleaning and lubrication materials with their quantity to be included in the offer. (Including not specified on the above).

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Document: Capital Medical Device Technical Specification

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Enbr-90	1. Generic Name:Endoscope - Video Bronchoscope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Video Bronchoscope is inserted into airway and lungs in order to diagnosis	
	and therapeutic interventions for airway disease.	
	4. Technical Specification:	
	Flexible Adult video bronchoscope:	
	Observational Depth (mm): 5-100	
	Angle of view: 120°	
	Distal end (mm): \leq 6mm	
	Operating channel (mm): 2mm	
	Bending capacity (up/down/Right/Left): 130°/130°	
	Working length 1000mm	
	Fully immersible in disinfectant solution]
	Flexible Pediatric video bronchoscope:	
	Observational Depth (mm): 3-50]
	Angle of view:120 degrees	
	Distal end (mm): ≤ 3mm	
	Operating channel (mm): ≤ 1.5mm	
	Bending capacity (up/down): 180°/130°	
	Working length: 600 mm	
	Fully immersible in disinfectant solution	
	Equipment cart:	1
	Cart with at least 4 shelves and drawer, for accommodation of all	
	components for video flexible endoscopy procedures	
	Sturdy medical grade stainless steel main structure	
	Mobile on antistatic castors, with front breaks and lateral bumpers	
	Complete with isolation transformer with main switch	
	Multiple sockets block (indicative sockets quantity 6 or more), with	
	dedicated socket type	
	Complete with lateral panels, cable ducts and back protection panels	
	Supplied with holders for endoscopes and camera cables	
	Complete with hanger for irrigation bottle	
	Complete with holder for Co2 insufflations cylinders	
	Endoscopy Monitor:	
	≥21", medical grade HDTV, DVI inputs/output/HDSDI/RGB/SVIDEO	
	Menu of functions appear on the screen.	
	Complete with robust anchoring accessories for the cart or holding arm	

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Complete with all cabling and connecting accessories

Endoscopy Video System:

Video processor for color standard definition high resolution endoscopy images

PAL/NTSC type video signal.

Controls to freeze images enhance a portion of frozen image (zoom & post-processing).

Patient and physician data input key board.

CCD compatibility scopes

Internal memory

Complete with all cabling and connectors

Accessories with endoscopes light source and monitor

Endoscopy Light source:

Operates on LED lamp, Automatic light control and saving

Emergency lamp with switchover mechanism

Automatic and manual variable light control

Front modes and setting controls with intuitive user interface

Easy access for lamp substitution

Complete with hours counter for bulb utilization

Integrated with Video Processing unit

Endoscopy Recorder, DVD

System for the recording (capture and storage) of videoendoscopy procedures and images in digital media, (DVD / SD / USB)

Suitable for the preparation of medical records

Standard common video and images format types input compatibility

Internal memory storage capacity (1TB)

Possibility of control via scope head buttons or footswitch.

User interface with controls and display

Irrigation pump unit:

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With "Stand-by" function mode

With special filters to ensure sterility.

Aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

5. System Configuration Accessories, Spares, Consumables and other components:

4 autoclavable blades-sets for adult and pediatric applications:

2x Spare LED

a) Macintosh 2 (pediatric)

b) Macintosh 4 (adult)

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c) Miller 2 (pediatric)

d) Miller 3 (adult)

Hard transport case with dedicated space for at least 3 blames, one handle and batteries.

All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Eneu-90	1. Generic Name: Endo-Urology Set	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Endourology set is used to diagnose the internal part of urinary and reproductive tracts.	
	4. Technical Specification:	
	Cystoscope and Resectoscope for TURP	
	Rigid Uretero-Renoscope	
	Flexible Uretero-Renoscopes	
	Light source, camera system and monitor	
	Ultrasonic / Pneumatic Lithotripter with Integrated Suction Pump	
	Irrigation System	
	Equipment cart	
	Cystoscope:	
	Telescope: 30 degree Telescope of size: 4mm, working length 30cm	
	High quality of rod lens system	
	Fiber optic light transmission incorporated.	
	Optical system: Field of view: 120°	
	Direction of view: Forward-viewing	
	Depth of field: 3–50 mm	_
	Insertion section: Outer diameter of distal end 11.7 Fr (4.6 mm × 2.6mm)	_
	Outer diameter of insertion tube 16.5 Fr (5.5mm)	\dashv
	Instrument channel: Diameter of inner channel 2.4 mm	
	Compatible Endotherapy accessories for 2 mm channel	\dashv

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Page 498 ISBN No: Minimal visible distance: 5 mm

Bending section: Angulation range Up 210°/down 120°

Autoclavable telescope

1x Cystoscope sheath: Cystoscope sheath with leur lock connection of two different size x1

20Fr and 17Fr sheath one each with slot for instrument with obutrator.

Graduated sheath

1x Telescope bridge with one instrument channel to fit with the cystoscope

1x Flexible Grasping forceps: 7Fr Grasping forceps to be provided to fit the purpose

1x Flexible biopsy forceps: 7Fr Biopsy forceps to be provided to fit the purpose

1x Compatible with 20Fr Cystoscope sheath to be provided

1x Toomey syringe 100 Cc: Toomey syringe of 100 cc with adaptor to fit with sheath

1x Toomey syringe 100 Cc: Toomey syringe of 100 cc with adaptor to fit with sheath

1x Evacuator: Evacuation with spare rubber bulb and adaptor to be provided

1x Urethrotonie sheath: 21Fr optical Uietlirotom sheath with one channel to be provided

2x Cold knife: Straight cold knife 2 nos

Resectoscope sheath: 26 Fr continues irrigation Resectoscope sheath

With ceramic beak to be provided to fit the purpose with set of silicon tube.

1x Sheath Provided with deflecting obutrator

Working element set: passive type with standard accessories like, Knife, HF cord, Protection tube, cutting loop to be provided

2x Cutting loop 24Fr: No 1 and 12

1x High Frequency cord No 2

Rigid Uretero-Renoscope

Length more than 41 cm, with an offset eyepiece (10deg with oval

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irrigation)

Outer diameter at the tip of about 6Fr- 8Fr with a working channel 4Fr to 5Fr

Two irrigation and preferably 2 instrument ports

Adaptor to connect the endoscope to light source of any make

Sterilizable with liquid, gas and autoclave

Flexible Uretero-Renoscopes

Instrument Channel: 3.5-3.8Fr

Style: Flexible

Flexible biopsy forceps

Angulation Range: 270 $^{\circ}$ Up / 270 $^{\circ}$

Field of view 80-90 ° forward

Distal shaft size of 8.8Fr or less.

Depth of view: 2-50 mm

Working length 650mm or more

Stone holding flexible forceps.

Easy to use

Resectoscope

Bipolar

Monopolar

Bipolar Electrodes for the Resectoscope System

Mono polar Electrodes for the Resectoscope System

Outer & inner Resectoscope sheath

Optical urothotomy sheath

High frequency cable & loops

Light Source: Rechargeable miniature light source with LED

1x Brief case: Plastic good quality brief case with slot for instruments is to

be provided for storage

Endovision camera system: Single Chip Endoscopy Camera system

1x With Digital Image Process module.

Image Sensor: 1/2" CCD Chip

Pixels - 752 (H) x 582 (V)

Resolution - 450 Lines Horizontal

AGC - Microprocessor based

Minimum Sensitivity: 3 Lux (f- 1.4 mm)

Exposure Control: 1/50 Sec - 1/10000 Sec

Freezing function & Antomoire filter function

Camera control unit have accessories output to control external devices Like video printer from the camera head buttons

Programmable Functional Keys on camera head for various functions like

Automatic white balance, gain control and brightness control

Integrated focus control

Digital zoom

Integrated Optical Parfocal zoom lens 25-50MM

DV output and S-VHS and Composite video output

Contrast enhancement and digital filter

Video Monitor:

20" TFT screen with pedestal.

Viewing angle of 170 degree vertical and brightness of 450cd/m2

Resolution of 1280 X 1024

Take RGB, SDI and S-Video signals

Electrosurgical cutting and coagulation unit, mobile x1

Electrosurgical unit, with accessories

Ultrasonic / Pneumatic Lithotripter with

Integrated Suction Pump

Pneumatic section

Supply Pressure: Compressed Medical Air (3.5 - 6.5 bar)

Pulse Mode: Single or multiple pulses

Pulse Frequency: 1-12 Hz increments

Applied Energy: Adjustable

Energy Transmission: Mechanical

Pneumatic Probes

Different lengths and diameters for rigid and flexible endoscopes.

Hand piece sterilization: steam, chemical sterilization

Ultrasonic Section:

Power: 150W

Applied Energy: Adjustable

Ultrasonic Probes

Combined Probes

Different lengths and diameters available

Hand piece Sterilization: Steam, Chemical.

Irrigation pump unit

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With Stand-by function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Equipment cart

Cart with at least 4 shelves and 1 low drawer, for accommodation of all components for video flexible endoscopy procedures sturdy medical grade stainless steel main structure, mobile on antistatic castors, with front breaks and lateral bumpers

Complete with isolation transformer, with main switch and multiple sockets block (indicative sockets quantity 6), with dedicated socket type

Complete with lateral panels, cable ducts and back protection panels

Supplied with holders for endoscopes and camera cables

Complete with hanger for irrigation bottle

5. System Configuration Accessories, Spares, Consumables and other components:

1x Cystoscope and Resectoscope for TURP

1x Rigid Uretero-Renoscope

1x Flexible Uretero-Renoscopes

1x Light source ,camera system and monitor

1x Ultrasonic / Pneumatic Lithotripter with Integrated Suction Pump

1x Irrigation System

1x Equipment cart

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety $\,$

Shall meet ISO 13485 Medical Device Quality Management system (Or

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Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

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Addis Ababa

D C 1	Many D. 4. 9	D (
Base Code	Item Detail	Department
Enhy-90	1. Generic Name: Endoscope - Hysteroscope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A device used for observation and treatment of abnormalities in the cervix	
	and inside of uterus of patient.	
	4. Technical Specification:	
	Video Hysteroscope:	
	Direction of View: Forward	
	Observation Range: 6 - 100mm	
	Field of View: minimum 120°	
	Distal End Diameter: ~5 mm	
	Flexible Portion Diameter: 4.8 mm	
	Bending Capability (Angulation Up/Down): 120°/ 120°	
	Forceps Channel Diameter: ≥ 1.8 mm	
	Working Length: ≥ 200 mm	
	Examination sheath of suitable size with lock adapter.	
	Operating sheath with instrument channel for operating hysteroscopy of suitable size.	
	Video output to be compatible with the video processor specified.	
	Endoscopy Light source	
	Operates on LED lamp, Automatic light control and saving	
	Automatic and manual variable light control	
	Emergency lamp with switchover mechanism	
	Microprocessor controlled	
	Front modes and setting controls with intuitive user interface	
	Easy access for lamp substitution	
	Complete with hours counter, for bulb utilization	
	With light weight flexible fiber optic light cable	
	Should be Integrated with Video Processing unit	
	Endoscopy Video system:	
	Video processor for color standard definition high resolution endoscopy]
	images	
	PAL/NTSC type video signal.	
	Controls to freeze images enhance a portion of frozen image (zoom &	
	post-processing). Potient and physician data input leav board	-
	Patient and physician data input key board.	-
	1x CCD compatibility scopes	

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Internal memory

System complete with all cabling and connectors accessories with endoscopes, light source and monitor

Endoscopy Monitor

≥19"or more, medical grade HDTV, DVI inputs/output/HDSDI/RGB/SVIDEO

Menu of functions appear on the screen.

Complete with robust anchoring accessories for the cart or holding arm for the cart

Complete with all cabling and connecting accessories

Endoscopy Recorder, DVD

System for the recording (capture and storage) of videoendoscopy procedures and images in digital media, (DVD / SD / USB)

Suitable for the preparation of medical records

Standard common video and images format types input compatibility

Internal memory storage capacity

Possibility of control via scope head buttons or footswitch.

User interface with controls and display

Irrigation pump unit:

Fully automatic

Able to aspirates & irrigates up to 3L per min.

With large 2L aspiration container.

With Stand-by function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Equipment cart

Cart with at least 4 shelves and 1 low drawer, for accommodation of all components for video flexible endoscopy procedures

Sturdy medical grade stainless steel main structure,

mobile on antistatic castors, with front breaks and lateral bumpers

Complete with isolation transformer, with main switch and

Multiple sockets block (indicative sockets quantity 6), with dedicated socket type

Preferably complete with lateral panels, cable ducts and back protection panels

Supplied with holders for endoscopes and camera cables

Complete with hanger for irrigation bottle

Complete with holder for Co2 insufflations cylinders

5. System Configuration Accessories, Spares, Consumables and other components:

Color printer compatabile with the endoscopy

Leakage tester

Cleaning brush

2x Sealing cup

Luer-lock sealing cup

Luer-lock tube connector

Biopsy and grasping forceps

Coagulation electrode

Examination sheath of suitable size with lock adapter.

Operating sheath with instrument channel for operating hysteroscopy of suitable size.

6. Operating Environment:

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65	
Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Engi-90	1. Generic Name: Endoscope - Video Gastro Intestinal	Endoscopy
	2. UMDN/GMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Gastro Intestinal video endoscope source is fiber-optic cable inserted to GI	
	Tract for Diagnostic and therapeutic purpose.	
	4.Technical specification	
	Endoscopy system include:	
	Equipment cart	
	Endoscopy Monitor	
	Endoscopy Video System	
	Endoscopy Light source	
	Video Gastroscope	
	Video Colonscope	
	Video Duodenoscope for ERCP]
	Video Sigmoidoscopy]
	Endoscopy Recorder, DVD	
	Irrigation System	
	Electrosurgical unit (Diathermy Unit), with all standard accessories	
	Co2 Insufflator	
	Equipment cart	
	Cart with at least 4 shelves and 1 drawer, for accommodation of all	1
	components for video flexible endoscopy procedures sturdy medical grade	
	stainless steel main structure, mobile on antistatic castors, with front	
	breaks and lateral bumpers	1
	Complete with isolation transformer, with main switch	-
	Multiple sockets block (indicative sockets quantity 6), with dedicated socket type	
	Complete with lateral panels, cable ducts and back protection panels	1
	Supplied with holders for endoscopes and camera cables	-
	Complete with hanger for irrigation bottle	1
	Complete with holder for Co2 insufflations cylinders	1
	Endoscopy Monitor	-
		-
	≥21", medical grade HDTV ,DVI inputs/output/HDSDI/RGB/VIDEO Menu of functions appear on the screen with scope guide	_
		_
	Complete with robust anchoring accessories for the cart or holding arm for the cart.	
	Complete with all cabling and connecting accessories	-
	Endoscopy Video System	-

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Video processor for color standard definition high resolution endoscopy images

PAL/NTSC type video signal.

Controls to freeze images enhance a portion of frozen image (zoom & post-processing).

Patient and physician data input key board.

1 CCD compatibility scopes

Internal memory

System with all cabling and connectors accessories with endoscopes, light source and monitor

Endoscopy Light source

Operates on LED lamp, Automatic light control and saving

Emergency lamp with switchover mechanism

Microprocessor controlled

Automatic and manual variable light control

Front modes and setting controls with intuitive user interface

Easy access for lamp substitution

Complete with hours counter, for bulb utilization

Integrated with Video Processing unit

Video Gastroscope

Direction of view should be zero degree.

Minimum of 130 degree of field of view.

Range of observation at least from 5 mm to 100 mm

Angulations of tip up at least 180 degrees and down 180 degrees with right and left movement of at least 120/120 degrees.

Insertion tube diameter of less than 10 mm.

Distal end diameter of not more than 10.5 mm

Instrument channel > 2.5 mm

Working length >1000mm

Compatible with the video system

Endotherapy compatible

Fully immersible in disinfectant solution

Video Colonscope

Direction of view zero degree

Minimum of 130 degree of field of view.

Range of observation at least from 5 mm to 100 mm.

Angulations of tip up at least 180 degrees and down 180 degrees with right and left movement of at least 120/120 degrees.

Inner diameter optimal

Distal end diameter of not more than 10.5 mm

Instrument channel of ≥ 2.5 mm

Working length ≥2000mm

Compatible with the video system

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Endotherapy compatible

Fully immersible in disinfectant solution

Video Duodenoscope for ERCP

Field of vision more than 100 deg.

Direction of view 5deg backward / oblique

Depth of view app 5-50 mm

Distal end outer diameter not exceeding 13.5

Insertion tube outer diameter not exceeding 13 mm

Bending angulation should be at least up 120 deg, down 90 deg, Right 110deg and Left 90 deg

Working length not below 1200 mm

Instrumental channel >4 mm

Compatible with video system

Video Sigmoidoscopy

Viewing Direction: Forward
Observation range: 3-100 mm

Field of view : ≥140 degree
Distal and Diameter: 12.8 mm

Flexible portion diameter: 12.8 mm

Bending Capability:

Up 180 degree

Down 180 degree

Left 120 degree

Right 120 degree

Forceps channel diameter: 3.8 mm

Working length: 1330 mm

Printer

color printer compatabile with the endoscopy

Irrigation pump unit

Able to aspirates & irrigates up to 3L per min.

With large two L aspiration container.

With "Stand-by" function mode

With special filters to ensure sterility.

With no special adjustments necessary, aspiration & irrigation are regulated and selected by the unit.

Equipped with Integrated overflow protection.

Metal case with cover for each scope separately.

Co2 Insufflator

Electronic Co2 insufflator with pin index connection.

Adjustable flow rate of 0 to 30 litres per minute and a pressure range adjustable between 0 - 30 mm Hg.

Pressure and flow rate displayed on the front panel with displays of actual

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and set values.

Provided with silicon autoclavable tubing with luer lock attachment.

Optical and acoustic warning signals for pressure exceeding set limits.

Constant monitoring of intra abdominal pressure with safety to reduce overpressure.

Provision for preheating gas to body temperature.

Fully automatic gas refill.

High Pressure Hose suitable to connect the insufflator with pin indexed Co2 cylinder

Supplied with Co2 cylinder, connecting pipe, main cord and silicon tubing set

Autoclavable wrench & Co2 gas filters disposable

5. System Configuration Accessories, Spares, Consumables and other components:

2x Spare bulbs

20x Snares (ESU Accessory)

20x Injection Needles

20x Clips

20 x Set of Rubber Band ligation

Suction machine: 60L/Min & -900mmHg

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Departmen
		-
Envl-90	1. Generic Name: Endoscope - Video Laryngoscope	Endoscop
	. 2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: - Video Laryngoscopes used to perform medical procedures in the larynx for removing foreign objects in the throat, collecting tissue samples, removing polyps from vocal cords, and performing laser treatments.	
	4. Technical Specification:	
	Video laryngoscope with blades and with integrated video monitor and it is portable battery operated airway visualization system.	
	Video laryngoscope convenient for tracheal intubation.	
	Camera for live Image capturing	
	LED light illumination	
	Color Image display facility LCD/TFT display	
	Provision to insert all sizes of endotracheal tube	
	Provision to introduce all sizes of suction catheters	
	Water proof protection	
	Battery backup facility ≥ 1 hr.	
	All blade sizes/adjustable for adult and pediatric laryngoscope.	
	Color TFT LCD	
	Batteries : DC 3 AAA batteries	
	Battery Life: ≥ 90 minute	
	Video adapter	
	Adapter with camera and white Led Light	
	Blades: Disposable channeled and Not Channeled blades	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	Rechargeable battery and provision for re-charge.	
	Blade 2c: 4.5-5.5 mm	
	Blade 3c: 6.0-8.0 mm	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	

Document: Capital Medical Device Technical Specification

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

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Addis Ababa

Base Code	Item Detail	Department
Enco-90	1. Generic Name: Endoscope - Colposcope	Endoscopy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Colposcope used in diagnosing the internal part of Vagina and cervix.	
	4. Technical Specification:	
	Digital camera(CCD)	
	Effective 14 Mega Pixels	
	40x Magnification	
	3D perception with Digital Matrix processor	
	Facility to choose from 3 color images	
	Facility for fast accessing images, deleting, collecting, focusing, Zooming & Image freezing	
	High MCD super bright white shadow less LED light for true color reproduction	
	Facility for Fast auto/manual focusing.	
	Auto Focal length: 300 mm	
	Side by Side Powerful Comparison of Colposcope images	
	LED lamp life \geq 50,000 hrs	
	Filter: green light filters	
	Light source type: white LED Ring Light	
	Variable Electronic Green Filter facility to choose from 3 different grades of EGF	
	Digital Video Colposcope with Management Software	
	Integrated Digital video Colposcope with HD ≥19 inch monitor	
	HDMI/AV connection	
	Can be integrated to LAN and HIS	
	Statistical Analysis function	
	Multi Format Report Facility	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	
	Colposcope head with camera	
	Post & rolling base with wheels	
	Connecting device to the computer	
	Software in English.	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools, cleaning and lubrication materials, with items not specified above.	
	6. Operating Environment;	

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Stel-90	1. Generic Name: Sterilizer - Chemical, H2O2, Low Temperature	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Instrument to provide simple & fast sterilization of surgical medical instruments like rigid endoscopes, lumen & non lumen, metal, non metal, heat & moisture sensitive instruments at low temperature using H ₂ O ₂ / ETCO ₂ gas plasma technology	
	4. Technical Specification:	
	Front loading with chamber of usable volume of more than 100 liters, with removable shelf	
	The sterilization temperature inside the chamber should be less than 55°C	
	Cycle time: 35 to 60 min	
	The sterility should be in a cassette/ bottle with H ₂ O ₂ concentration more than 55%	
	Sterilizer endorsed by leading instruments and scopes	
	The system should use minimum quantity of sterility which should be less than 6-8ml per injection to deliver dry terminal sterilization to ensure safety of Instruments against corrosion. The unit should be equipped with all the safety features	
	Sterilizer should have LCD display control interface that shows cycle/ phase/	
	control parameters; storage of cycle records data's.	
	Inbuilt printer and touch screen LCD control panel	
	Should not have a need for to have additional dryer machine.	
	Facility to store/upload data on Ethernet/USB port for sterilization cycle recall and printing.	
	Facility to seal and store sterilized items of different sizes.	
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator.	
	Forced air convection (hot air circulation).	<u> </u>
	Fully automatic provided with timer and fan.	
	Temperature range: Room temperature to 250 degree Celsius (adjustable)	
	Temperature Variation : +/- 1 deg C.	
	Temperature and time display unit	
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel	
	With two adjustable mesh shelves of stainless steel	
	Capacity of mesh: 25L	
	5. System Configuration Accessories, spares and consumables -	
	All consumables required for installation and standardization of system to be given free of cost.	

Supplied with all startup chemical indicator tape/strips which change from red to yellow or gold and so show exposure to hydrogen peroxide.

Pouches and rolls of different size which display directly on the bag chemical exposure to hydrogen peroxide.

Supplied with all startup incubators, instrument tray of all sizes

3x set of readymade gasket

3x fuse

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Departmen
Steh-90	1. Generic Name:Instrument - Sterilizer Hot Air 60L	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:-	1
	Hot Air Sterilizers are required for sterilizing an object in high temperature by using dry heat to sterilize and operate in the principle of patented fine air circulation achieved by means of a fan in an electrically heated chamber.	
	4. Technical Specification:	
	Should be table top and front loading	
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator. Thermostatically controlled system.	
	Hot air circulation	
	Fully automatic provided with timer and fan.	_
	Temperature range: Room temperature to 250 degree Celsius (adjustable)	
	Temperature Variation: +/- 1 deg C.	
	Temperature display unit	
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel	
	With three adjustable mesh shelves of stainless steel	
	Capacity: 60 liters/ above	
	5. System Configuration Accessories, spares and consumables -	
	System as specified - All consumables required for installation and standardization of system to be given free of cost. Timer and touching pad	
		+
	3x set of Spare Heater	-
	3x set of readymade gasket 3x thermostat, 3x fuse	-
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	=
	Relative humidity: < 85%	=
	7. Utility Requirements:	=
	Electrical Power Supply: 220VAC ±10%	1
	8. Standards and Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Buse Coue	Tem Dean	Deput timent
Stds-90	1. Generic Name: (Instrument - Washer/Disinfector)	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Washer/Disinfector: An automated washing unit that uses high-temperature water and detergent to clean and high-level disinfects instruments and trays.	
	4. Technical Specification:	
	Washer/Disinfector: An automated washing unit that uses high-temperature water and detergent to clean and high-level disinfects instruments and trays. 4. Technical Specification:	
	Front loading, Electronically controlled, Single door with forced air drying system	
	Volume: 60L	
	Touch screen, with LED/TFT control panel, about 7" or above screen size	
	Motor driven sliding door made of stainless steel medical grade of 316 with thermal insulation.	
	Freshwater circulating system	•
	Hot water Connections:	
	Total Power: 9KW	
	Pump Power: 150W	-
	Dryer Blower: 150m3	
	Total Power: 3KW	
	Dryer Heater: 750W	
	Cold Water Connection:	
	Min/max pressure: 0.5 – 2bar	
	Min/max temperature: 55 – 60 Celsius	
	Flow rate: 30L/min	
	Hydraulic connection: 25mm	
	Heating up to 95 degrees C.	
	Automatic dosing systems for liquid and powder cleaning substances	1
	Interior parts of stainless steel, 2 shelves	
	Machine is insulated against noise and works also with low-water pressure of 0.5 bars.	

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With specially selected insert and baskets for cleaning surgical instruments.

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

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Addis Ababa

Base Code	Item Detail	Department
Stes- 90	1. Generic Name: Sterilizer - Steam, 300/500L	OR
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Steam Sterilizer used in the destruction of all forms of microbial life on medical	
	instrument by exposing the object to moist heat at 121°C-134°C under high pressure	
	4. Technical Specification:	
	Front Loading 300/500L	
	Touch screen, with LED/TFT control panel, about 7" or above screen size	
	Motor driven sliding door made of stainless steel medical grade of 316 with thermal insulation.	
	Fitted with load indicator and safety thermostat take over indicator lamp. LED Indicator	
	High Grade strong stainless steel 316, Triple walled construction	
	Positive radial self-locking safety doors	
	Hydrostatically tested to withstand 2.5 times the working pressure	
	Manual and automatic filling option	
	Internal data archiving with 5000 cycle capacity	
	Air ballast system for fast and safe processing of fluids	
	Control System: Microcontroller Based	
	The safety value will be open automatically when the inner pressure over and the steam be exhausting to the water tank	
	The door opening mechanism cannot be operated until the pressure in the chamber reached atmospheric Pressure	
	A complete record of every cycle is produced on the built-in thermal printer, with 1 box of thermal paper	
	316 stainless steel pressure vessel	
	Fan cooling system	
	automatic and real time self diagnosis system in case of failure and have means of reporting to the operator	
	Having alarm for preventive maintenance	
	A safety micro switch is fitted to the door which will only allow the cycle to start if the door is properly closed and locked.	
	Water system: Automatic water fill with inbuilt/external reverse osmotic water softener in the system	
	water supply line fitted with extra water filter	
	Sealed with Silicon long-lasting and durable gasket.	

Digital display for jacket and chamber pressure, steam generator and temperature with gauge display

Outer jacket of stainless steel 316 to prevent heat loss

Mounted on tubular stainless steel 316 frame with ground leveling flanges

Integral drip tray

Double chamber made of medical grade 316 stainless steel

Internal chamber with capacity not less than 300L

The steam generator made of medical grade 316 stainless steel

Thermal insulation to prevent overheat

Heat dissipation: maintain nominal temp and the heat dispersed through a cooling mechanism

Input voltage: 380VAC, 50Hz, 3-phase

Pressure gauge: 0-2.2Kgf/cm²

Operating pressure from: 15-31 psi

Sterilizing pressure: 1.2-2.2Kgf/cm(15-31 psi) at 121°C-134°C

Protection: over-charging cut-off with visual symbol

Pressure control switch

Low water level cut-off device

Vacuum breaker

Barcode reader and software

Modem link

Mounted Air compressor

3x Readymade Spare Gaskets

Steam generator

Rapid water re-cooling

Inbuilt vacuum pump

Low water protection device

Air removal filter

Timer with alarm system

Digital temperature indicator

Printer & Digital chart recorder

Stainless steel flush mounting

Carriages, trays, and baskets

Overpressure release valve

Sterilization indicator

Indicator color must not fade when it is exposed to light

Distinctive color change

Dual strip can be divided into two for economy of use

1x 300pcs/box, Dimension 150×90×200mm

Lead free steam indicator tape

Document: Capital Medical Device Technical Specification

For stem range of temperature of application: between 121°C and 134°C

Shelf life: 5 years

5. System Configuration Accessories, Spares, Consumables and other components:

2x Trolleys for contaminated and for sterilized instruments can be fitted thethe sterilizer door/Each

Pneumatic valves, Pressure switch

Temperature sensor

3x Spare heater

2x Door gasket

1x Spare contactor

3x Spare fuse

5x Gasket lubricant

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Document: Capital Medical Device Technical Specification

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Toeh-90		OR
	1. Generic Name: Table – Operating, Electro hydraulic	_
	2. GMDN/UMDN Code/Name:	4
	3. Clinical Purpose/Description:	4
	It used during surgery on which the patients lie and easily adjustable	
	4. Technical Specification:	_
	Four section table, electro-hydraulic table	4
	Should be adjustable to all essential positions.	4
	Should have frame and bottom made of 304 grade Stainless Steel material .Height	_
	Height should be adjustable by oil pump, foot step control. Should have detachable head rest which can be easily adjustable to any desired	
	position, above or below the table top.	
	Table top can be rotated 360° through base. Durable and leak-proof hydraulic pump.	
	Kidney-position should be achievable by breaking the table	
	Should have handset for position selection by in-built stand-by control	
	Tabletop should be radio-translucent Can be controlled with and without remote controlled with battery and battery indicator, electro-hydraulic operated	_
	Facility to remove or interchange head and leg sections	_
	Antistatic and liquid-tight mattresses with shock absorbing foam	
	Table made of corrosion resistant and disinfectant- proof stainless steel.	
	Traction facility	
	High density memory foam, 1-piece mattress, with cut- outs to fit the mattress frame at all positions with mattress size of 60mm	
	Powered height adjustment from 0.6m to 1.2m	
	Powered Trendelenburg adjustment -30 deg up to +45 deg	
	Lower Back :+100°/-30°	
	Upper Back:+80°/-30	
	Lateral tilt (left/right) up to ±30 deg	
	Adjustment of backrest -25 to +70	1
	Adjustment to flex/reflex position	7
	Adjustment leg section +70° / -90°	1

Document: Capital Medical Device Technical Specification

Table dimension (lx w x h) 970mm x 500mm x 2000mm

Support at least 250 Kg

Leg Sections (UP/Down) :+25°/-90°

Head Sections (Up/Down):±40°

5. System Configuration Accessories, Spares, Consumables and other components:

1x Screen frame

1x I.V. stands

Shoulder support (pair): Lateral support (pair)

2x Arm table

6x Clamps

1x Restraint strap

1 x Jelly mattress to prevent nerve distortion for every surface of the table

Orthopedic Surgery's accessories: Orthopedic extension, Raised arm tabled / Adjustable arm support

ENT accessories: Head rest

Gynecology Surgery's accessories: Knee crunches (Pair) Rotary clamps (2 pcs)

Neuro Surgery's accessories: Mayfield and head rest

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30 °C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Mioe-90	1. Generic Name: Operating microscope	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	An operating microscope is an optical microscope specifically designed to be used in a surgical setting, typically to perform microsurgery.	
	4. Technical Specification:	
	Optics:	
	Apo chromatic optics	
	Binocular tube 0-180 degrees of rotation.	
	Should have high quality red reflex/enhance for better red reflex or stereo coaxial illumination	
	standard magnification for operating microscope (3.4x, 5.3x, 8.5x, 13.6x, 21.2x)	
	Eye piece should be minimum 10x or 12.5x wide with eye guards.	
	Should have universal coupling	
	Should have tools free design for stand-by bulb change over and for failed bulb replacement.	
	Monitor and Camera	
	Standard Display and Camera	
	Illumination	
	Integrated LED	
	90 degree binocular with converging optics.	
	Cold light coaxial illumination by fiber light guide	
	Heat absorbing, IR and UV filters for protection eye	
	Floor stand system:	
	Should be floor standing type with fiber wheels with 4 castors brake	
	Foot switch functions	7
	Stand height adjustment	
	Weight carry capacity stand	
	Should have counter balanced arm mechanism.	7
	Should have rust free design.	
	X-Y Coupling	1
	Should have motorized x-y movement	1
	Adjustment range not less than +30mm	
	Key for initial position of x-y coupling and focus	7

Document: Capital Medical Device Technical Specification

5. System Configuration Accessories, Spares, Consumables and other components:

Objective lens

1x Chip camera CCTV camera

Suitable adapter for 1 chip Camera

Eye pieces

Halogen lamp/LED

Beam filters

Sterilization process for accessories

Comply with standard cleansing and disinfection

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Document: Capital Medical Device Technical Specification

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Addis Ababa

Base Code	Item Detail	Depar
Lioc-90	1. Generic Name: Light-Operating, Ceiling	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A ceiling type provides an optimal shadow free lighting for carrying out surgical procedures in an emergency environment.	
	4. Technical Specification:	
	The unit consists of spring balanced articulating arm with one large copula and one satellite heads.	
	Capablerotating 360° around vertical axes	
	Control unit to regulate light intensity and to switch on/off the unit	
	Shall have continuous dimmer, continuous focus adjustment, continuous field adjustment	
	Sterilizable removable handle to regulate light field size	
	Diameter of domes: large copula, approx. 0.70 m, and satellite heads of each not less than 0.45 m	
	Light intensity: for large copula not less than 130,000 lux at 1m distance from light source and for each satellite heads not less than 100,000 lux at 1m distance from light source	
	Brightness control to allow full adjustment from zero to maximum illumination.	
	Color rendering index: 95	
	Heat filtrating: 99%	
	Luminance Field size: 14 - 25 cm	
	Vertical adjustment: not less than 110 cm	
	Working distance range (focal length): 70 - 140 cm	
	Depth of field with focused light: > 60 cm	
	Color temperature: ≥ 4300 K	
	Light source: LED, lifetime of $\geq 50,000 \text{ hrs}$	
	Adjustable light and color temperature Indicator	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1 x Ceiling anchoring ring, extension and fixation material	
	1x spare of Sterilizable removable handle	
	3x Spare, spare fuse for each place, and one power supply bord	
	1x LED matrix board	

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 100 - 240VAC

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Document: Capital Medical Device Technical Specification

Base Code	Item Detail	Departmen
Liom-90	1. Generic Name: Light-Operating, Mobile	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	A mobile type provides an optimal shadow free lighting for carrying out surgical procedures in an emergency environment.	
	4. Technical Specification:	
	The unit comprises of spring balanced articulating arm	
	Head with button/touch screen digital control to regulate light intensity and to switch on/off the unit	_
	Have continuous dimmer, continuous focus adjustment, continuous field adjustment	
	Auxiliary light source included for extra operations	
	No infrared or ultraviolet radiation Sterilizable removable handle to regulate light field size	
	Light intensity: not less than 100,000 lux at 1m distance from light source	
	Color rendering index: 95	
	Heat filtrating: 99%	
	Color temperature: ≥ 4300 K	
	Luminance Field size: 14 - 25 cm	
	Diameter of light head: not less than 0.60cm	
	Working distance range (focal length): 70 - 140 cm	
	Depth of field with focused light: > 60 cm	
	Lifetime of LEDs ≥ 50,000 hrs	
	Adjustable light and color temperature indicator	
	Mobile stand:	
	Light weight easily moveable stable support with at least 4 castors with locking counter balance mechanism in order to ensure stability of light head in all positions and with swivel arm.	
	Castor must be medical chemical resistant	
	Battery:	
	Built in rechargeable batteries with capacity sufficient for operating in battery mode (fully charged) for minimum of 45 min	
	Battery power (charge) indicator	

5. System Configuration Accessories, Spares, Consumables and other components :

1x spare of Sterilizable removable handle

2x spare of fuses

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 100 - 240VAC

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Tender and Purchase Order No.
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Addis Ababa
PO Box 25-11-276-32-65 Tel: +251-11-276-32-65 Fax: +251-11-275-25-55

Base Code	Item Detail	Department
Cryu-90	1. Generic Name: Cryotherapy Unit – Gynecology	Gyn
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal.	
	4. Technical Specification:	
	The system typically includes a mechanical regulator to control the flow of cryogen, contained in an attached cylinder, and the probe(s) to apply the cold	
	Unit consist of a tank, a pressure regulator, and a probe attached by tubing to the tank	
	Fully mobile Cryo-surgical system with a wide array of interchangeable probes designed for the use of gynecologic surgical procedures	
	The interchangeable probes must include both different sizes for the cervix besides flat one for vaginal lesions	
	Nitrous oxide or carbon dioxide can be used as refrigerant	
	Units should support various probes and tips	
	Nitrous based unit should have scavenging ability	
	Adjustable freezing temperatures, gas flow and pressures through a regulation system	
	Non-electric defrosting system	
	Autoclavable Cryo probes	
	Operating pressure: 450 to 800 psi.	
	Operating temperature: -70 to -10°C for Carbon dioxide and -90 to -25°C for Nitrous oxide	
	Supplied with triggers/connection for N2O or CO2	
	Rolling cart	
	Unfilled cylinder for N2O or CO2	
	Supplied with all kinds of probes required for gynecology.	
	Require several different probe designs	
	Temperatures at the Cryo tip below -79°C (-110.3oF) with CO2 or -89°C (-128.2oF) with N2O	
	The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred)	
	Removable circular, closed design Cryo tips	
	Diameter: (19 +/- 2)mm	
	Flat surfaces or with a cone extrusion < 5mm	
	Insulated Cryo shaft	
	Length 170mm to 200mm	
	Hose assembly (high pressure) with cylinder connector pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas	

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User adjustable Cryometer range

Portable and easy to transport

Hose assembly length of 150cm

Hose is constructed with flexible plastic or rubber suitable for use with pressurized carbon dioxide or nitrous oxide.

Indicator for which type of refrigerant gas is under use

Color coded Pressure gauge, to indicate the safe working range

Pressure relief valve, with an internal rupture disk to protect excessive tank pressure

Pressure regulator to maintain constant pressure

Silencer reduce noise levels

Timer to indicate duration of tissue exposure

Cryo Tips:

Withstand routine sterilization

Smooth and sharpless Cryo tip edges

Closed design, rounded in shape and should be (19 +/- 2) mm in diameter

The surface that contacts the tissue should be either flat or with a cone extrusion (nipple shaped), not exceeding 5mm

Length of the Cryo shaft and Cryo tip assembly: 170 and 200mm.

Hose assembly length of 150cm

Single-hand control from three-position trigger (freeze, off, defrost)

Instant defrost

Trigger position for immediate active defrost process

Autoclavable tips, Cryo shaft

"O" ring design to provide better gas seals where tips attach to probe system

Built-in regulators, control pressure at tips for added safety and gas economy

Change tip during procedure without shutting off gas tank

Nitrous Oxide (N2O) and Carbon Dioxide (CO2)

Cylinder Support of 20 lb.

Surgical grade Cryo Tips:

Micro, 2mm Diameter

Skin Lesion, 5mm 45°

Endocervical (Nulliparous)

Endocervical, Round

Skin Lesion, 8mm 45° angle

Ano-Rectal

Exocervical, 19mm Flat

Exocervical Convex, 19mm

Endo/Exocervical Small

Exocervical, 25mm Flat

Endo/Exocervical Large

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5. System Configuration Accessories, spares, Consumables and other consumables:

1x Hose assembly

1x Cryotips for each type

1x Cryoshafts

1x O-ring, and sealing washers

1x Compressed gas in cylinders (nitrous oxide or carbon dioxide)

Cryoprobes to according the specific use

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +43 °C

Relative humidity: <85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Anes - 90	1. Generic Name: Anesthesia Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Anesthesia Machine used to control the patients gas exchange and administer anesthetic agents to patient during surgery	
	4. Technical Specification:	
	The complete set-up shall included patient circuit, monitor and ventilator	
	Patient monitoring system with vital parameter ECG, SPO2 (Pulse Oximeter) including adult pediatric and neonatal probe, Capnography(EtCO ₂), and airway pressure, NIBP inclusive of adult, pediatric & neonatal with NIBP cuffs, rectal & skin temperature, Anesthetic gases, IBP with necessary arterial lines, and CVP should be present pressure transducers and necessary accessories as per requirement.	
	Anesthesia machine of closed breathing circuit configuration Suitable for Adult and pediatric including maplson D neonatal and pediatric system.	
	Anesthesia gas delivery system.	
	Equipped with anesthesia vaporizer (Halothane& Isoflorine) and Anesthesia ventilator.	
	Independent attachments for connecting central gas supply and pin indexed cylinders and non interchangeable gas specific connection to pipe line inlets	
	Should have audio- visual oxygen failure warning system with nitrous oxide cut off.	
	Trolley with upper shelf and medical utility rail Integrated support for two 10L anesthetic gas bottles (O_2, N_20) , Soda lime absorber, with 2.5 kg reservoir and adjustable pressure limiting valve	
	Flow meter:	
	The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters	
	For O2: 0.1-10L/mi	
	For N2O: about 0.1-10L/mi	
	For Air: 0.1-10L/mi	
	Oxygen and Nitrous oxide anesthetic agent in the inspired mixture	
	Oxygen saturation of the blood with both adult & pediatric probes & sensors	
	Airway pressure monitoring should be present	
	Temperature monitoring with 2 probes esophageal/rectal and skin probes	
	Mounting:	
	Mobile stand mount for the unit	
	Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes	
	Individual locking front castor brake	

O2 flash valve: Push button type o2 flow volume approximately not less than 50-70 L/min.

Canister: Easily detachable double chambered clear acrylic type. Its volume should be greater than 1400ml.

Extendable rear platform for two cylinders.

Features:

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/

A flow meter with a N2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Alarm safety system features:

Low O₂ concentration alarm sound with indicator light

When O_2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O_2 supply pressure alarm sound & N_2O supply shut off system shut off system

A N_2O safety device which automatically cut off the N_2O flow when the O_2 supply pressure drops below 1kgf/cm2

 N_2O shall not be obtained until at least 1.5lt of flow is surely obtained constantly.

POP of valve should prevent over pressure with surplus gas evacuation adaptor and open close circuit selector knops.

Ventilator:

Modes: Automatic Volumetric (IPPV), SIMV and Manual

Electrically powered compressor, minute volume: 2 to 25 L/min

Tidal volume: 20 - 1500 ml

Respiratory rate: 5 to 70 cycles/min

I/E ratio: (1:2 to 1:6)

Inspiration pressure: 0 to 80 mbar

Peak inspiratory flow: 0 to 60 L/min

Trigger sensitivity: 0 to -20 mbar

PEEP: 0-30 cm H20

Gas flow rate and volume indicator

Gas type indicator

Fio₂ indicator

Display fit with manometer, range approx: - 10 to 100 mbar

Front panel shows status, errors and sensors failure (low/high pressure, power failure)

Audio-visual alert on low/high pressure, apnea, power failure

Display of operational status, with set and measured values

Front panel shows status and errors (low/high pressure, power failure, battery status)

Safety features for: hypoxic mixtures, oxygen failure (emergency O_2 bypass), overpressures

Self diagnosis with each start-up and integrity testing of all system parameters

With adjustable patient-circuit support arm

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Anesthetic gas scavenging system

Inbuilt suction unit for direct patient suctioning in oral cavity during intubation and extubation

Oxygen flush: 25-75ml

5. System Configuration Accessories, Spares, Consumables and other components:

4x Oxygen sensor

1x reusable ECG sensors and connectors set.

2x reusable adult and or pediatric, neonateoxygen saturation sensor and connector set.

2x reusable adult and or pediatric invasive pressure transducer and connector set with appropriate arterial lines

2x reusable adult and or pediatric non-invasive pressure transducer and connector set.

2x rectal temperature transducer and connector set.

2x adult and or pediatric cardiac output connector set.

5x EtCO2 sensor.

High and medium pressure regulating gauge compatible with the machine

5 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)

5 x Adult reusable breathing circuits (tubes / balloons / valves / masks)

5 x Maplson D neonatal reusable breathing circuit tube/(tubes / balloons / valves / masks)

5 x Spare parts/maintenance kit (air filters, tubing, O rings)

2 x Set of spare fuses.

Should be supplied with necessary attachments for use of the breathing circuits with all other complete standard accessories

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

Built-in rechargeable battery, autonomy approx 2 hrs with Automatic switch to battery in case of power failure, automatic recharge when connected to mains

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including

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laborand spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Department
Elsu-90	1. Generic Name:Electrosurgical unit	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	-
	Use high frequency electrical energy in a radio-frequency (RF) band to develop heat directly within targeted soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures	
	4. Technical Specification:	
	Modes of operation to include pure cut, pure coagulation and blended (combined)	
	Operation to be controlled by foot pedal, with minimum 2m connection cable, and also by hand switch on probe	
	RF generator to be within the range 0.5 to 3.5MHz, output to be electrically isolated from ground.	
	Monopolar maximum power to be at least 350W (cut) and 200W (coagulate)	
	Bipolar maximum power to be at least 50 W (coagulate)	
	Visual and audible activation indicators required	
	Visual and audible cable disconnection alarm required	
	Display and keyboard for all parameters visualization and setting.	
	Power control in the main panel.	
	Coagulation: high power for contact coagulation current with high crest factor for spray coagulation.	
	Memory for at least 10 programs with their waveforms and power levels.18) Monitoring system of the electrode-patient connection of at least 1 Khz measurement frequency.	
	Automatic power tuning with dynamic control and automatic stop in case of any working problem.	
	Protection against defibrillator discharges.	
	Convection refrigeration without ventilator.	
	Output Waveform: 445 kilohertz (kHz) square wave variable burst length Frequency Range: 445 kilohertz	
	Output Current Range: 10 - 641 milli amperes (mA rms) into a 50 non inductive load, continuously variable	
	Output Power: 0.5 - 21 watts into a 50ohms non-inductive load	
	Continuously variable Test Load: 50ohms non-inductive load	1
	Neuron-surgical forceps input, using electrosurgical analyzer Rated Accessory Voltage: 210V Peak	
	Minimum nominal high frequency output powers for cutting:	1

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- Mono polar 300W at 500 ohms
- Bipolar 100W at 500 ohms.

Minimum nominal high frequency output powers for coagulation:

- Bipolar 100 W at 125 ohms;
- Mono polar spray 100 W at 500 ohms;
- Mono polar forced 120 W at 350 ohms.

5. System Configuration Accessories, Spares, Consumables and other components:

Foot switch

5x Spare fuses

2x Reusable, sterilizable, Monopolar patient plates with minimum 2m long connection cable

Supplied with two each of reusable, sterilizable, monopolar and bipolar probe with selection of tip sizes for each; pencils, ball electrodes, loop electrodes, reusable return electrodes, coagulators, adapters and blade electrodes

Mono polar pedal, bipolar pedal

Bipolar forceps

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Department
Suc-90	1. Generic Name: Suction Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a	
	body cavity or lumen by means of suction. This system can be used in a wide variety of settings within healthcare facilities ICU.	
	4. Technical Specification:	
	Vacuum Adjustment: Continuous	
	Must be able to generate a vacuum of at least 0.85 bar (650mmHg)	
	Maximum vacuum: 700 mmHg	
	Minimum open tube flow rate at least 3L/min	1
	Twin suction bottles, minimum size 3 liters each made of non-glass materials	1
	Bottles to have an automatic cut off when full to prevent ingress of fluid to motor	1
	Airline to pump to incorporate bacterial filter	1
	Tubing to patient to be minimum 3m long, non-collapsible type	1
	Sound Level: < 60 dBA.	1
	Castors: 100mm diameter, with brakes	1
	To be protected against fluid ingress from above	
	Machine cover should be open able for repair and maintenance	
	Oil-free pump operation preferred	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	2x Spare suction bottles	
	5x Spare inlet filters at least	
	2x spare sets of fuses,	
	3x Suction tubes`	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Protective replaceable fuses fitted on live and neutral supply lines	
	Electrical source requirements: Voltage: 220V ± 10, Frequency: 50Hz single phases	
	Electrical source with line connection plug type.	
	Protections against over-voltage and over-current line conditions	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	

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The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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3	Pulse Oximetry 2. GMDN/UMDN Code/Name: 3. Clinical Purpose/Description: A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of hemoglobin oxygen saturation (SpO ₂). 4. Technical Specification: SpO ₂ measurement range at least 60 to 99 %, minimum resolution 1% Accuracy of SpO ₂ better than ± 2% Pulse rate range at least 30 to 250bpm, minimum gradation 1bpm Accuracy of pulse rate better than ± 2bpm Automatic power-off facility required after minimum of 1 minute Low battery display required Supplied with rechargeable battery Digital equipment with autocorrelation algorithm	OR
3	3. Clinical Purpose/Description: A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of hemoglobin oxygen saturation (SpO ₂). 4. Technical Specification: SpO ₂ measurement range at least 60 to 99 %, minimum resolution 1% Accuracy of SpO ₂ better than ± 2% Pulse rate range at least 30 to 250bpm, minimum gradation 1bpm Accuracy of pulse rate better than ± 2bpm Automatic power-off facility required after minimum of 1 minute Low battery display required Supplied with rechargeable battery	
## A A A A A A A A A A A A A A A A A A	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of hemoglobin oxygen saturation (SpO ₂). 4. Technical Specification: SpO ₂ measurement range at least 60 to 99 %, minimum resolution 1% Accuracy of SpO ₂ better than ± 2% Pulse rate range at least 30 to 250bpm, minimum gradation 1bpm Accuracy of pulse rate better than ± 2bpm Automatic power-off facility required after minimum of 1 minute Low battery display required Supplied with rechargeable battery	
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I S I I I V b	Low battery display required Supplied with rechargeable battery	
S I I I V b	Supplied with rechargeable battery	
I I I V b	11 0	
I I V b	Digital aggingment with autogenication algorithm	
I V E	Digital equipment with autocorrelation algorithm	
b F	Internal memory continuous data storage time not less than 12 hours	
b F	Integrated display for data visualization with size not less than 5 inches.	1
F	Video display of at least the following parameters, SpO2 sensor connected, alarms disabled, low	7
	battery, battery in charge.	
A	Plethysmography curves and tendency lines visualization capabilities for monitored parameters	7
	At least the following audio alarms: high frequency, low frequency, low saturation.	
h	hard and splash proof case	
I	Display must allow easy viewing in all ambient light levels	
S	Supplied in protective case for clean storage and safe transport	
I	Handle bar or facilities for easy transportation.	
5	5. System Configuration Accessories, Spares, Consumables and other components:	
1	1x Cable with a length of at least 1.5m	
1	1x Reusable pulse oximeter sensors adult, pediatric, neonatal patient	1
6	6. Operating Environment;	1
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Charger electrical source requirements: Voltage: 220V ± 10 /50Hz single phases	
<u> </u>	Protections against over-voltage and over-current line conditions.	
H	Battery charger to be wall output fitted and has AC to DC adapter	-

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

Supplier to perform safety and operation checks before handover for some samples

Training of users in operation and basic maintenance shall be provided

The case is to be cleanable with alcohol or chlorine wipes

10. Warranty and After Sale service:

The supplier must be provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

Certificate of calibration and inspection to be provided

Advanced maintenance tasks required shall be documented

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

	Item Detail	Departmen
Oxy - 90	1. Generic Name: Oxygen concentrator	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Oxygen concentrator is a device which concentrates oxygen from atmospheric air (typically ambient) to supply the patient.	
	4. Technical Specification:	
	Compact and easy to transport (Mobile on Castors).	
	Dual-head Compressor.	
	Capacity: 1 to 5 l/Min of O2 at minimum of 90% concentration at maximum flow	
	Pressure- Compensated flow meter shall permit use of long cannula	
	Audible and visual safety alarms: Power Failure, Restricted Flow, Low O2	
	Pressure-relief Valve and thermal protection of the Compressor.	
	Double - insulated Unit, Two-prong plug.	
	Flame-retardant Cabinet	
	Sound Level: 60 dB average	
	Fixed humidifier port and recess shall prevent bottle and connector breakage	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	O2 Tubing	
	3x Face Masks (Adult, Infant, New Born)	
	2x Humidifier	
	1x Set of Filters	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical source requirements: Voltage: 220V± 10 /60Hz single phases	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	Supplier to perform safety and operation checks before handover for some samples	
	Training of users in operation and basic maintenance shall be provided	
	10. Warranty and After Sale service:	
	The supplier must provide minimum of one year warranty including labor and spare part from the date of commissioning.	

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Denu-90	1. Generic Name: Dental Unit	Dentistry
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Dental Unit is used to operate or treat the patient by looking into mouth easily	
	for the purpose of dental examination, minor surgery and other dental	
	procedures.	
	4. Technical Specification:	
	Dental chair with microprocessor controlled programmable dental chair with different programs	
	≥5 reprogrammable patient chair position with control panel	
	Foot Pedal to control the dental chair movement, hand piece and scaler	
	Adjustable Height	
	Backrest: slim and adjust table between 90° to 180°	
	Headrest: adjustable upward, backward and forward.	1
	The movements are controlled through digital panel	
	Genuine leather chair with seamless washable cushion	
	Swivel arm	
	Carrying capacity: 200 kg	
	Pediatric Headrest	
	Rotatable ceramic spit on with auto-water flushing	
	Operating light	
	Adjustable to different heights with variable, horizontal and inverse movements	
	for proper focusing.	
	Light source: LED	
	Illumination of \geq 30,000 Lux incidents in rectangular shape	
	Color temperature of ≥ 4000 K	
	Dual intensity control switch	
	Water Unit	
	Cold water	
	Automatic flush Bowl]
	Automatic Cup filler	
	Water bottle with switch	
	Clinician Side	
	Push button fiber optic Air turbine, 4 holes individual control of water and air, autoclavable.	
	Fiber optic electric Motor with rotation of bur clockwise and anticlockwise, autoclavable.	
	The motor features high torque and quiet operation	

With micro motor from 300-50000 rpm with digital display of speed

Straight hand piece and contra Angle hand piece, autoclave able.

Automatic hand pieces selection through sensitive pneumatic valves

The quick locking connectors have also an integrated USB connection

6 way syringe with light

Straight or angled syringe

Adjustment for water, air and spray

Heating element for water and air inside the hand piece

Tips and cover are removable, autoclavable at 134°C

Monitor:

Integrated 19" medical grade LCD/TFT monitor

Resolution: 1080 x 1080

USB port with media player

Intra oral camera:

True lens intraoral camera, undistorted images with Not less than 6 lenses optics

Progressive video: No jagged edges

Instrument tray:

Tray table mounting arm swivels 360°

Tray table size: 300 x 380 mm

Assistant's Side

Triple syringe with removable nozzle, autoclave able

Saliva ejector (strong and weak)

Light control

Spray

Assistant control system

Portable Scaler with LED ultrasonic cleaner

Ultrasonic vibration between 25,000-35,000 per second

Micro processor based

Auto calibration and power control

Built in lens in the grip

Auto fault diagnosis

Water heated at the hand piece

The output power and water to be adjustable by controls on the front panel.

Complete with 6 different pieces of tips.

Sterilizable hand piece, tips holder and torque tools.

Autoclavable Scaler tip fixer and remover

Sterilization box

Portable light curing unit

Base unit with holder for hand piece

Hand piece

Digital Timer for adjusting of different time settings.

Standard cable operation

Standard light probe

Portable-tooth polishing unit

Flexible air polishing unit

Tooth cleaning and polishing

Interior and posterior teeth application

Twin flow system

Complete with powder holder and jet polishing/cleaning powder

Suction aspirator

High electric dry suction aspirator which is connected with central system and suction machine

Vacuum: 150 - 170 mbar

Flow rate: 500 - 800 L/min.

Connector accessory to central septic unit

Doctor's and assistant's stool

Adjustable height operating stool with anatomically shape seat.

Gas spring mechanism for adjustments.

Integrated four stable castors with brake

Arm support and adjustable backrest.

Compressor

Supply medical grade dry air which is absolutely oil free

Pressure gauge, air moisture filter and non-retraction valve

Auto cut-off switch

Maintenance free type covered in a cabinet

Noise level: ≤ 60 Db

Air Pressure range: 5 to 8 bar

Compressed air supply: 100 L/min

Air tank capacity: $\geq 40L$

Dental X-ray film viewer

Chair mounted type LED generated

5. System Configuration Accessories, Spares, Consumables and other Components:

3x Saliva ejector

2x Extra LED diodes that can fit for operating light and film viewer

4x set suction tip compatible with the dental chair suction aspirator

3x set of polishing tips

3x set of extra scaler tips

1x set extra piece low speed hand piece burs

1x set extra piece of high speed hand piece burs

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials

Document: Capital Medical Device Technical Specification

including items not specified above.

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity : < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%, 50HZ

8. Standards and Safety Requirements:

Meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

- a). Water Connection
- b). Drain Connection
- c). Electrical Connection

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Xrd-90	1. Generic Name: X-Ray- Dental	Dentistry
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Dental x-ray used in orthodontic/maxillofacial diagnostic and treatment	
	planning of ear, nose, and throat (ENT) disorders.	
	4. Technical Specification:	
	Radiological exams: Full panoramic and cephalometric	
	X-ray system for dental exams and temporo mandibular joint (tmj with	
	panoramic program/cephalometric, facial bone program, maxillary sinus	
	program, dental program, tmj program)	
	Automatic Facial Contour (AFC) method for soft tissue enhancement in lateral views.	
	Dose reduction is achieved for orthodontic applications with a fully adjustable	
	lateral cephalometric imaging area.	
	Stand model with fiber wheels and locking system	
	Compatible for digital radiograph.	
	X-ray tube head swing angulations of at least 290° in the vertical plane and 360	
	° continuous rotations in the horizontal plane	
	X-ray tube head angle indication	
	Counter balanced arm mechanism	
	AEC Reduces Radiation Exposure	
	Digital linear tomography in digital unit	
	True linear tomography/Linear tomography in film unit	
	Tube voltage: 70-90 kV]
	Tube current: 2 - 20 mA	
	Frequency: 150 kHz	
	Tube focal spot: 0.5 mm	
	Cephalometric	
	Image Detector: CCD	1
	Sensor Pixel Size: 50 x 50 µm	-
	Image Pixel Size: 96 x 96 µm	-
	Scan/Exposure Time: 2–10Sec	-
	Panoramic	1
	Sensor Pixel Size: 50 x 50 µm	
	Image Pixel Size: 96 x 96 µm	1
	Scan/Exposure Time: 2–15seconds	1
	Exposure mode: patient sizes (Ped., Adult: small, medium, large) / 3 dental	-
	arch morphology (normal, square, sharp)	
	Lateral TMJ (closed & open)	1

Document: Capital Medical Device Technical Specification

PA TMJ (closed & open)

PA sinus

Standard panoramic

User friendly graphical user interface on a computer and from the console on the machine

Exposure time 1 to 5secs. Depending upon the patient's type and programme selection.

Standard bite blocks, edentulous blocks, Panoramic chin rest, TMJ Nose rest sinos chin rest

Supports the most versatile range of 2D and 3D imaging modalities

DICOM, RIS and PACS compatible unit

Universal power input including power factor corrector, mains voltage fluctuations automatically compensated

Automatic primary collimator

Graphical user interface

Advanced collimation

Upgradable software

Optimized image geometry and constant magnification

High resolution CCD sensors with protective optical fibre layer for protection and longevity of the sensor and adjustable panel size

Ethernet connection to computer sensor

Motorized column

Laser patient positioning

Microcomputer controlled movements for multiple projection programs

CCD-type electronic x-ray detector with CsI, high resolution scintillator

Memory card slot

Connection to computer via high-speed USB port

Pedestal mount

Storage compartments

Face to Face patient positioning with laser beams for better patient comfort and accurate positioning

Cater to all types of patients including adult, pediatrics, standing, sitting and wheel chair patients.

Positioning accessories like, Standard Bite blocks, edentulous bite blocks, panoramic chin rest, Sinus chin rest, TMJ nose rest.

The patient information must be arranged in user friendly and simple format with built in patient information management service

Computer Intel core i5 Processor with 1T Hard disk, 8 GB RAM, Ethernet interface, Graphic Board, 19" TFT/LED Monitor

Online UPS with 30 minutes backup

Low radiation dose with good image quality, with computerized operator's guide and programs

Expose in either direction

25 plastic bite guides

3 point head positioning system

Lateral Cephalometric,

Anterior – Posterior (AP) & Posterior – Anterior (PA)

Submento-vertex (SMV)

Oblique Lateral

Hand image (carpus view)

Software provided with various orthodontic filters to enhance hard tissue / soft tissues on need basis.

Generator Constant potential, resonance mode high

Programs:

Adult/Ped. Panoramic

Adult/Ped. Hemi Panoramic Right

Adult/Ped. Hemi Panoramic Left

Adult/Ped. TMJ Open/Close Mouth

Adult/Ped. Bi-Axial TMJ

Adult/Ped. Maxillary Sinus P-A

Maxillary Sinus L-L

Improved Orthogonality Dentition

Implantologic

Full Panoramic (Adult and child)

Segmented panoramic

Lateral TMJ-2 views

Lateral TMJ-4 views

Maxillary sinus

Interproximal panoramic

Orthogonal (perio) panoramic

Lateral-PA TMJ

Lateral multiangle TMJ

PA multiangle TMJ

PA linear sinus

Lateral sinus

All required programs not disclosed above need to be included

5. System Configuration Accessories, Spares, Consumables and other components:

3x X- ray unit with lead apron, gonadal sheath and thyroid protection collar/Each

1x Wheel chair/Ped/Adult/each

Set of Quality assurance accessories

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment

Operating Temperature:+10 °C to + 45°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%, 50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Xrad -90	1. Generic Name: X Ray - Radiography, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Digital Radiography Machine used for imaging of internal structures of the body made by electromagnetic radiation passing through the body.	
	4. Technical Specifications:	
	A fully digital radiography system capable of detector exposure in vertical, horizontal and oblique positions to perform general radiography	
	Completely integrated (integrated Generator and Image Acquisition) and auto quality control features incorporated	
	System must have a method of measuring and recording patient absorbed dose (Dose Area measurement system)	
	System should have Anatomical programming radiography (APR)	
	System should have over load protection feature	
	System should have switch on x ray indicator	
	Generator	
	Latest high frequency inverter technology for constant output and lowest radiation doses.	
	KVp range: $40 - 150$, with 1KV increment, and KVp accuracy of $\pm 10\%$	
	Protection level against electric shocks: type B	
	mA range: 10 to 600 mA (with 12 values of high voltage current adjustment)	
	Power: 45-50KW	
	mAS maximum: 400 per exposure	
	The X-ray exposure time (radiography time) should be automatically adjusted	
	Exposure time: for patient exposure should be $\leq 1s$ and for tube capacity should be up to $5s$	
	System should have Automatic Exposure Control (AEC)	
	Over load protection feature	
	X-Ray tube and collimator	
	Floor mounted, with longitudinal not less than 210cm and lateral movement not less than 24cm	
	Dual Focal spot sizes of 1.3mm sq. or less	
	Tube stand vertical movement is 120 to 180cm	
	Tube rotation angle: $\geq \pm 120^{\circ}$	
	X-ray tube anode heat monitoring with thermal switch control	
	High speed rotating anode and dual focus tube compatible with the generator	
	Over loading protection feature	
	High speed rotating anode dual focus tube compatible with the generator Anode heat capacity: 300KHU or more.	

Document: Capital Medical Device Technical Specification

Housing Material: built in material resistant to blows and falls

Multi leaf collimator having halogen/bright light source with auto shut provision for the light

Adjustable multi leaf collimation system with SID laser localizer

Automatic shut-off timer to preserve the collimator field lamp.

Has a rectangular light field with cross hair markings and lamp/timer feature

With cross hair centering and pre-indication of field sizes at certain source to image distance (SID)

Radiographic table:

Integrated Bucky unit for flat panel detector

Grid rate: 10/1

Film to Focal distance (FFD): 100cm

Balanced at counter weight

Table movement : 4 ways with breaks

The table must have easy access from both sides (for patient transfer purposes and cross table imaging)

The table must have foot activated locks for hands free position

The table should be mounted on high quality fiber wheels with brakes

Horizontal table with carbon fiber table top of minimum 210cmx80cm

The tabletop move in the lateral direction and the imaging system move in the longitudinal direction.

Allowable patient weight: Min. 200kg

Flat panel detector

Flat panel wireless detector solid state technology or latest with cesium iodide scintillator

Separate detector for table and Bucky

Detector size: 43 cm x 43 cm or more

The detector should be movable to the entire length of the table

Pixel size: 148 um or less

Facility for tracking with X-Ray tube

Detector Quantum Efficiency (D.Q.E) 65% or more @ Zero Line pairs

Active matrix size: approx. 2.8k x 2.8k

Minimum image depth of 16 bit

The machine a detector storage compartment

Vertical Bucky Stand

Grid ratio: 10/1

Film to Focal distance (FFD): 140cm

Balanced at counter weight

The unit should be provided with vertical Bucky having tilting facility across +90 degrees

Control Console:

With technique selector and digital display for KV, mAs and/or mA and exposure time

Document: Capital Medical Device Technical Specification

switch on indicators

Auto Bucky Selection switch

Auto tube focal spot selection switch

Audiovisual indication of the x-ray exposure

Provided with hand switch for control of radiographic exposure.

Tube readiness for exposure

Self diagnostic Programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc...

Picture Archiving Communication System (PACS)

Should provide image and report distribution software with all the necessary hardware to connect terminals for image viewing with undefined end user license

This system should be able to provide on-line accessibility of processed image data.

The server hardware should consist of Intel multi core latest version, 3.6 GHz processor, 32GB RAM, 1TB HDD With 21 inch flat monitor

Each viewing terminal should have a monitor with Intel multi core latest version, 3.6 GHz processor, 8GB RAM, 500 GB HDD, CD/DVD, combo drive, 19 inch or more flat monitor

Image acquisition and image processing workstation:

A separate workstation for image positioning and patient demographic data

The digital workstation should be based on the latest high speed processors of at least 64 bit.

The processing station must have 8 GB RAM, Intel core i7 latest generation, at least 1TB, HDD and 21 inch or higher medical grade high definition color display TFT/LED touch screen monitor with external keyboard and all necessary software package

The machine an integrated workstation with a color display TFT touch screen monitor.

Real-time image processing: Digital Compensation Filter and Super Noise Reduction Filter

The server provide full amount of post processing features viz. geometric corrections, window level algorithms, annotation like markers, predefined text, drawing lines and geometrical shapes, multi-scale image processing, measuring distance and angles, shuttering, histograms, zoom, grey scale reversal, edge enhancement, noise reduction, indication of gray scale saturation level, latitude reduction.

The post processing features should also include contrast and brightness adjustment, storage of image with a memory of at least 200,000 images.

The machine should be fully network ready and it should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless connectivity

Read and Write in CD/DVD for data Storage and review

Document: Capital Medical Device Technical Specification

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Worklist Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, spares and consumables

X-ray unit with x-ray generator, x-ray tube -----1

Bucky stand ----1

Radiographic table---- 1

Flat panel detector----2 (One for the Bucky stand and one for the radiographic table)

UPS with stabilizer with 30 minutes backup---1

Image acquisition Workstation ---- One main and one additional fully networked workstation with high resolution

Archiving System (PACS) with four monitors----1

CD-R/W based long term archiving with envelope-----10,000

Exposure switch----2

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Lead glass with frame -----1

Lead door as per room requirement

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

All consumables required for installation, standardization and smooth functioning of equipment for 3 months period should be given free of cost along with supplied Equipment (if any)

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}\text{C}$ to $+40^{\circ}\text{C}$

Relative Humidity: <85%

Document: Capital Medical Device Technical Specification

7. Utility Requirements:

Suitable Power input to be 380VAC, 50Hz

8. Standards & Safety Requirements:

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation, Training and Commissioning

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training.

Turnkey works

The Supplier is responsible to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include but not limited to the following:

a). Radiation safety:

Proper X-Ray shielding lead lined door of 2mm thickness (or equivalent) should provided for the main equipment.

Proper lead glass window of 2mm lead thickness (or equivalent)

Red Warning Light 220V Above Exposure Room Door

b). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (grounding should be included)

Three phase breaker with size as per manufacturer recommendation

c). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

d). Network:

Network Outlet provided on the control and 4 doctors room and connected and working

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Document: Capital Medical Device Technical Specification

Tender and Purchase Order No.
Name and Model of the product
PO Box 25-11-276-32-66
Tel: +251-11-276-32-66
Fax: +251-11-275-25-56
Addis Ababa

Base Code	Item Detail	Department
Xrmd-91	1. Generic Name: X Ray - Mobile, Digital	Imaging
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description	
	Clinical Purpose/Description: A compact, light weight device used in emergency, trauma and ICU departments as well as operating theaters for conventional radiography	
	4. Technical Specification:	
	Mobile stand	
	Compact and light weight design with mobile castors for easy maneuverability	
	Fully counterbalanced with compact flat detector	
	Backup battery with continues operating time of 2hrs/100 exposures	
	Dose area measurement system	
	Automatic exposure control	
	KV, mA increase & decrease	
	Effective braking system for parking, transport and emergency.	
	Articulated arm for maximum positioning flexibility in any patient position.	
	Emergency stop button	
	Standby and exposure release switch	
	Ready and X-Ray on switch with Indicators	
	All cables shall be concealed in the arm system	
	Storage facility for flat panel detector and other supplies	
	Digital display of kV, mAS and/or mA and time	
	X-ray generator:	
	High Frequency generator without put power 25Kw	
	kV range: 40-125Kvp	
	mA: 20 mA to 320 mA	
	mAs: max. 280 per exposure	
	Exposure time: for patient exposure should be ≤1s and for tube capacity should be up to 5s	
	Self diagnostic programme with Indicators like tube over heating/high voltage, power supply not ready, broken filament error, earth fault error, etc	
	X-ray tube and collimator:	
	Output should match the output of the generator	
	Dual focus rotating anode with spot size less than 1.3mm	
	Tube focal spot selection Switch	
	Total filtration: minimum 2 mm Al	
	Tube voltage: 40-125Kvp	

Document: Capital Medical Device Technical Specification

Anode heat capacity: 300KHU

Anode cooling rate: 40KHU/min.

Tube horizontal movement: 45 cm or more

Tube vertical movement: 100 cm or more

Adjustable multi leaf collimator with SID laser localizer

Collimator lamp on switch

Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector active size: 35cm x 43cm or more.

Pixel size: 148 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero LP/mm or more.

With at least two user selectable input fields

Active matrix size: 2.8k x 2.3k

Image acquisition and image processing:

Shall have integrated 17" high brightness LCD/TFT color button/touch screen monitor.

The digital workstation should be based on the latest high speed processors of at least 32 bit.

Patient data management- Electronic record with name, date, anatomy, etc..

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold

Annotation (text, trace, arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc...

Connectivity:

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network

Storage of 3000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Work list Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Document: Capital Medical Device Technical Specification

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, Spares, Consumables and other components:

Main unit with x-ray generator, x-ray tube----1

Flat panel detector----1

All software packages shall be provided as standard

A CD-R/W based long term archiving with envelope----10,000

Whole body lead aprons with $0.5 \text{mm}, \, 0.35 \text{mm}, \, 0.25 \text{mm}$ lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: $+10^{\circ}\text{C}$ to $+40^{\circ}\text{C}$

Relative Humidity: <85%

7. Utility Requirements:

Power input: 220V/50Hz

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device

The supplier must provide sufficient technical and end user training on site.

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including Labor, X-ray tube, detectors and spare parts and accessories from the date of installation as well as after sale services.

The supplier must provide extended warranty from 3rd year to 5th year inclusive of labor, spare parts, accessories, detector and X Ray tube.

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard

accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Departmen
Ultg-90	1. Generic Name: Ultrasound- Ob/Gyn	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Used for obstetrics, gynecology, Abdomen, Urology and Emergency Medicine Packages scanning	
	4. Technical Specification:	
	The system with one active probe ports for easy use and convenient operation.	
	Controls for depth, gain compensation preferably automatic gain and depth control	
	The system have dedicated calculation software package including Obstetrics, Gynecology, Abdomen, Urology and Emergency Medicine Packages) The system have impose storage and enablished with CP, USP flesh and DICOM.	
	The system have image storage and archiving with CD, USB flash and DICOM	
	System with 15 inch LCD monitor and also can connect to external display	
	Probe: Convex (2-5MHz)	
	Number of elements:192	
	FOV:58	
	Physical foot print:55x18 mm	
	Convex radius:60mmR	
	with battery support to operate the machine in case of power failure	
	5. System Configuration Accessories and Consumables	
	System with main unit and mobile cart (trolley)	
	Laser Printer for direct image and report print out1pcs	
	Convex probe1pcs	
	Ultrasound paper100 rolls	
	Gel: 250 ml 2pcs	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity : < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards & Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation/Training/Commissioning	
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	1
	10. Warranty/ After sales service:	
	The supplier must be provide minimum of Two years warranty including labor and	

Document: Capital Medical Device Technical Specification

spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

Base Code	Item Detail	Department
Ugcd-90	1. Generic Name: Ultrasound - General Purpose, Color Doppler, portable	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	=
	A portable laptop type and detachable diagnostic imaging ultrasound with mobile cart used to see internal body structures in Abdomen, Obstetrics, Gynecological, Vascular, Urology, Musculoskeletal, Small Parts, pediatrics and neonatal.	
	4. Technical Specification:	
	With internal battery capable of operation 60 minutes	
	System broad band beam former capable of processing signals from 2-13 MHZ	
	Should incorporate facility for high resolution 2D, M-mode, color M-mode, THI mode, PW, CW mode, Color Flow imaging, Duplex mode, triplex mode etc.	
	full spectrum imaging, Speckle Reduction Filter, Spatial Compound imaging, Beam steering Imaging,	
	Post processing technology	
	Tissue harmonic imaging Capability of analyzing 3D data set.	1
	Real time triplex mode facility in 2D, color and Doppler modes.	-
	Dynamic range of 150 dB or higher and high Pulse repetition frequency (PRF) Minimum 254 gray shades	
	1000 frames per second or more and Panoramic extended field of view.	
	Software packages: Abdomen, Obs/Gyn, Vascular, Musculoskeletal, Urological, Small Parts, pediatrics and neonatal	
	Skin line scaling markers, curved distance measurement tool and zoom, pan, rotate and trim facility to trim panoramic images from start or end of the panoramic capture.	
	Independent steering of B mode and color/PW/CW mode in linear probe.	
	Minimum 15" high resolution medical grade TFT/LCD screen monitor display	
	Should be provided with following transducers	=
	a) Curved (Convex) Probe (2-5 MHz) applicable for Abdomen and OB/GYN, etc (Specify model/cat no) Number of elements:192	
	FOV: 65 deg	
	Physical foot print: 61 x 17	
	Convex diameter:55 mmR	
	b) Micro-curved Probe (4-9MHz) applicable for neonatal and pediatrics, etc (Specify model/cat no)	
	Number of elements:128	
	FOV:134 deg	
	Physical foot print: 22 x 6mm	
	c) Linear probe (5-12 MHz) applicable for small parts, vascular, peripheral,	

musculoskeletal, etc.. (Specify model/cat no)

Number of elements: 64

FOV: 128 deg

Number of elements: 64

d) Endo cavity Probe (4-9MHz) applicable for examining internal organs such as vagina, cervix, uterus, fallopian, ovaries, etc... (Specify model/cat no)

Number of elements: 128

FOV:150 deg

Physical foot print:25 x 5 mm

Number of elements: 128

Capable of supporting at least three or more transducers ports with switching form console.

System built in image Management software, such as image manipulation, Multi Planner reformatting, surface & volume rendering etc.

Hard disk memory of 400 GB or more with built in CD/DVD read write.

System Should be DICOM Compatible, RIS/HIS

Shall have push handle for pushing

Trolley on Double Castors with Brake

5. System Configuration Accessories, Consumables and other components:

Color Laser Printer----1

Ultrasound paper---100 rolls

Gel 250 ml ---- 2

Linear probe---1

Convex probe---1

Trans-vaginal probe---1

Micro-convex probe ----1

Trolley-01

All standard accessories, consumables and parts required to operate the equipment, cleaning and lubrication materials with their quantity to be included in the offer. (Including not specified on the above).

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Laum-90	1. Generic Name: Laundry Machine	Hospital Equp.
	1. Generic Name: Laundry Machine	
	2. GMDN/UMDN Code/Name: N/A	†
	3. Clinical Purpose/Description:	
	Used to receive contaminated items for cleaning and to provide an adequete efficient ,economic, continous quality supply of clean disinfected linen to all patient care services in the hospital.	
	4. Technical Specification:	
	Washer Extractor machine:	1
	Both hot and cold water washing Horizontal drum type made of non-magnetic stainless steel, Front loading type,	1
	Method of washing should be tumble wash.	
	Machine should be made of 304 grade of stainless steel (Inner cage should have die-sunk perforations on adequate area and thickness should be of 14 SWG S.S and outer body thickness 16 SWG 304 stailess steel).	
	• Machine should have large stainless steel front door with toughened glass.	
	Large loading and unloading doors with up to 180 degree opening angle for easy access	
	Machine should have automatic door locking system while machine is in operation.	
	• Machine should have auto-reverse / open pocket with low spin extract.	
	Machine should have level indicator.	
	Capacity of 40kg to 45 kg dry linen.	
	Nose lebel (dB) <70	
	Wash speed / Spin speed r.p.m. Not less than 38	
	Extracting speed r.p.m,=Not less than 750	
	Machine should have heavy duty Motor, Power Not more than 5.0 kwt	
	Machine should have Dual operating system options i.e. both electrical and steam heating provisions.	
	Steam pressure :-0.2 to o.6Mpa	1
	Air pressure :-0.4 to o.6 Mpa	1
	Drum volume :- Not less than 300 Liter	1
	Heating power :- 18-27 kw	

Rotation direction: forward/reverse/stop, one way drive With electrical water heater, adjustable rotation speed of greater than 1000 rpm (max).

With operating valves Material: stainless steel

Automatic stop alarming mechanism

With washing options for dirty and colored clothes

Automatic stopping and stop signaling when finishing With braking system.

The machine shall have features like wash timer, automatic forward/reverse cyclic timer. Sensor to detect level in soap tank and easy refilling system.

Sensor for water in chamber to avoid dry run.

Built in steam condenser for washing and drain.

Singl phase motor invertor

Freely programable control with advanced 7 " colour display for easy operation

Programmeble water temprature for each bath

Programmable overnight bath soak

Long, short and extra short programm

Temprature adjustment

Fresh water flashing chemical mainfold

Shock absorbing system

Two way circulation pump

hose with flat inner surface

Autowash feature

Dirt resistan drain hose

Emergency stop switch

Connections:

voltage inlet: 380V frequency of 50Hz

Hot and Cold Water connections: Machine should have adequate water inlet and drain outlet size with appropriate connection, pressure and satisfactory flow rate.

Dryer:

Tumble dryers are used, machines in which textiles are dried by tumbling in a rotating drum through which heated air is passed.

Capacity 45 to 50kg of wet linen

Dryer/tumbler should be ,Electrically Heated, Heavy duty, Front Loading, Cool down Feature, Auto-timed, Auto-reversible, Auto digital temperature control, Dual Motor drive, Open Pocket & Front display

Programmable microprocessor controlled with touch panel, color screen LCD/TFT display for working parameters and multi-level interface

Heating Power: Not more than 20 kW

Motor power/Drive and fan: 0.37Kwt to 1.0 kwt

Electric, steam heating type

Steam pressure: 0.3-0.5mpa

Equipped with removable lint screen

Automatic signal display when finishing

Tumble dryers with stainless steel drum

Alarms and free display of operating parameters

Auto adjustible vacuum power to the existing condition

Professional brushless motor

Bi-directional drum movement, with auto reversing and exhaust sytem

Perfect tumble dry system

Tumble dryers with humidity sensor and display

Large wide opening door, with semi-perforated inner drum for easy removal of hot air

Easy water empiting to accessible drain out

Noise < 50dB

Adjustible drum speed and rotation

Trap system to remove fine particles

Exact dry moisture sensor

Door minimal heat loss

Less steam consumption but quick dry time

Stainless steel dryer drum

Outer chamber dryer should be made of stainless steel 304 sheet

Inner chamber dryer should be made of stainless steel 316

Heating and time control should be done digital temperature, time controller

Trays should be made from stainless steel 316 sheets

Racks and trolleys racks should be provided for trays inside the dryer

Racks should be provided with wheels to slide them in and out of the dryer

Machine should be fitted with anchor bolt with vibration damper

Safety microswitches on door, depression and filter check

Self-diagnostic fault alarm systems, safety protection system

Power supply: 380v +-10%, 50hz

With all standard accessories

Equipped with removable lint screen Automatic and gives signal when finishing

Stainless steel drum Safety microswitches on door, Electrical heating system,

Air particle filter to ensure the drying air is free from particles.

Tumbler drier of solid steel construction

machine should have thermal overload protection system

cycle programing should be by varying temp or time

Ironing machine

Roller type :- Electrical heating system Heating range : (10- 200 dgree C) Heater

temperature adjustment for various types of clothes/garments Having maximum and minimum speeds and reversing Roller lenngth. used to dry ironing. Water spray. Variable thermostat control.

Roller length: - 2.5 meter

Roller diameter:= not less than 500 mm

Ironing speed (Rotation speed:)m/minit - 0-8

Motor power (KW):- 0.75 to 1.0

Electic heating power (KW) 25 to 27

Roller type, stainless steel body

Electrical heating system

Heating range: max 200degC

Heater temperature adjustment for various types of garments

Having maximum and minimum adjustible speed

Noise level < 65dB

Automatic control of overheating

Built in electric heating system with temperature setting unit

Having driving and exhaust motors with brake system

Indication of ironing speed and temperature

Separate delivering and receiving table for dirty and clean linen

Variable setups for folding

Built-in feeding and length folding system

Frequency controlled motor

Automatic cool down

Power supply: three phase, 380v,+-10% 50hz

an ironer with exhaust fan for the removal of vapours produced while ironning is preferable

the roller padding should ensure uniform pressure through out its length

final cover of the roller should be made with NOMEX which is high temp. resistant

The machine must have Emergency stop button

Ironing speed must be adjustable

Laundry trolley for wet clothes:

Material: chrome plated steel/polymers Capacity of not less than 45 kg Built on heavy duty castors . Mobile box of non-rust polymer construction for solidity and durability. dimensions: approx. $736 \times 660 \times 965$ mm (h x w x l). With 2 rigid and 2 swivel castors.

With outlet tap.

Laundry trolley for dry clothes:

Material: chrome plated steel Capacity of not less than 40kg about 55kg

Built on heavy duty castors Material: chrome plated steel/polymers

Capacity of not less than 40kg Built on heavy duty castors . Mobile box of non-rust polymer construction for solidity and durability. dimensions: approx. $736 \times 660 \times 965 \text{ mm}$ (h x w x l).

With 2 rigid and 2 swivel castors.

Gloves:

Heavy duty type Rubber Gloves For laundry purpose

5. System Configuration Accessories, Spares, Consumables and other componenets:

washerextractor, drayer and ironor should provide With all standard and complete accessories

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+40 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power supply: Three phase, $380VAC \pm 10\%$, 50hz

The system must be inclusive of water supply with proper pressure

Should have proper drainage system

Should have heat ventilation and air cerculation system

8. Standards & Safety Requirements:

Shal meet, ISO, and CE, Certification, This shall include standard and safety requirement and also meet the following:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 10472 ,safety requirments for hospital laundery machine

machine should have thermal overload protection system and adequate in-built safety measures.

Overall Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the Laundry machine. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

b). Drain Connection:

Bidder shall do drain outlet via either drilled floor or any other for drainage purpose

c). Electrical Connection:

Three phase electrical line from hospital MDB/Generator near to the machine (Proper grounding should be included)

Three phase breaker with size as per manufacturer recommendation near to the machine.

d). Mechanical installation:

Bidder shall do if the machine needs a concrete floor with thickness recommended by the manufacturer.

e). Evacuation system:

To allow dryer, ironer to work at its best, air inlet passes through an opening outside

Air inlet opening should be standard and placed behind the machine

Exhaust duct is made from galvanized steel not be from plastic ducting

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsight technical and end user training

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

10. Documentation:

The supplier must provide user manuals/operation manuals and Services manuals in English.

11. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product :-

PO Box 21904

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

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Base Code	Item Detail	Department
Defi-90	1. Generic Name: Defibrillator	Emergency
	2. GMDN/UMDN Name, Code:	
	3. Clinical Purpose/Description:	
	Fully automated external defibrillators (AEDs) deliver a high amplitude current impulse to the heart in order to restore normal rhythm and contractile function in patients who are experiencing ventricular fibrillation (VF) or ventricular tachycardia (VT) that is not accompanied by a palpable pulse.	
	4. Technical Specification	
	High-resolution TFT color LCD display of not less than 5.8 inches for showing 12 lead ECG, pulse, selected energy and delivered energy charge, mains, battery charge, led indicator	
	Defibrillator with ECG. DC defibrillator for short time depolarization, impulse energy adjustable for extra- and intracranial defibrillation with 2 electrodes (pre-anterior / post-anterior).	
	Defibrillator with pediatric and adult paddles and cardioverter	
	The machine should be compact, portable with built in rechargeable battery & light weight.	
	Operation Modes: synchrony defibrillation and extrathoracical stimulation	
	Defibrillator with pediatric and adult paddles minimum of 4.5cm and 8cm respectively	
	The instruments with a bi-phasic wave form Defibrillation	
	Monitor vital parameters and display them (ECG, SpO2, NIBP, and temperature)	
	Able to print the ECG on thermal recorders	
	Output energy ranges across 50Ω: 2J-360 J Able to work on manual and automated external defibrillation (AED)	
	Charging time:-	

Manual mode_ Charging time should be less than 5 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)

AED mode: Charging time should be from 8-15 sec to maximum energy, 360J. (When AC power is used OR new full charged battery at 20 degrees)

Should have rechargeable battery (Lithium-ion battery) that is capable of monitoring for minimum of 180 minutes

Thermal array ECG Recorder for Lead selection, II, III aVR, aVL, V, paddles

Heart frequency monitoring with alarms for exceeding or falling below set limits.

A low energy biphasic defibrillator monitor with recorder, having capability to arrest all arrhythmia within a maximum energy of 360 Joules

Monitor ECG through paddles, pads and monitoring electrodes and defibrillate through pads and paddles.

Should have automatic lead switching to see patient ECG through paddles or leads

Able to measure and compensate for chest impedance for a range of 25 to 150 ohms

The machine should have inbuilt auto & manual thermal recorder for printing ECG trace & stored information.

Charge indicator: audible and graphic.

Facility for self-test/check before usage.

The machine should have AED feature as inbuilt with manual override for manual operations.

SPO2 and NIBP integrated facility

5. System Configuration Accessories, Spares, Consumables and other components:

Paddles Adult (pair)-01

Paddles pediatrics (pair)-01

Patient cable-02

Compatible thermal paper for printer - 20 roll

Compatible Gel; 300mL

Disposable pads – 20

NIBP Cuff Adult – 02

NIBP Cuff Pediatrics- 02

NIBP Cuff Infants- 02

SPO2 Finger Probe - pediatric 01

SPO2 probe Adult -01

Ear Probe – 02

Complete set of ECG Leads – 02

Carrying case-01

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 40°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601 General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

ISO 14971: Medical devices -- Application of risk management to medical devices

Document: Capital Medical Device Technical Specification

IEC 60601-2-4 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for aftersales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55	
Addis Ababa	

Base Code	Item Detail	Department
Ccan-91	1. Generic Name: Analyzer - Clinical Chemistry	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: Chemistry Analyzer is required for the	
	detection and quantification of blood chemistry and other body fluids.	
	4. Technical Specification:	
	For analysis of serum, plasma, urine, cerebrospinal fluid (CSF), hemolysate and/or whole blood and other	
	A discrete patient prioritized automated random access clinical chemistry	
	analyzer, For chemistries, immunoglobulins, drug assay etc. in	
	blood/urine/fluid with ISE electrolyte module (Na+, K+, Cl ⁻). Independent calibration of photometer and electrolyte analysis and closed reagent system.	
	Operating Mode: End point, Kinetic, initial rate, monochromatic, bichromatic, turbidi metric, serum blanking (differential) and fixed time.	-
	Wavelength range: 340 – 800nm	
	Through put: 400 test/hour with ISE module (Na ⁺ , K ⁺ , Cl ⁻).	
	Reagent/sample tray: Not less than 40 reagent position, 80 sample position	
	Reagent volume: 20 -350ul	_
	Error Check: Automatic flagging for errors	-
	Auto dilution Capability: For high value samples	=
	Repeat Run Capability: Capable to check the results by repeat run on desired samples	
	Sample clot and Probe crash detection Capability: For excluding erroneous analysis	-
	Self diagnosis and troubleshooting: For minor day-to-day problems	
	Calibration modes: Linear, Non-Linear and Multipoint	
	Reagent storage facility: Onboard refrigeration for not less than 40 reagent bottles and STAT mode	

LAN interface facility: Online data transmission facility through LAN

Cuvette washing system: Inbuilt with automatic cuvette washing facility and/or disposal system for one time use.

OPTICAL SYSTEM:

Light Source: Halogen/ Xenon Lamp.

Wave Length Range: 340 – 800 nm with polychromatic correction

The Operational Requirements: should be with programmable memory -

The Processing mode: - patient by patient , Test by test and STATmode Operating Mode: End point, Kinetic, initial rate, monochromatic, dichromatic, turbid metric, serum blank (differential), fixed time, optics and wavelength

System: open system-able to work with reagents and supplies from other manufacturers

- Operating Mode: End point, Kinetic, initial rate, monochromatic dichromatic, turbid metric, serum blank (differential), fixed time and optics wavelength range
- Assay: End point, rate assay, fixed point assay
- Calibration: Linear, non-linear, with possibility of two and multi point calibration; multi point calibration for kinetic and fixed type modes.
- Light Source: long life halogen or equivalent lamp.
- resolution: 0.0001 Abs

Temperature control: cuvette heating (electrical) in caruousel and reading path: 37 0C

- **5.** System Configuration Accessories, Spares, Consumables and other components:
- 1- System as describes
- 2- Graphic printer- for printout of parameters, results, calibration curves, kinetic and statistics, facility to store data in PC through connecting data cable and related software must be provided.
- 3- Desktop PC (microprocessor with speed not less than 3.00 GHz, 512MB RAM, 80 GB HDD,, 105 keys Board, scroll mouse,

multimedia kit, 56 kbps modem 32 MB AGP Card, 52xCD CD-RW Drive, with 17" TFT Digital Color Monitor) with compatible Operating system must be provided along

4-Complete Start up kits consumables (reagents, kits, controls...),

accessories, and spares required for installation and standardization of the System to be provided.

5- Reusable: cuvette block for 4 tests Each

: Reagent bottles

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Mibl-90	1. Generic Name: Microscope - Binocular, LED	Laboratory
	2 CMDN/IIMDN C-1-N	
	2. GMDN/UMDN Code/Name:	_
	3. Clinical Purpose/Description: To magnify and study specimens and small objects by transmitted visible light	
	4. Technical Specification:	-
	Microscope frame with revolving, 30 degree inclined binocular tube 360 degree	-
	rotatable head illuminator LED light source with white light intensity control	
	and LED light life more than 10,000 Hrs.	
	Fixed graduated mechanical stage approx. 200 x 150 mm, travelling approx. 80 x 50 mm	
	Double slide holder	
	Coarse focusing: approx. 3 mm per rotation	
	Fine focusing: approx. 0.3 mm per rotation	1
	Range of magnification: 40 to 1000x	
	Reverse angle quadruple revolving nose-piece, with distinct click-stop, with rubber	1
	grip for easy handling	
	Objectives, full plan achromatic: 4x (0.10 NA), 10x (0.25 NA), 40x (0.65 NA), 100x	
	(1.25 NA, oil) and 100X oil immersion	
	Condenser: Abbe with iris diaphragm aperture, 1.25 NA	
	Eyepieces: Focusable pair, 10x (FN 20), with inter-pupillary distance- and diopter	
	Adjustment	
	Retractable eye guards	
	Filter: blue	
	All optics anti-fungus treated	
	Brightness control: 0 to 100 % (linear)	
	Detachable plano-concave mirror unit with adjustable convex and concave	
	mirror on alternate side	
	5. System Configuration Accessories, Spares, Consumables and other	
	components:	_
	Ø 1 x Pair eye shades	4
	Ø 1 x Pair of tube caps	4
	Ø 1 x Oil, immersion	-
	Ø 1 x Lens cleaning kit consisting of lens cleaning tissue, 100 ml cleaning	
	solution, dust blower	1
	2 x Fuse	-
	1 x Power cord	-
	1 A LOWEL COLU	1

dust cove and storage box

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

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Addis Ababa

Base Code	Item Detail	Department
Hema-90	1. Generic Name: Analyzer-Hematology, 3 Differential	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	-
	Used in clinical laboratory, Hematology tests can be used to indicate,	-
	diagnose, and evaluate many conditions, including infection,	
	inflammation, and anemia. Hemoglobin (HgB) - the oxygen-carrying	
	protein in red blood cell.	
	4. Technical Specification:	
	Principles: Electrical impedance method with advanced SRV technology	
	for accurate & precise total count	
	Diode based LASER Technology for 3 part differential	-
		-
	Photometry – LED based technology for hemoglobin	
	Parameters: Not less than 20 parameters (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM#, MON#, Gran#, LYM%, MON%, Gran%, RDW-SD, RDW-CV, PDW-SD, PDW-CV, MPV, PCT)	
	Plus: 3 histograms –RBC, WBC & PLT	
	Throughput: Not less than 40 tests / hour	-
	Sample mode: whole blood in open mode	-
	Chambers: Dual chamber advanced system	-
	Auto Clean Modes: Available	-
	Quality control : 3 levels, average, + (-) range SD and CV for all measured and calculated parameters, Separate QC database	-
	Automatic system	-
	Sample volume: approx. 30 ul	

- Determination of: Red blood cell (RBC), White blood cell (WBC), Hemoglobin (HGB),
- Calibration: independent automated calibration and manual calibration for two test modes minimum
- Data storage approximately 40,000 sample results with Histogram WBC,RBC, and platelet
- Calibrator and control shelf life at least 3 months and reagent 1 year
- Operation by screen touch and key board
- Printer built in thermal printer (standard)and external printer optional
- Typical counting time: approx. 60 seconds for differential
- With self-test capability
- Display: LCD screen
- Indication of self-test failures and assistance messages
- Sample ID, date and time are reported with test results
- Supplied complete with dedicated data analysis and data management software
- Results are reported on external inkjet printer
- Casing, corrosion proof material such as plastic or epoxy coated steel
- With built-in RS232, USB 2.0 or equivalent, allowing data transfer

5. System Configuration Accessories, Spares, Consumables and other components:

- Supplied with: UPS and stabilizer as one unit
- Supplied with dust cover
- Bar code reader with handheld accessories

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

Document: Capital Medical Device Technical Specification

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one

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Base Code	Item Detail	Departmen
Afcc-90	1. Generic Name: Analyzer – CD4	Laborator
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	CD4 [abs] counter, provide absolute and percentage results of CD4 T	
	lymphocytes) concentration in whole blood samples.	
	4. Technical Specification:	
	Output: Quantitative CD4 Absolute count, CD4 %	
	Sample type: Capillary or venous whole blood	
	Sample volume: 20 - 25 μL	
	Reading time to results: 20 - 22 min for first sample. Then 4 minutes per sample	_
	Throughput (per 8 hrs working day/operator):90 - 110 tests	
	System Batching capabilities	
	System Built-in printer and optional external printer ,USB, RS232	
	connectivity	
	Number of tests results printed with 1 paper roll: 100 - 120	
	Data storage: Approx. 10,000 test results	
	Connectivity	
	System Built-in voltage surge protection	
	Capacity battery life (in hours and test runs): 8 hours	
	System Factory calibrated	
	System Internal quality control (IQC)	
	System Compatible with external quality control scheme(s)	
	5. System Configuration Accessories, Consumables and other	
	components:	
	probes, different types of tubes, with all standard accessories and	
	consumables must be provided.	
	All standard accessories, consumables and parts required to operate the	
	equipment, including all standard tools and cleaning and lubrication materials	
	including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	1
	Electrical Power Supply: 220VAC <u>+</u> 10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for	
	Electromagnetic Compatibility	1
	Shall meet ISO 13485 Medical Device Quality Management system (Or	

Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

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Base Code	Item Detail	Department
Frev-90	1. Generic Name: Freezer - Vaccine, 500 L	Pharmacy
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	
	Freezer is an horizontal Pharmaceutical Freezers for storage of vaccines and other	
	sensitive materials under stable temperature conditions @-15°C to -50°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	The Chamber is Double Walled with PUF Insulation, inside 304 Stainless Steel, CFC Free (eco-friendly)	
	Lockable door, solid	
	Freezer must have battery back-up and PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure, battery low etc.	
	Freezer ≥3 Compartment	
	Freezers with heated air vent and front panel air filter.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	
	Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.	
	Heavy duty hinge for closure and un-interruptive service.	
	Informative display and control screen with history tracking	
	Easy data transportation through USB port and it must also have on board diagnostic software.	
	Attachable external remote alarm system	
	Independent Dual Compressor System	
	Electronic temperature control: -15°C to -50°C with 1°C Increment	
	Accuracy, whatever the load: +/- 1°C	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device, with connection/interface for external read-out	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording device	
	Integrated four castors with break	
		_

Minimum compressor starting voltage: 22% below nominal voltage

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \, ^{\circ}\text{C}$ to + $30 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Base Code	Item Detail	Departmen
Refg-90	1. Generic Name: Refrigerator - General Purpose, 300L/500L	Pharmacy
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	General purpose Refrigerator is an Upright refrigerator for storage and conservation of vaccine, chemicals and reagents in clinical laboratory and pharmacy @ 0°C to 10°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	Internal net volume: 300L/500L	
	Easily adjustable ≥ 3 shelves	
	Insulation material: polyurethane, CFC-free	
	Lockable door, solid	
	Electronic temperature control: 0°C to 10°C.	
	Accuracy, whatever the load: +/- 1°C	
	Lighting System: Top LED	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording device	
	Integrated four castors with break	
	Minimum compressor starting voltage: 22% below nominal voltage	
	Microprocessor controlled spike and surge protection, and protection against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status, voltage fluctuation and load as % of nominal current	
	Electronic fuse disconnects and reconnects automatically	
	KVA rating matches power consumption of the refrigerator	
	PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure, battery low, Door Ajar etc.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	

Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.

Heavy duty hinge for closure and un-interruptive service.

Informative display and control screen with history tracking

Easy data transportation through USB port and it must also have on board diagnostic software.

Adjustable LED lighting for efficient energy

Illumination with auto-on feature and ON/OFF switch

Forced-air circulation maintains chamber uniformity and provides

Quick recovery after door openings

Bacteria-resistant interior, exterior, and door handle

Voltage stabilizer of appropriate rating

Keeping inside temperature for 8Hr during power failure

Accepted input range: -20 % to +20 %

Response time: <15 ms

Power consumption: 500 W

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601 (Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including

Document: Capital Medical Device Technical Specification

laborand spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Base code	Item detail	Departmen
BiP-90	1. Generic Name: BiPAP	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway pressure (CPAP)	
	that gives a constant flow of oxygen/air to the patient at a preselected pressure,	
	thereby imposing a small overpressure within the lungs that assists the gas	
	exchange	
	4. Technical specification	
	The system should meet all the numerical values given in the technical	
	specifications within a tolerance of +/- 10 %	
	IPAP 4 to 30 cmH2O	
	EPAP 4 to 25 cmH2O	
	Breath rate 0 to 30 BPM with spontaneous for time mode	
	Timed inspiration: 0.5 to 3.0 sec	
	Rise Time: 100 to 600 m-sec	
	Machine should be based on the solenoid valve technology and should offer	
	preferably auto track sensitivity and adjustable risetime. Filter: foam and ultrafine	
	LCD digital control	
	Altitude compensation: auto	
	Light weight, portable hand	
	Limiting the delivered pressure in the event of an occlusion	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 db at mid pressure range	
	User adjustable settings	
	Patient alarms	
	Equipment alarms to alert user to power failure,	
	low battery,	
	overheating,	
	mask / tube fault Inlet air filter to be fitted.	
	5. System Configuration Accessories, Spares, Consumables and other	
	Components:	
	Five of each size of reusable, sterilizable masks and tubes (adult, pediatric,	
	neonatal)	
	Two sets of fuses, if replaceable type used Five replacement inlet air filters	
	Supplier to specify if the following are available as options:	
	flow meter, humidifier, oxygen analyzer	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 45°C	
	Relative humidity: < 85%	
	7. utility requirement	
	Electrical Power Supply: 220VAC +/-10%, 50Hz	
	UPS of suitable rating with voltage regulation, spike protection and	
	maintenance free inbuilt batteries for 2hrsback up	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of	

Safety for Electromagnetic compatibility. Or should comply with 89/366/EEC; EMC-directive.

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

CE marked

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

b). Drain Connection:

Drain outlet via either drilled floor or any other for drainage purpose

Connection: Ø 50 / 45 mm or copper Ø 35 / 30 mm

Capacity: ≥10 L/min

c). Electrical Connection:

Single phase electrical line from hospital MDB/Generator near to the machine (with grounding)

Single phase breaker with size as per manufacturer recommendation near to the machine.

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User/operating and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa	

Base code	Item detail	Department
CP-90	1. Generic Name: CPAP	ICU
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	The Device is used for Delivery of a continuous positive airway pressure	
	(CPAP) that gives a constant flow of oxygen/air to the patient at a	
	preselected pressure, thereby imposing a small overpressure within the	
	lungs that assists the gas exchange	
	4. Technical specification	
	Pressure range to be user settable and to include the range 4 to 20 mbar.	
	Controls to be easy to operate, numbers and displays to be clearly visible.	
	Pressure support: 0 - 45 cm H2O	
	Pressure ramp function required to assist falling asleep	
	Manual breath button	
	Feedback control of the warming.	
	Digital display of temperature.	
	Humidity compensation system.	
	Working flow range between 4 and 40 l/m.	
	Alarms at least for: lack of water; sensor failure; high, low temperature.	
	Monitoring of the air temperature: precision ± 1° C	
	Compressor incorporated pediatric and adult	
	Noise level to be less than 35 db at mid pressure range	
	Displayed parameters	
	Tidal volume,	
	Inspiratory pressure,	
	Inspiratory time,	
	expiratory time,	
	IE ratio,	
	FiO2	
	User adjustable settings	
	Patient alarms	
	Equipment alarms to alert user to power failure,	
	low battery,	
	overheating,	
	mask / tube fault Inlet air filter to be fitted.	
	5. System Configuration Accessories, Spares, Consumables and other	
	Components:	
	Five of each size of reusable, sterilizable masks and tubes (adult, pediatric,	
	neonatal)	
	Two sets of fuses, if replaceable type used	
	Five replacement inlet air filters	
	Supplier to specify if the following are available as options:	
	flow meter, humidifier, oxygen analyzer	
	Bubble CPAP ventilator:	
	1) 400 to 700 ml container.	

- 2) Mean positive pressure provided between 2 and 12 cm of H2O.
- 3) Single use entry and exit connectors.
- 4) Patient circuits for adult, pediatric or neonatal patients. AirO2 mixer
- 5) Oxygen regulation scale between 21% and 100%.
- 6) Stainless steel or metallic antioxidant material.
- 7) Different connectors for Air and O2.
- 8) Flow meter for low flow values from 0 to 1 lt/min.

6. Operating Environment;

Operating Temperature: $+10 \, ^{\circ}\text{C}$ to $+45 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. utility requirement

Electrical Power Supply: 220VAC +/-10%, 50Hz

UPS of suitable rating with voltage regulation, spike protection and maintenance free batteries for 2hrs back up

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

CE marked

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

a). Water Connection:

All water intake connection to the machine should be fitted with manual shut-off valves.

Water pressure range: 3 to 5 bar

Flow rate: ≤ 4 L/min. (maximum consumption at any instance)

b). Drain Connection:

Drain outlet via either drilled floor or any other for drainage purpose

Connection: \emptyset 50 / 45 mm or copper \emptyset 35 / 30 mm

Capacity: ≥10 L/min

c). Electrical Connection:

Single phase electrical line from hospital MDB/Generator near to the machine (with grounding)

Single phase breaker with size as per manufacturer recommendation near to the machine.

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User/operating and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Department
		-
Wari-90	1. Generic Name: Warmer - Radiant, Infant	NICU
	2. GMDN/UMDN Name/ Code:	
	3. Clinical Purpose/Description:	
	Infant radiant warmer used for the treatment of hypothermia on infants and it	
	consists of a biocompatible bed, overhead heater.	1
	4. Technical Specification:	
	Mobile, mounted on 4 double swiveling castors wheels, all 4 with brakes.	
	Antistatic castors, with breaks	
	Table surface with conductive mattress with infant head/shoulder support	
	Mattress-padding: foam density approx 25 kg/m3.	
	Mattress cover: Memory Foam Mattress, waterproof, washable.	
	resistant to cleaning with chlorine based solution and flame retardant	
	Side boards transparent acryl, drop down and lockable	
	It separate bassinet trolley; bed should be tilt able and have provision for X-Ray cassette holder.	
	Markings on the bassinet and X-Ray cassette holder are mandatory to enable	
	proper positioning of the baby while doing the X-Ray.	
	Integrated T-piece resuscitator with adjustable controls of PIP and PEEP.	
	Under table 2 storage drawers.	
	Side rails allow for mounting of accessories.	
	Hood suspended above the table integrates heating element and overhead light.	
	Overhead light: LED	
	Display with LED screen full color for displaying graphics and trends of air temperature, skin temperature (main temperature and peripheral temperature), Oxygen concentration in the environment, newborn's weight, heart pulse and newborn data.	
	a feather touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection	
	Heating element: emitter with parabolic reflector and protected by metal grid Control unit allows air and skin temperature preset (LED indicator) and drives radiant heater Output (servo and manual)	
	Integrated timer: 1 to 59 min, with count-up and count-down feature	
	Temperature range, skin: 34 to 38 deg C (user pre-settable)	
	Monitoring of skin temperature by means of sensor, range: 30°C to 42°C	
	Heater output: 0 to 100% in increments of 5%	
	Audio and visual alarms for: Power failure or disconnected ,Heater failure	
	,Temperature higher or lower than set temperature	
	Display reports systems errors, failure.	

Control unit: audiovisual alarms according to timer and temperature presets avoiding overheating

Protection: OVP, earth leakage protection.

5. System Configuration Accessories, Spares, Consumables and other components:

- 1 x Memory Foam Mattress
- 3 x skin temperature probe (including connection cable)
- 3 x spare skin temperature probe (including connection cable)
- 1 x spare heating element

Acrylic helmet – 1 set of 3 sizes

5 x spare 0f set fuses

IV pole

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Department
Incn-90	1. Generic Name: Incubator - New born	NICU
	2. GMDN/UMDN Name/ Code:	
	3. Clinical Purpose/ Description:	
	Used to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns that cannot effectively regulate their body temperature.	
	4. Technical Specification:	
	Electronic control of humidity, oxygen concentration, air temperature and infant skin temperature.	
	Clear, hard cabinet for infant viewing.	
	Double wall with air circulation.	
	Easy access control panel, with light touch operation switches.	
	Facility to elevate base, adjustable range.	
	Self-test functions are performed.	
	Built for stable, stationary operation in ward environment	
	Controlled by microprocessor or microcontroller.	
	Servo controlled modeadjustable patient's skin temperature 34°C up to 38°C +/_1	
	Servo controlled mode to adjustable air temperature up to 37°C or more.	
	Air filter	
	Minimal resolution of 0.1 °C.	
	Monitored parameters: air temperature, patient's skin temperature, oxygen concentration and humidity	
	Micro controlled humidifier with range 40 to 90%	
	Oxygen input flow rate 3to15 litres/min or oxygen concentration range 21 to 70%.	
	Maximum CO2 concentration inside incubator 0.2%.	
	Noise level in the interior of the hood less than 60 dBA.	
	Head end raise facility with auto lock.	
	Capable of use in X-ray without removing baby.	
	Auto-calibration of measurement circuits.	
	Displayed parameters	
	Patient temperature	
	Air Temperature, humidity and oxygen concentration	
	Visual and audible alarms for:	
	Patient and air high/low temperature alarm.	
	Air circulation / probe / system / power failure alarm.	
	Humidity alarm.	

Power failure.

Temporal alarm silencer.

Heater power indicator

User Adjustable Parameters

Air temperature control from 23°C/73.4°F to 37°C/98.6°F

Patient temperature control from 34°C/93.2°F to 37°C/98.6°F

Humidity control from 40 to 80%

Oxygen input flow rate from 3 to 15 lpm

Components:

Transparent cabinet.

Double-wall with air circulation between the hood and the double wall.

One door with air curtain.

Mattress with washable and waterproof covers; removable and not smaller than 55 cm (length) x 34 cm (wide).

Accommodates shelves and I/V poles.

Mounted on stationary table, base of which is at least 80 cm high

At least four ports for tubes access to the interior of the hood.

At least four ports to access the patient.

At least one door or drawer or accessories base

Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes. Mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium.

Humidifier Water tank capacity not less than 1 liter.

5. System Configuration Accessories, spares, Consumables and other consumables:

One extra mattresses

3 extra sets of skin temp sensors

3 extra sets of air temp sensors

Two extra sets of air filters

Two reusable temperature sensor probes.

Sticky reflective patches.

Sleeves

oxygen analyzer

Two extra sets of fuses

Mattress with washable and waterproof cover.

• Internal Quality control and calibration system and control material

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Pamo-90	1. Generic Name: Monitor - Patient	NICU
	2. GMDN/UMDN Name/Code:	
	3. Clinical Purpose/Description: Patient monitors record and display Spo2	
	Temp. ECG, NIPB and Respiration.	
	4. Technical Specification	
	Adult, pediatric and neonate patient monitoring	
	15" LED/TFT color display with 5 waveforms	
	Measuring Parameters: ECG, Respiration Rate, NIBP, SpO2, Temperature,	
	and with all its measuring accessories and spares.	
	SPO2 Range 0 – 100%	
	12-lead: I; II; III; avR; avL; avF; V1-V6	
	Automatic Sweep Speeds 12, 25, 50 mm/s	
	Heart Rate Range Adult: 15 – 300 bpm Neonate/Pediatric: 15 – 350 bpm	
	RESPIRATION	1
	Method: Thoracic Impedance	1
	Modes: Automatic / Manual	7
	Range: Adult: 0 – 120 BrPM Neonate/Pediatric: 0 – 150 BrPM	1
	with Apnea and Audiovisual Alarm recallable Alarm Events	1
	NIBP	1
	Method: Automatic Oscillometric	1
	Modes: Manual / Automatic / Continuous	-
	Types :Systolic, Diastolic, Mean	1
	Measurement Range	-
	Range of Systolic Pressure	-
	Adult Mode: 40 – 270 mmHg	
	Pediatric Mode: 40 – 200 mmHg	
	Neonate Mode: 40 – 135 mmHg	
	Range of Diastolic Pressure	
	Adult Mode: 10 – 210 mmHg	
	Pediatric Mode: 10 – 150 mmHg	
	Neonate Mode: 10 – 95 mmHg	_
	Range of Mean Pressure Adult Mode: 20 – 230 mmHg	
	Pediatric Mode: 20 – 250 mmHg	
	Neonate Mode: 20 – 110 mmHg	
	Accuracy of Blood Pressure Measurement	7
	The Mean error less than ±3 mmHg.	7
	The Standard deviation less than 5 mmHg	1
	Over-Pressure Protection: Double safety protection	=

Alarm Systolic, Diastolic, Mean

12-lead ECG with 10 hour data storage, ST Segment and Arrhythmia Analysis

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

Automatic Zoom In Facility in the monitor display.

Silencing feature for audio alarms

Trend display of 48hours

Data interface (for ECG): RS232, BNC or equivalent

Defibrillator sync and protection during defibrillation

Pacemaker detection/rejection

Display reports system errors, leads and sensors failure and built-in battery status

Automatic switch to batteries in case of power failure

User preset of high/low alarms on all monitored parameters

Capability of storage of patient data and printing of patient reports.

Should provide hemodynamic, oxygenation, Ventilation calculation package. - drug calculation package.

Audiovisual alarm in case of Apnea and physiological measurements are outside preset range

Automatic Zoom In Facility in the monitor display.

Silencing feature for audio alarms

Trend display of 48hours

Data interface (for ECG): RS232, BNC or equivalent

Defibrillator sync and protection during defibrillation

Pacemaker detection/rejection

Display reports system errors, leads and sensors failure and built-in battery status

Automatic switch to batteries in case of power failure

Thermal recorder and printer (4Roll)

1 x Spare rechargeable battery pack

1 x Set of spare fuses

NIBP accessories:

- 3 x NIBP hose (1 x neonate, 1 pediatric, 1 x adult)
- 3 x Blood pressure cuff (1 x neonate, 1 x pediatric, 1 x adult, 1 obese adult)
- $20\ \text{Nos}$ of Disposable IBP transducers with all standard accessories & 6 nos of reusable adapter cable.

ECG accessories:

- 5 x Patient cable extremities (1x neonate/pediatric, 1 x adult)
- 5 x Set of electrodes (1x neonate/pediatric, 1 x adult)
- 1 x Electrode gel, 350 ml

Temperature accessories:

2 x Skin temperature probes and rectal probe (including connection cable)

Pulse Oximetry (SpO2) sensors with cable and plug:

- 5 x Adult size, reusable clip-on type
- 5 x Infant size, reusable clip-on type
- 6 x Newborn size, reusable clip-on type
- 10 x Newborn size, single use wrap-around type

Disposable SpO2 probes for neonatal use - 50 nos.

5. System Configuration Accessories, Spares, Consumables and other components:

Reusable adult, neonate and pediatric SpO2 finger probes – 1 each

NIBP cuffs for standard Adult, Obese Adult, Child and infant – all 1 each

Rechargeable Li-ion battery with a capacity of 4hr.

wireless and cable networking

Prompt knob and touch screen control

Intelligent cooling system keeps the unit running quietly during use

Separate indicator lights for technical and physiological alarms

memory card for increased data storage

Rolling stand trolley, carrying handle with bed-hooks

Thermal recorder and printer (4Roll)

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Document: Capital Medical Device Technical Specification

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

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Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

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Addis Ababa

Base Code	Item Detail	Department
Stds-90	1. Generic Name:(Instrument - Washer/Disinfector)	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Washer/Disinfector: An automated washing unit that uses high-temperature water and detergent to clean and high-level disinfects instruments and trays.	
	4. Technical Specification:	
	Washer/Disinfector: An automated washing unit that uses high-temperature water and detergent to clean and high-level disinfects instruments and trays.	
	4. Technical Specification:	_
	Front loading, Electronically controlled, Single door with forced air drying system Volume: 60L	
	volume. ool	
	Touch screen, with LED/TFT control panel, about 7" or above screen size	
	Motor driven sliding door made of stainless steel medical grade of 316 with thermal insulation.	
	Freshwater circulating system	
	Hot water Connections:	
	Total Power: 9KW	
	Pump Power: 150W	
	Dryer Blower: 150m3	
	Total Power: 3KW	
	Dryer Heater: 750W	1
	Cold Water Connection:	
	Min/max pressure: 0.5 – 2bar	-
	Min/max temperature: 55 – 60 Celsius	
	Flow rate: 30L/min	
	Hydraulic connection: 25mm	
	Heating up to 95 degrees C.	
	Automatic dosing systems for liquid and powder cleaning substances	
	Interior parts of stainless steel, 2 shelves	
	Machine is insulated against noise and works also with low-water pressure of 0.5 bars.	
	With specially selected insert and baskets for cleaning surgical instruments.	

With specially selected insert and baskets for cleaning surgical instruments.

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Document: Capital Medical Device Technical Specification

Name and Model of the product
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Tel: +251-11-276-32-65
Fax: +251-11-275-25-55
Addis Ababa

Base Code	Item Detail	Department
Steh-90	1. Generic Name:Instrument - Sterilizer Hot Air 25L	OR
	To desire i mineralisti ument. Steringer 1200 ini 202	
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:-	
	Hot Air Sterilizers are required for sterilizing an object in high temperature by using dry heat to sterilize and operate in the principle of patented fine air circulation achieved by means of a fan in an electrically heated chamber.	
	4. Technical Specification:	
	Should be table top and front loading	
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator. Thermostatically controlled system. Hot air circulation	
	Fully automatic provided with timer and fan.	1
	Temperature range: Room temperature to 250 degree Celsius (adjustable)	1
	Temperature Variation: +/- 1deg C.	1
	Temperature display unit	1
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel	
	With three adjustable mesh shelves of stainless steel	
	Capacity: 25L	
	5. System Configuration Accessories, spares and consumables -	
	All consumables required for installation and standardization of system to be given free of cost.	
	Timer and touching pad	
	3x Set of Spare Heater	
	3x Set of readymade gasket 3x Thermostat, 3x fuse	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC <u>+</u> 10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent) 9. Installation, Training and Commissioning:	_

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Department
Stes- 90	1. Generic Name: Sterilizer - Steam, 45/100L	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Steam Sterilizer used in the destruction of all forms of microbial life on medical instrument by exposing the object to moist heat at 121°C-134°C under high pressure	
	4. Technical Specification:	
	Front Loading table top steam sterilizer	
	Touch screen, with LCD control panel, about 5" or above screen size	
	Manual/Hinged door made of stainless steel medical grade of 316 with thermal insulation.	
	Fitted with load and safety thermostat take over LED indicator lamp.]
	High Grade strong stainless steel 316, Triple walled construction	
	Positive radial self-locking safety doors	1
	Hydrostatically tested to withstand 2.5 times the working pressure	1
	Manual and automatic filling option	1
	Air ballast system for fast and safe processing of fluids	1
	Control System: Microcontroller Based	1
	The safety value will be open automatically when the inner pressure over and the steam be exhausting to the water tank	-
	The door opening mechanism cannot be operated until the pressure in the chamber reached atmospheric Pressure	
	A complete record of every cycle is produced on the built-in thermal printer, with 1 box of thermal paper	
	316 stainless steel pressure vessel	
	Fan cooling system	
	automatic and real time self diagnosis system in case of failure and have means of reporting to the operator	
	A safety micro switch is fitted to the door which will only allow the cycle to start if the door is properly closed and locked.	
	Water system: Automatic water fill with inbuilt/external reverse osmotic water softener in the system	
	water supply line fitted with extra water filter	
	Sealed with Silicon long-lasting and durable gasket.	
	Digital display for jacket and chamber pressure, steam generator temperature]
	Outer jacket of stainless steel 316 to prevent heat loss	1
	Mounted on tubular stainless steel 316 frame with ground leveling flanges	1
	The steam generator made of medical grade 316 stainless steel	1

Thermal insulation to prevent overheat

Heat dissipation: maintain nominal temp and the heat dispersed through a cooling

mechanism

Input voltage: 220VAC, 50Hz, 1-phase

Pressure gauge: 0-2.2Kgf/cm²
Operating pressure from: 15-31 psi

Sterilizing pressure: 1.2-2.2Kgf/cm(15-31 psi) at 121°C-134°C

Protection: over-charging cut-off with visual symbol

Pressure control switch

Low water level cut-off device

Vacuum breaker

3x Readymade Spare Gaskets

Steam generator

Rapid water re-cooling

Low water protection device

Air removal filter

Timer with alarm system

Digital temperature indicator

Printer & Digital chart recorder

Stainless steel flush mounting

Carriages, trays, and baskets

Overpressure release valve

Sterilization indicator

Indicator color must not fade when it is exposed to light

Distinctive color change

Dual strip can be divided into two for economy of use

1x 300pcs/box, Dimension 150×90×200mm

Lead free steam indicator tape

For stem range of temperature of application: between 121°C and 134°C

Shelf life: 5 years

5. System Configuration Accessories, Spares, Consumables and other components:

2x Trolleys for contaminated and for sterilized instruments can be fitted the sterilizer door/Each

Pneumatic valves, Pressure switch

Temperature sensor

3x Spare heater

2x Door gasket

1x Spare contactor

3x Spare fuse

5x Gasket lubricant

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not

Document: Capital Medical Device Technical Specification

specified above

6. Operating Environment;

Operating Temperature: +10 °C to + 43 °C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Addis Ababa

Base Code	Item Detail	Departmen
Anem-90	1. Generic Name: Anesthesia Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Anesthesia Machine used to control the patients gas exchange and administer anesthetic agents to patient during surgery 4. Technical Specification:	
	The complete set-up shall included patient circuit, monitor and ventilator	4
	Patient monitoring system with vital parameter ECG, Pulse Oximeter(SPO2) including adult, pediatric and neonatal probe, capnography(EtCO2), and airway pressure, NIBP inclusive of adult, pediatric & neonatal with NIBP cuffs, rectal & skin temperature, Anesthetic gases, IBP with necessary arterial lines and other vital accessories as per requirement. Anesthesia machine of closed breathing circuit configuration suitable for Adult and pediatric including maplson D neonatal and pediatric system.	_
	Anesthesia gas delivery system. Equipped with anesthesia vaporizer (Halothane, & Isoflorine) and Anesthesia	
	ventilator. Attachments for connecting pin indexed cylinders and non interchangeable gas specific connection to pipe line inlets	
	Should have audio-visual oxygen Failure warning system with nitrous oxide cut off.	
	Trolley with upper shelf and medical utility rail Integrated support for two 10L anesthetic gas cylinders (O2, N20), Soda lime absorber, with 2.5 kg reservoir and adjustable pressure limiting valve	
	Flow meter:	
	The apparatus should use gases (O2 and N2O, air) accommodates the following main parameters:	
	For O2 : 0.1-10L/mi	
	For N2O: about 0.1-10L/mi	
	For Air : 0.1-10L/mi	
	Oxygen and Nitrous oxide anesthetic agent in the inspired mixture	
	Oxygen saturation of the blood with both adult & pediatric probes & sensors	
	Airway pressure monitoring should be present	
	Temperature monitoring with 2 probes esophageal/ rectal and skin probes	
	Mounting:	
	Mobile stand mount for the unit	
	Heavy duty steel of enamel finished with strong drawer, compartment for ventilation and anti-static castors with two brakes Individual locking front castor brake	
	Vaporizer: it should be easily removed and refilled and be monitored. Gas tight and removed. O2 flash valve: push button type o2 flow volume approximately not less than 50-70	

Canister: easily detachable double chambered clear acrylic type. Its volume should be greater than 1400ml.

Extendable rear platform for two cylinders.

Features:

Incorporate a surplus gas removal device /disposal of surplus anesthetic gas/

A flow meter with a N_2O safety mechanism incorporating a special interlocking gear system is equipped as standard accessories

Easily adjusted and replaceable flow glass tube

Alarm safety system features:

Low O2 concentration alarm sound with indicator light

When O_2 sensor is dead defective (calibration unavailable) an alarm sound & indicator should be blinked

Low O2 supply pressure alarm sound & N2O supply shut off system shut off system

A N_2O safety device which automatically cut off the N_2O flow when the O_2 supply pressure drops below 1 kgf/cm2

N₂O shall not be obtained until at least 1.5Lt of flow is surely obtained constantly.

POP of valve should prevent over pressure with surplus gas evacuation adaptor and open close circuit selector knops.

Ventilator:

Modes: Automatic Volumetric (IPPV), SIMV and Manual

Electrically powered compressor, minute volume: 2 to 25 L/min

Tidal volume: 20 - 1500 ml

Respiratory rate: 5 to 70 cycles/min

I/E ratio: (1:2 to 1:6)

Inspiration pressure: 0 to 80 mbar

Peak inspiratory flow: 0 to 60 L/min

Trigger sensitivity: 0 to -20 mbar

PEEP: 0-30 cm H20

Gas flow rate and volume indicator

Gas type indicator

Fio2 indicator

Display fit with manometer, range approx: - 10 to 100 mbar

Front panel shows status, errors and sensors failure (low/high pressure, power failure)

Audio-visual alert on low/high pressure, apnea, power failure

Display of operational status, with set and measured values

Front panel shows status and errors (low/high pressure, power failure, battery status)

Safety features for: hypoxic mixtures, oxygen failure (emergency O2 bypass), overpressures

Self diagnosis with each start-up and integrity testing of all system parameters

With adjustable patient-circuit support arm

Anesthetic gas scavenging system

Inbuilt suction unit for direct patient suctioning in oral cavity during intubation and extubation

Oxygen flush: 25-75ml

Document: Capital Medical Device Technical Specification

5. System Configuration Accessories, Spares, Consumables and other components:

4x Oxygen sensor

1x reusable ECG sensors and connectors set.

2x reusable adult and or pediatric, neonate oxygen saturation sensor and connector set.

2x reusable adult and or pediatric invasive pressure transducer and connector set with appropriate arterial lines

2x reusable adult and or pediatric non-invasive pressure transducer and connector set.

2x rectal temperature transducer and connector set.

2x adult and or pediatric cardiac output connector set.

5x EtCO2 sensor.

High and medium pressure regulating gauge compatible with the machine

5 x Pediatric reusable breathing circuit (tubes/balloons/ valves / masks)

5 x Adult reusable breathing circuits (tubes / balloons / valves / masks)

5 x Maplson D neonatal reusable breathing circuit tube/(tubes / balloons / valves / masks)

5 x Spare parts/maintenance kit (air filters, tubing, O rings)

2 x Set of spare fuses.

Should be supplied with testing, calibrating tools, analyzers for each type of gas

With All other complete standard accessories

Should be supplied with necessary attachments for use of the breathing circuits

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

Built-in rechargeable battery, autonomy approx 2 hrs with Automatic switch to battery in case of power failure, automatic recharge when connected to mains

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

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Addis Ababa

Base Code	Item Detail	Department
Toeh-90		OR
	1. Generic Name: Table – Operating, Electro hydraulic	
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	It used during surgery on which the patients lie and easily adjustable	
	4. Technical Specification:	
	Three section table, electro-hydraulic table	
	Should be adjustable to all essential positions with frame and bottom made of 304 grade stainless steel material.	
	Height should be adjustable by oil pump, foot step control.	
	Detachable head rest which can be easily adjustable to any desired position, above or below the table top.	
	Table top can be rotated 360° through base. Durable and leak-proof hydraulic pump.	_
	Kidney-position should be achievable by breaking the table. Table-top should be radio-lucent	
	Handset for position selection by in-built stand-by control.	
	Can be controlled with and without remote controlled with battery and battery indicator, electro-hydraulic operated	
	Facility to remove or interchange head and leg sections	
	Antistatic and liquid-tight mattresses with shock absorbing foam	
	Table made of corrosion resistant and disinfectant- proof stainless steel.	
	Traction facility	
	High density memory foam, 1-piece mattress, with cut- outs to fit the mattress frame at all positions with mattress size of 60mm	
	Powered height adjustment from 0.6m to 1.2m	
	Powered Trendelenburg adjustment -30 deg up to +45 deg	
	Lower Back :+100°/-30°	
	Upper Back:+80°/-30	
	Lateral tilt (left/right) up to ±30 deg	
	Adjustment of backrest -25 to +70	
	Adjustment to flex/reflex position	
	Adjustment leg section +70° / -90°	
	Table dimension (1 x w x h) 970mm x 500mm x 2000mm	
	Support at least 250 Kg	
	Leg Sections (UP/Down) :+25°/-90°	
	Head Sections (Up/Down):±40°	
	5. System Configuration Accessories, Spares, Consumables and other	
	componenets:	_
	1x Screen frame	_
	1x I.V. stands	_
	Shoulder support (pair): Lateral support (pair)	_
	2x Arm table	

6x Clamps

1x Jelly mattress

1x Restraint strap

Orthopedic Surgery's accessories: Orthopedic extension, Raised arm tabled / Adjustable arm support

ENT accessories: Head rest

Gynecology Surgery's accessories: Knee crunches (Pair) Rotary clamps (2 pcs)

Neuro Surgery's accessories: Mayfield and head rest

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \, ^{\circ}\text{C}$ to + $30 \, ^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65 Fax: +251-11-275-25-55

Addis Ababa

Paga Cada		_
Base Code	Item Detail	Departmen
Liom-90	1. Generic Name: Light-Operating, Mobile	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	A mobile type provides an optimal shadow free lighting for carrying out surgical procedures in an emergency environment.	
	4. Technical Specification:	_
	The unit comprises of spring balanced articulating arm	
	Head with button/touch screen digital control to regulate light intensity and to switch on/off the unit	
	Have continuous dimmer, continuous focus adjustment, continuous field adjustment	
	Auxiliary light source included for extra operations	
	No infrared or ultraviolet radiation	
	Sterilizable removable handle to regulate light field size	
	Light intensity: not less than 100,000 lux at 1m distance from light source	
	Color rendering index: 95	
	Heat filtrating: 99%	
	Color temperature: ≥ 4300 K	
	Luminance Field size: 14 - 25 cm	
	Diameter of light head: not less than 0.60cm	1
	Working distance range (focal length): 70 - 140 cm	1
	Depth of field with focused light: > 60 cm	
	Lifetime of LEDs ≥ 50,000 hrs	-
	Adjustable light and color temperature indicator	
	Mobile stand:	
	Light weight easily moveable stable support with at least 4 castors with locking counter balance mechanism in order to ensure stability of light head in all positions and with swivel arm.	
	Castor must be medical chemical resistant	
	Battery:	
	Built in rechargeable batteries with capacity sufficient for operating in battery mode (fully charged) for minimum of 45 min	
	Battery power (charge) indicator	

1x spare of Sterilizable removable handle

2x spare of fuses

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 100 - 240VAC

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Document: Capital Medical Device Technical Specification

Base Code	Item Detail	Departmen
Cryu-90	1. Generic Name: Cryotherapy unit – Gynecology	Gyn
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	_
	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal.	
	4. Technical Specification:	
	The system typically includes a mechanical regulator to control the flow of cryogen, contained in an attached cylinder, and the probe(s) to apply the cold.	
	Unit consist of a tank, a pressure regulator, and a probe attached by tubing to the tank	
	Fully mobile cryo-surgical system with a wide array of interchangeable probes designed for the use of gynecologic surgical procedures.	
	The interchangeable probes must include both different sizes for the cervix besides flat one for vaginal lesions.	
	Nitrous oxide or carbon dioxide can be used as refrigerant	
	Units should support various probes and tips	
	Nitrous based unit should have scavenging ability	
	Adjustable freezing temperatures, gas flow and pressures through a regulation system	
	Non - electric defrosting system	
	Autoclavable Cryo probes	
	Operating pressure: 450 to 800 psi.	
	Operating temperature: -70 to -10°C for Carbon dioxide and -90 to -25°C for Nitrous oxide.	
	Supplied with triggers/connection for N ₂ O or CO ₂	
	Rolling cart	
	Unfilled cylinder for N ₂ O or CO ₂ .	
	Supplied with all kinds of probes required for gynecology.	
	Require several different probe designs	
	Handheld compressed gas (nitrous oxide or carbon dioxide)	
	Temperatures at the Cryo tip below -79°C (-110.3oF) with CO2 or -89°C (-128.2oF) with N2O	
	The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential),	
	Removable circular, closed design Cryo tips	
	Diameter: (19±2) mm	
	Flat surfaces or with a cone extrusion <5 mm	
	Insulated Cryo shaft	

Length 170 mm to 200 mm

Hose assembly (high pressure) with cylinder connector pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas

User adjustable cryometer range

Portable and easy to transport

Hose assembly length of 150 cm

Hose is constructed with flexible plastic or rubber suitable for use with pressurized carbon dioxide or nitrous oxide.

Indicator for which type of refrigerant gas is under use

Color coded pressure gauge, to indicate the safe working range

Pressure relief valve, with an internal rupture disk to protect excessive tank pressure

Pressure regulator to maintain constant pressure

Silencer reduce noise levels

Timer to indicate duration of tissue exposure.

Cryo Tips:

Withstand routine sterilization

Smooth and sharp less Cryo tip edges

Closed design, rounded in shape and should be (19 +/- 2) mm in diameter

The surface that contacts the tissue should be either flat or with a cone extrusion (nipple shaped), not exceeding 5 mm

Length of the Cryo shaft and Cryo tip assembly: 170 and 200 mm.

Hose assembly length of 150 cm

Single-hand control from three-position trigger (freeze, off, defrost)

Instant defrost

Trigger position for immediate active defrost process

Autoclavable tips, Cryo shaft

"O" ring design to provide better gas seals where tips attach to probe system

Built-in regulators, control pressure at tips for added safety and gas economy

Change tip during procedure without shutting off gas tank

Nitrous Oxide (N2O) and Carbon Dioxide (CO2)

Cylinder Support of 20 lb.

Surgical grade Cryo Tps:

Micro, 2mm Diameter

Skin Lesion, 5mm 45°

Endocervical (Nulliparous)

Endocervical, Round

Skin Lesion, 8mm 45° angle

Ano-Rectal

Exocervical, 19mm Flat

Exocervical Convex, 19mm

Endo/Exocervical Small

Document: Capital Medical Device Technical Specification

Exocervical, 25mm Flat

Endo/Exocervical Large

5. System Configuration Accessories, spares, Consumables and other consumables:

1x Hose assembly

1x Cryotips for each type& 1x Cryoshafts

1x O-ring, and sealing washers

1x Compressed gas in cylinders (nitrous oxide or carbon dioxide)

Cryoprobes to according the specific use

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

 $Relative \ humidity: < 85\%$

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Departmen
Elsu-90	1. Generic Name:Electrosurgical unit	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Use high frequency electrical energy in a radio-frequency (RF) band to develop heat directly within targeted soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures	
	4. Technical Specification:	
	Modes of operation to include pure cut, pure coagulation and blended (combined)	
	Operation to be controlled by foot pedal, with minimum 2m connection cable, and also by hand switch on probe	
	RF generator to be within the range 0.5 to 3.5MHz, output to be electrically isolated from ground.	
	Monopolar maximum power to be at least 350W (cut) and 200W (coagulate)	
	Bipolar maximum power to be at least 50 W (coagulate)	
	Visual and audible activation indicators required	
	Visual and audible cable disconnection alarm required	
	Display and keyboard for all parameters visualization and setting.	
	Power control in the main panel.	
	Coagulation: high power for contact coagulation current with high crest factor for spray coagulation.	
	Memory for at least 10 programs with their waveforms and power levels.18) Monitoring system of the electrode-patient connection of at least 1 Khz measurement frequency.	
	Automatic power tuning with dynamic control and automatic stop in case of any working problem.	
	Protection against defibrillator discharges.	
	Convection refrigeration without ventilator.	
	Output Waveform: 445 kilohertz (kHz) square wave variable burst length Frequency Range: 445 kilohertz	
	Output Current Range: 10 - 641 milli amperes (mA rms) into a 50 non inductive load, continuously variable	
	Output Power: 0.5 - 21 watts into a 50 ohms non-inductive load	
	Continuously variable Test Load: 50 ohms non-inductive load	
	Minimum nominal high frequency output powers for cutting:	
	Monopolar 300W at 500 ohms;	
	Minimum nominal high frequency output powers for coagulation:	
	Monopolar spray 100 W at 500 ohms;	_
	Monopolar forced 120 W at 350 ohms.	

5. System Configuration Accessories, Spares, Consumables and other components:

Foot switch

2x Spare fuses

2x reusable, sterilizable, monopolar patient plates with minimum 2m long connection cable

Supplied with two each of reusable, sterilizable, monopolar and bipolar probe with selection of tip sizes for each; pencils, ball electrodes, loop electrodes, reusable return electrodes, coagulators, adapters and blade electrodes

Monopolar pedal, bipolar pedal

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC <u>+</u>10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Document: Capital Medical Device Technical Specification

Name and Model of the product
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Addis Ababa

Base Code	Item Detail	Department
Denu-90	1. Generic Name: Dental Unit	Dentistry
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Used to operate or treat the patient by looking into patient mouth easily for	
	the purpose of dental examination and treatment.	
	4. Technical Specification:	
	Dental chair to be adjusted up and down, backrest front and back for different requirement.	
	Assistant Console to control the function of the water spraying	
	Foot switch to control the dental chair movement, hand pieces and Scaler	
	Light Adjusting Arm to adjust angle and direction of operation light Adjustable Height	
	Balance Arm to connect the instrument tray	1
	Post-mounted service console to control dental unit system	1
	Genuine leather chair with seamless washable cushion	1
	Carrying capacity: 200 kg]
	Pediatric Headrest]
	Rotatable ceramic spit on	
	Operating light	
	Adjustable to different heights with variable, horizontal and inverse	
	movements for proper focusing. Light source: LED	-
	Illumination of \geq 30,000 Lux incidents in rectangular shape	_
	Color temperature of \geq 4000K	-
	Dual intensity control switch	-
	Water unit	1
	Cold and hot water	1
	Automatic flush Bowl	
	Automatic Cup filler	
	Water bottle with switch	1
	Instrument tray:	
	Tray table mounting arm swivels 360°	1
	Tray table size: 230 x 380 mm	1
	Doctor's and assistant's stool	
	Adjustable height operating stool with anatomically shape seat	
	Compressor	
	Supply medical grade dry air which is absolutely oil free	1

Pressure gauge, air moisture filter and non-retraction valve

Auto cut-off switch

Maintenance free type covered in a cabinet

Noise level: $\leq 60 \text{ Db}$

Air Pressure range: 5 to 8 bar

Compressed air supply: 100 L/min

Air tank capacity: $\geq 30L$

5. System Configuration Accessories, Spares, Consumables and other Components:

3x Saliva ejector

2x Extra LED diodes that can fit for operating light and film viewer

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+ $10 \,^{\circ}\text{C}$ to + $30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%, 50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

Shall meet medical device quality assurance 93/42/EEC

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

Turnkey Works

It is the responsibility of the Supplier to provide any turnkey works in all aspects for successful installation and commissioning of the equipment. This shall include everything required for successful commissioning but not limited to the following:

- a). Water Connection
- b). Drain Connection
- c). Electrical Connection

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

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Addis Ababa

Base Code	Item Name	Department
Xrayd-90	1. Generic Name: X-Ray- Dental	Dentistry
	2. GMDN/UMDN Code/Name: Code:	
	3. Clinical Purpose/Description:	
	Digital RVG Dental x-ray used to diagnose and for dental treatment planning.	
	4. Technical Specification:	
	X-ray tube: 70 Kv, 10mA	1
	Focal spot: 0.5mm	1
	Compatible for digital radiograph	
	X-ray tube head angle indication	1
	X-ray tube head swing angulations of at least 270° in the vertical plane and 360° continuous rotations in the horizontal plane	
	Counter balanced arm mechanism	
	RVG mode for RVG Sensor]
	High voltage protection for the X-ray Tube]
	Audible & visual indication of X-ray On]
	Pedestal stand with freely movable round wheels with locking devices to prevent unusual and excessive movement	
	Excellent, smooth mechanical maneuverability, long reach scissor arm	
	Compatible Voltage Stabilizer (built in /external)	
	Feather touch keypad and length of exposure cable 5 to 6 meters.	
	Ease of operation as all the functions can be selected from the remote control as well as Timer.	
	A lead partition and lead apron provided with a standard and properly tested for operator's safety	
	Hand controlled	
	Sensor size: Adult and Pediatric	_
	Focus to skin distance: 20cm	
	Filtration: ≥2.0 mm Aluminum	
	High quality image not less than 20 lp/mm true resolution	
	Maximum reduction in patient radiation as compared to X-ray film	
	Best detail and contrast	
	3 piece of sensor holder	
	High speed USB connection	
	Pixel size: 14 μm x 14 μm - 19 μm x 19 μm	
	High resolution RVG based on CCD/CMOS technology with optical fibre	
	Input voltage 5V DC (USB interface)	

5V DC (USB interface) USB 2.0 high speed

Computer with LCD color monitor 20 inch screen, latest processor, DVD-RW, 500 GB HDD, 4 GBRAM, All-in A4 laser jet printer, with thermal paper

Dental X-ray unit with RVG (with software) supplied with adequate and compatible computer system with latest operating system

Sensor cable length 4 meters and reinforced for durability & reliability

Fiber optic & scintillator technology

Exposure time: 0.01 - 3 seconds

Anatomic programmed: pre-set times with cordless remote

Voltage corrector/stabilizer of appropriate ratings meeting

Provision for Remote Diagnostics through RS-232C serial interface or equivalent.

Upgradable software

Optimized image geometry and constant magnification.

High resolution CCD sensors with protective optical fibre layer for protection and longevity of the sensor and have small and adjustable Panel size

Ethernet connection to computer sensor have low radiation dose.

Motorized column

Laser patient positioning

Microcomputer-controlled movements for multiple projection programs

CCD-type electronic x-ray detector with CsI, high resolution scintillator

Memory card slot

Connection to computer via high-speed USB port

Pedestal mount

Storage compartments

Face to Face patient positioning with laser beams for better patient Comfort and accurate positioning.

Cater to all types of patients including adult, pediatrics, standing, sitting and wheel chair patients.

Positioning accessories like, Standard Bite blocks, edentulous bite blocks, panoramic chin rest, Sinus chin rest, TMJ nose rest.

The patient information must be arranged in a very user friendly and simple format with built in patient information management service.

Low radiation dose with good image quality, with computerized operator's guide and with pc and programs

Expose in either direction

25 plastic bite guides

3 point head positioning system

Patient Selection Switches (Thin, Normal & Obese).

RVG mode for RVG Sensor

High Voltage Protection for the X- Ray Tube

Audible & Visual indication of "X-Ray On" (Radiation indications).

Document: Capital Medical Device Technical Specification

Collimating device and a pointed cone provided with built in Aluminum filter

Electronic selection of exposure time/radiation according to tooth number.

5. System Configuration Accessories, Spares, Consumables and other components:

UPS with 30min capacity

2x Dental Led apron

2x Gonadal sheath

2x Thyroid protection collar

X-ray film viewer, processor and positioner

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to +45°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%, 50Hz

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide a minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

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Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Document: Capital Medical Device Technical Specification

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Name and Model of the product
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Addis Ababa

Base Code	Item Detail	Department
Xrmd-91	1. Generic Name:X ray - Mobile, Digital	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	1
	A compact, light weight device used in emergency, trauma and ICU	-
	departments as well as operating theaters for conventional radiography	
	4. Technical Specification:	
	Mobile stand	
	Compact and light weight design with mobile castors for easy maneuverability	
	Fully counterbalanced with compact flat detector	
	Backup battery with continues operating time of 2hrs/100 exposures	
	Dose area measurement system	
	Automatic exposure control	
	KV, mA increase & decrease	
	Effective braking system for parking, transport and emergency.]
	Articulated arm for maximum positioning flexibility in any patient position.]
	Emergency stop button	
	Standby and exposure release switch]
	Ready and X-Ray on switch with Indicators]
	All cables shall be concealed in the arm system	1
	Storage facility for flat panel detector and other supplies]
	Digital display of kV, mAS and/or mA and time	
	X-ray generator:]
	High Frequency generator without put power 25Kw]
	kV range: 40-125Kvp]
	mA: 20 mA to 320 mA	
	mAs: max. 280 per exposure	
	Exposure time: for patient exposure should be ≤1s and for tube capacity should]
	be up to 5s	-
	Self diagnostic programme with Indicators like tube over heating/high voltage,	
	power supply not ready, broken filament error, earth fault error, etc	-
	X-ray tube and collimator: Output should match the output of the generator	-
		-
	Dual focus rotating anode with spot size less than 1.3mm Tube focal spot selection Switch	-
	Total filtration: minimum 2 mm Al	-
		-
	Tube voltage: 40-125Kvp	-
	Ande heat capacity: 300KHU	-
	Anode cooling rate: 40KHU/min.]

Tube horizontal movement: 45 cm or more

Tube vertical movement: 100 cm or more

Adjustable multi leaf collimator with SID laser localizer

Collimator lamp on switch

Detector System:

The detector should be solid state flat detector or latest technology with cesium iodide scintillator.

Detector active size: 35cm x 43cm or more.

Pixel size: 148 um or less.

Detector Quantum Efficiency (D.Q.E): 65% @ Zero LP/mm or more.

With at least two user selectable input fields

Active matrix size: 2.8k x 2.3k

Image acquisition and image processing:

Shall have integrated 17" high brightness LCD/TFT color button/touch screen monitor.

The digital workstation should be based on the latest high speed processors of at least 32 bit.

Patient data management- Electronic record with name, date, anatomy, etc..

Automatic digital brightness and contrast control for optimal image quality

Image rotation, reversal (left/right), and up/down on last image hold

Annotation (text, trace, arrow, line, rectangle, circle in images)

Measurements (length, distance and angles in images)

Image post processing features: zoom & pan, edge enhancement, contrast and brightness, etc...

Connectivity:

Integrated data interface via LAN/Wi-Fi enables to connect into the hospital network.

Storage of 3000 images on hard disc

Integrated facility documentation with DVD/CD, USB and DVD recording

DICOM functionality and connectivity

FULL DICOM Compatible

DICOM 3.0 print Service Class User

DICOM 3.0 Storage Service Class User

DICOM 3.0 Storage Commitment Class

DICOM 3.0 Work list Service Class User

DICOM 3.0 Query/Retrieve

DICOM 3.0 MPPS

Media Export/Import

Automated transfer of the image acquisition parameters for each exposure in to the DICOM header

Capability of export unprocessed and processed DICOM images

Networking capability with RIS/HIS/PACS

5. System Configuration Accessories, Spares, Consumables and other

components:

Main unit with x-ray generator, x-ray tube----1

Flat panel detector----1

All software packages shall be provided as standard

A CD-R/W based long term archiving with envelope----10,000

Whole body lead aprons with 0.5mm, 0.35mm, 0.25mm lead thickness (or equivalent) ----2 of each

Thyroid shield -----3

Gonad shield small, medium, large size----2 of each

Lead goggles ----3

Phantoms and meters for the quality control and calibration of the various components (x ray, medical displays) of the system shall be provided

All standard accessories and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.

6. Operating Environment:

The unit shall be capable of operating continuously in ambient temperature of: +10°C to +40°C

Relative Humidity: <85%

7. Utility Requirements:

Power input: 220V/50Hz

8. Standards & Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical Safety

9. Installation/Training/Commissioning:

The supplier must provide installation, and commissioning of the device

The supplier must provide sufficient technical and end user training on site.

10. Warranty/ After sales service:

The supplier must be provide minimum of Two years warranty including Labor, X-ray tube, detectors and spare parts and accessories from the date of installation as well as after sale services.

The supplier must provide extended warranty from 3rd year to 5th year inclusive of labor, spare parts, accessories, detector and X Ray tube.

10. Warranty and After Sale service

The supplier must provide minimum of Two year basic warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User, and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Document: Capital Medical Device Technical Specification

Each item with all accessories /spare part shall be configured and packed in one unit.

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Name and Model of the product

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Tel: +251-11-276-32-66

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Addis Ababa

Base Code	Item Detail	Department
Ultg-90	1. Generic Name: Ultrasound- Ob/Gyn	Imaging
	2. GMDN/UMDN Code/ Name:	
	3. Clinical Purpose/Description:	=
	Used for obstetrics, gynecology, Abdomen, Urology and Emergency Medicine Packages scanning	
	4. Technical Specification:	
	The system with one active probe ports for easy use and convenient operation.	
	Controls for depth, gain compensation preferably automatic gain and depth control	
	The system have dedicated calculation software package including Obstetrics, Gynecology, Abdomen, Urology and Emergency Medicine Packages)	
	The system have image storage and archiving with CD, USB flash and DICOM	
	System with 15 inch LCD monitor and also can connect to external display	
	Probe: Convex (2-5MHz)	
	Number of elements:192	
	FOV:58	
	Physical foot print:55x18 mm	
	Convex radius:60mmR	
	with battery support to operate the machine in case of power failure	
	5. System Configuration Accessories and Consumables	
	System with main unit and mobile cart (trolley)	
	Laser Printer for direct image and report print out1pcs	
	Convex probe1pcs	
	Ultrasound paper100 rolls	
	Gel: 250 ml 2pcs	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards & Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation/Training/Commissioning	-
	The supplier must provide installation, and commissioning of the device at health Facility	
	The supplier must provide onsite technical and end user training	-
	10. Warranty/ After sales service:	1
	The supplier must be provide minimum of Two years warranty including labor and spare	1

part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-66

Tel: +251-11-276-32-66

Fax: +251-11-275-25-56

Addis Ababa

D C- J-	I4 D-4-21	D4
Base Code	Item Detail	Department
Laum-90	1. Generic Name: Refrigerator - General purpose, 300L	Pharmacy
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Clinical Purpose: General purpose Refrigerator is an Upright refrigerator for storage and conservation of vaccine, chemicals and reagents in clinical laboratory and pharmacy @ 0°C to 10°C.	
	4. Technical Specification:	
	Compression type, CFC-free refrigerant, with spark free ignition	
	Fan-cooled for even distribution of air in the cabinet	
	Stainless steel structure	
	Easily adjustable ≥ 3 shelves	1
	Insulation material: polyurethane, CFC-free and Lockable door, solid	
	Electronic temperature control: 0°C to 10°C and Accuracy, whatever the load: +/- 1°C	
	Lighting System: Top LED	
	Temperature monitoring:	
	External digital display with actual interior temperature, minimal graduation 0.1°C	
	Electronic temperature recording device	
	Audio and visual alarm system indicates unsafe temperatures	
	Battery back-up for audio and visual alarm system, and temperature recording device	
	Integrated four castors with break	
	Minimum compressor starting voltage: 22% below nominal voltage	
	Microprocessor controlled spike and surge protection, and protection against disturbances	
	Multiple LED bar-graphs display: connected/disconnected status, voltage fluctuation and load as % of nominal current	
	Electronic fuse disconnects and reconnects automatically; KVA rating matches power consumption of the refrigerator	
	PIN security lock for unauthorized tampering	
	Audible and visible alarms for temperature, power failure, system failure,	
	battery low, Door Ajar etc.	
	Slow motion Lid opening: Pneumatic door opening system	
	Door gasket made of silicone rubber and with stand the temperature variation throughout the range.	
	Heavy-duty Rear wheel locking casters Fitted at Bottom for Easy Movement.	
	Heavy duty hinge for closure and un-interruptive service.	1

Informative display and control screen with history tracking

Easy data transportation through USB port and it must also have on board diagnostic software.

Adjustable LED lighting for efficient energy

Illumination with auto-on feature and ON/OFF switch

Forced-air circulation maintains chamber uniformity and provides

Quick recovery after door openings

Bacteria-resistant interior, exterior, and door handle

Voltage stabilizer of appropriate rating

Keeping inside temperature for 8Hr during power failure

Accepted input range: -20 % to +20 %

Response time: <15 ms

Power consumption: 500 W

5. System Configuration Accessories, Spares, Consumables and other components:

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%/50HZ

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of electrical safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Document: Capital Medical Device Technical Specification

Each item with all accessories /spare part configured and packed in one unit.
Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency
(EPSA)
Tender and Purchase Order No.
Name and Model of the product
PO Box 25-11-276-32-65
Tel: +251-11-276-32-65
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Addis Ababa

Base Code	Item Detail	Department
Steh-90	1. Generic Name:Instrument - Sterilizer Hot Air 25L	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:-	
	Hot Air Sterilizers are required for sterilizing an object in high temperature by using dry heat to sterilize and operate in the principle of patented fine air circulation achieved by means of a fan in an electrically heated chamber.	
	4. Technical Specification:	
	Should be table top and front loading	_
	Microprocessor based system with temperature controller with integrated auto diagnostic system with fault indicator. Thermostatically controlled system. Hot air circulation	
	Fully automatic provided with timer and fan.	
	Temperature range : room temperature to 250 degree Celsius (adjustable)	
	Temperature Variation +/- 1 deg C.	_
	Temperature display unit	_
	Fan cooling system after full time sterilization	
	Timer range: 0 to 120 minutes (adjustable)	
	With interior in stainless steel -	
	With three adjustable mesh shelves of stainless steel	
	Capacity: 25 liters	
	5. System Configuration Accessories, spares and consumables -	
	System as specified - All consumables required for installation and standardization of system to be given free of cost. Timer and touching pad	
	3x set of Spare Heater	_
	3x set of readymade gasket 3x thermostat, 3x fuse	_
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	-
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	
	Electrical Power Supply: 220VAC ±10%	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Addis Ababa

Base Code	Item Detail	Departmen	
Stes- 90	1. Generic Name: Sterilizer - Steam, 45/100L	OR	
	2. GMDN/UMDN Code/Name:		
	3. Clinical Purpose/Description:		
	Steam Sterilizer used in the destruction of all forms of microbial life on medical instrument by exposing the object to moist heat at 121°C-134°C under high pressure 4. Technical Specification:		
	Front Loading table top steam sterilizer		
	Touch screen, with LCD control panel, about 5" or above screen size		
	Manual/Hinged door made of stainless steel medical grade of 316 with thermal insulation.	_	
	Fitted with load and safety thermostat take over LED indicator lamp.		
	High Grade strong stainless steel 316, Triple walled construction		
	Positive radial self-locking safety doors		
	Hydrostatically tested to withstand 2.5 times the working pressure		
	Manual and automatic filling option		
	Air ballast system for fast and safe processing of fluids	=	
	Control System: Microcontroller Based		
	The safety value will be open automatically when the inner pressure over and the steam be exhausting to the water tank	-	
	The door opening mechanism cannot be operated until the pressure in the chamber reached atmospheric Pressure	-	
	A complete record of every cycle is produced on the built-in thermal printer, with 1 box of thermal paper	•	
	316 stainless steel pressure vessel		
	Fan cooling system	1	
	automatic and real time self diagnosis system in case of failure and have means of reporting to the operator	-	
	A safety micro switch is fitted to the door which will only allow the cycle to start if the door is properly closed and locked.		
	Water system: Automatic water fill with inbuilt/external reverse osmotic water softener in the system		
	water supply line fitted with extra water filter		
	Sealed with Silicon long-lasting and durable gasket.	1	
	Digital display for jacket and chamber pressure, steam generator temperature	1	
	Outer jacket of stainless steel 316 to prevent heat loss		
	Mounted on tubular stainless steel 316 frame with ground leveling flanges	1	
	The steam generator made of medical grade 316 stainless steel	1	
	Thermal insulation to prevent overheat		
	Heat dissipation: maintain nominal temp and the heat dispersed through a cooling mechanism	-	
	Input voltage: 220VAC, 50Hz, 1-phase	1	

Pressure gauge: 0-2.2Kgf/cm²

Operating pressure from: 15-31 psi

Sterilizing pressure: 1.2-2.2Kgf/cm(15-31 psi) at 121°C-134°C

Protection: over-charging cut-off with visual symbol

Pressure control switch

Low water level cut-off device

Vacuum breaker

3x Readymade Spare Gaskets

Steam generator

Rapid water re-cooling

Low water protection device

Air removal filter

Timer with alarm system

Digital temperature indicator

Printer & Digital chart recorder

Stainless steel flush mounting

Carriages, trays, and baskets

Overpressure release valve

Sterilization indicator

Indicator color must not fade when it is exposed to light

Distinctive color change

Dual strip can be divided into two for economy of use

1x 300pcs/box, Dimension 150×90×200mm

Lead free steam indicator tape

For stem range of temperature of application: between 121°C and 134°C

Shelf life: 5 years

5. System Configuration Accessories, Spares, Consumables and other components:

 $2x\ Trolleys$ for contaminated and for sterilized instruments can be fitted the sterilizer door/Each

Pneumatic valves, Pressure switch

Temperature sensor

3x Spare heater

2x Door gasket

1x Spare contactor

3x Spare fuse

5x Gasket lubricant

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

Document: Capital Medical Device Technical Specification

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Departmen
Cryu-90	1. Generic Name: Cryotherapy unit - Gynecology	Gyn
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/ Description:	
	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) [e.g., liquid nitrogen (LN2), nitrous oxide (N2O), carbon dioxide (CO2)] to a target tissue for its destruction and removal.	
	4. Technical Specification:	
	The system typically includes a mechanical regulator to control the flow of cryogen, contained in an attached cylinder, and the probe(s) to apply the cold.	
	Unit consist of a tank, a pressure regulator, and a probe attached by tubing to the tank	
	Fully mobile cryo-surgical system with a wide array of interchangeable probes designed for the use of gynecologic surgical procedures. The interchangeable probes must include both different sizes for the cervix besides flat one for vaginal lesions. Nitrous oxide or carbon dioxide can be used as refrigerant	1
	Units should support various probes and tips.	
	Nitrous based unit should have scavenging ability.	
	Adjustable freezing temperatures, gas flow and pressures through a regulation system	
	Non-electric defrosting system.	
	Autoclavable Cryo probes	
	Operating pressure: 450 to 800 psi.	
	Operating temperature: -70 to -10°C for Carbon dioxide and -90 to -25°C for Nitrous oxide.	
	Supplied with triggers/connection for N ₂ O or CO ₂	
	Rolling cart	
	Unfilled cylinder for N ₂ O or CO ₂ .	
	Supplied with all kinds of probes required for gynecology.	
	Require several different probe designs	
	Temperatures at the Cryo tip below: -79°C (-110.3oF) with CO ₂ or -89°C (-128.2oF) with N_2O	
	Trigger mechanism to control the freeze/thaw cycle with active defrost	
	Removable circular, closed design Cryo tips	
	Diameter: (19 ±2) mm	
	Flat surfaces or with a cone extrusion <5mm	
	Insulated Cryo shaft	
	Length: 170mm to 200mm	
	Hose assembly (high pressure) with cylinder connector pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas User adjustable cryometer range	

Portable and easy to transport

Hose assembly length of 150 cm

Hose is constructed with flexible plastic or rubber suitable for use with pressurized carbon dioxide or nitrous oxide.

Indicator for which type of refrigerant gas is under use

Color coded Pressure gauge, to indicate the safe working range

Pressure relief valve, with an internal rupture disk to protect excessive tank pressure

Pressure regulator to maintain constant pressure

Silencer reduce noise levels

Timer to indicate duration of tissue exposure.

Cryo Tips:

Withstand routine sterilization

Smooth and sharp less Cryo tip edges

Closed design, rounded in shape and

should be (19 \pm 2) mm in diameter

The surface that contacts the tissue should be either flat or with a cone extrusion (nipple shaped), not exceeding 5 mm

Length of the Cryo shaft and Cryo tip assembly: 170 and 200 mm.

Hose assembly length:150 cm

Single-hand control from three-position trigger (freeze, off, defrost)

Instant defrost

Trigger position for immediate active defrost process

Autoclavable tips, Cryo shaft

"O" ring design to provide better gas seals where tips attach to probe system

Built-in regulators, control pressure at tips for added safety and gas economy

Change tip during procedure without shutting off gas tank

Nitrous Oxide (N2O) and Carbon Dioxide (CO2)

Cylinder Support of 20 lb.

Surgical grade Cryo Tips:

Micro, 2mm Diameter

Skin Lesion, 5mm 45°

Endocervical (Nulliparous)

Endocervical, Round

Skin Lesion, 8mm 45° angle

Ano-Rectal

Exocervical, 19mm Flat

Exocervical Convex, 19mm

Endo/Exocervical Small

Exocervical, 25mm Flat

Endo/Exocervical Large

Document: Capital Medical Device Technical Specification

5. System Configuration Accessories, spares, Consumables and other consumables:

1x Hose assembly

1x Cryotips for each type

1x Cryoshafts

1x O-ring, and sealing washers

1x Compressed gas in cylinders (nitrous oxide or carbon dioxide)

Cryoprobes to according the specific use

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be providing minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Base Code	Item Detail	Department
Sucm-90	1. Generic Name: Suction Machine	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a	
	body cavity or lumen by means of suction. This system can be used in a wide variety of settings	
	within healthcare facilities.	
	4. Technical Specification:	
	Vacuum Adjustment: Continuous	
	Must be able to generate a vacuum of at least 0.85 bar (650mmHg)	
	Maximum vacuum: 700 mmHg	
	Minimum open tube flow rate at least 3L/min	
	Twin suction bottles, minimum size 3 liters each made of non-glass materials	1
	Bottles to have an automatic cut off when full to prevent ingress of fluid to motor	
	Airline to pump to incorporate bacterial filter	
	Tubing to patient to be minimum 3m long, non-collapsible type	1
	Sound Level: < 60dBA	
	Castors: 100 mm diameter, with brakes	
	To be protected against fluid ingress from above	1
	Machine cover should be open able for repair and maintenance	
	Oil-free pump operation preferred	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	2x Spare suction bottles	
	5x pare inlet filters at least	1
	2x pare sets of fuses,	
	3x Suction tubes`	7
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	7
	Relative humidity: < 85%	7
	7. Utility Requirements:	7
	Protective replaceable fuses fitted on live and neutral supply lines	7
	Electrical source requirements: Voltage: 220V +10, Frequency: 50Hz	-
	Electrical source with line connection plug type.	
	Protections against over-voltage and over-current line conditions	
	8. Standards and Safety Requirements:	=
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	1
	9. Installation, Training and Commissioning:	7

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Health Center Capital Medical Equipment Technical Specification

Base Code	Item Detail	Department
Pulo-90	1. Generic Name: Pulse Oximeter	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	1
	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement	7
	and display of hemoglobin oxygen saturation (SpO ₂).	
	4. Technical Specification:	1
	SpO ₂ measurement range at least 60 to 99 %, minimum resolution 1%	1
	Accuracy of SpO ₂ better than ±2%	
	Pulse rate range at least 30 to 250bpm, minimum gradation 1bpm	1
	Accuracy of pulse rate better than ± 2bpm	1
	Automatic power-off facility required after minimum of 1 minute	
	Low battery display required	†
	Must supplied with rechargeable battery	
	Digital equipment with autocorrelation algorithm	
	Internal memory continuous data storage time not less than 12 hours	
	Integrated display for data visualization with size not less than 5 inches.	1
	Video display of at least the following parameters, SpO2 sensor connected, alarms disabled, low	1
	battery, battery in charge.	
	Plethysmography curves and tendency lines visualization capabilities for monitored parameters	
	At least the following audio alarms: high frequency, low frequency, low saturation.	7
	Hard and splash proof case	†
	Display must allow easy viewing in all ambient light levels	
	Supplied in protective case for clean storage and safe transport	
	Handle bar or facilities for easy transportation.	
	5. System Configuration Accessories, Spares, Consumables and other components:	-
	Battery charger, Batteries	1
	1x Cable with a length: 1.5m	
	1x Reusable oximeter sensors for adult, pediatric, neonatal patients	
	6. Operating Environment;	_
	Operating Temperature:+10 °C to + 30°C	1
	Relative humidity: < 85%	
	7. Utility Requirements:	1
	Charger electrical source requirements: Voltage: 220V ± 10 /50Hz	1
	Protections against over-voltage and over-current line conditions.	1
	Battery charger to be wall output fitted and has AC to DC adapter	1

Document: Capital Medical Device Technical Specification

Version 1: November, 2019 G.C.

Page 670 ISBN No: Battery to allow at least 12hr continuous operation

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

Supplier to perform safety and operation checks before handover for some samples

Training of users in operation and basic maintenance shall be provided

The case is to be cleanable with alcohol or chlorine wipes

10. Warranty and After Sale service:

The supplier must provide minimum of one year warranty including labor and spare part from the date of commissioning.

11. Documentation:

User and service manual in English

Certificate of calibration and inspection to be provided

Advanced maintenance tasks required shall be documented

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Departmen
Oxy-90	1. Generic Name: Oxygen concentrator	OR
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Oxygen concentrator is a device which concentrates the oxygen from an atmosphere (typically ambient air) to the patient	
	4. Technical Specification:	_
	Compact and easy to transport (Mobile on Castors).	
	Dual-head Compressor.	
	Capacity: 1 to 5 l/Min of O ₂ at minimum of 90% concentration at maximum flow	
	Pressure-compensated Flow meter shall permit use of long cannula	
	Audible and visual safety alarms: Power Failure, Restricted Flow, Low O ₂	
	Pressure-relief Valve and thermal protection of the Compressor.	
	Double - Insulated Unit, Two-prong plug.	
	Flame-retardant Cabinet	
	Sound Level: 60 dB average	
	Fixed humidifier Port and Recess shall prevent bottle and connector breakage	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1x O2 Tubing	
	3x Face Masks (Adult , Infant , New Born),	
	2x Humidifier	
	1x Set of Filters	
	6. Operating Environment;	
	Operating Temperature: +10 °C to + 43 °C	
	Relative humidity: <85%	
	7. Utility Requirements:	
	Electrical source requirements: Voltage: 220V± 10 /60Hz	
	8. Standards and Safety Requirements:	
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)	
	9. Installation, Training and Commissioning:	
	Supplier to perform safety and operation checks before handover for some samples	
	Training of users in operation and basic maintenance shall be provided	
	10. Warranty and After Sale service:	
	The supplier must be providing minimum of one year warranty including labor and spare part from the date of commissioning.	
	11. Documentation:	

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

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Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base	Item Detail	Department
Code		2 opus ussuss
Wari-90	1. Generic Name: Warmer - Radiant, Infant	NICU
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/Description:	
	Infant radiant warmer used for the treatment of hypothermia on infants and it consists of a biocompatible bed, overhead heater.	
	4. Technical Specification:	
	Mobile, mounted on 4 double swiveling castors wheels, all 4 with brakes.	
	Antistatic castors, with breaks	
	Table surface with conductive mattress with infant head/shoulder support	
	Mattress-padding: foam density approx 25 kg/m3.	
	Mattress cover: Memory Foam Mattress, waterproof, washable.	
	resistant to cleaning with chlorine based solution and flame retardant	
	Side boards transparent acryl, drop down and lockable	
	Under table 2 storage drawers and Overhead light: LED	
	Side rails allow for mounting of accessories.	
	Hood suspended above the table integrates heating element and overhead light.	
	Display with LED screen full color for displaying graphics and trends of air	
	temperature, skin temperature (main temperature and peripheral temperature	
	a feather touch/button operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection	
	Heating element: emitter with parabolic reflector and protected by metal grid Control unit allows air and skin temperature preset (LED indicator) and drives radiant heater Output (servo and manual)	
	Integrated timer: 1 to 59 min, with count-up and count-down feature	
	Temperature range, skin: 34 to 38 deg C (user pre-settable)	
	Monitoring of skin temperature by means of sensor, range: 30°C to 42°C	
	Heater output: 0 to 100% in increments of 5%	
	Audio and visual alarms for: Power failure or disconnected ,Heater failure ,Temperature higher or lower than set temperature	
	Display reports systems errors, failure.	
	Control unit: audiovisual alarms according to timer and temperature presets avoiding overheating	
	Protection: OVP, earth leakage protection.	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	1 x Memory Foam Mattress	
	3 x skin temperature probe (including connection cable)	

3 x spare skin temperature probe (including connection cable)

1 x spare heating element

Acrylic helmet – 1 set

5 x spare of set fuses and IV pole

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide on sight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

Fax: +251-11-275-25-55

Addis Ababa

Base Code	Item Detail	Department
Incn-90	1. Generic Name: Incubator - New born	NICU
	2. GMDN/UMDN Code/Name::	
	3. Clinical Purpose/ Description:	
	Used to maintain appropriate temperature and humidity levels mainly for	
	premature infants and other newborns that cannot effectively regulate their	
	body temperature.	
	4. Technical Specification:	
	Electronic control of humidity, oxygen concentration, air temperature and infant skin temperature.	
	Clear, hard cabinet for infant viewing.	
	Double wall with air circulation.	
	Easy access control panel, with light touch operation switches.	
	Self-test functions are performed.	
	Built for stable, stationary operation in ward environment	
	Controlled by microprocessor or microcontroller.	
	Servo controlled mode to adjust patient's skin temperature not lower than	
	34°C up to 37°C. Can be raised on the range from 37°C to 38°C.	
	Servo controlled mode to adjust air temperature from 23°C or less to 37°C	
	or more. Can be raised on the range from 37°C to 39°C.	
	Air filter	
	Minimal resolution of 0.1 °C.	
	Monitored parameters: air temperature, patient's skin temperature, oxygen concentration and humidity	
	Micro controlled humidifier with range 40 to 90%	
	Oxygen input flow rate 3to15 litres/min or oxygen concentration range 21 to 70%.	
	Maximum CO2 concentration inside incubator 0.2%.	
	Noise level in the interior of the hood less than 60 dBA.	
	Head end raise facility with auto lock.	
	Displayed parameters	
	Patient temperature	
	Air Temperature, humidity and oxygen concentration	
	Visual and audible alarms for:	
	Patient and air high/low temperature alarm.	
	Air circulation / probe / system / power failure alarm.	
	Humidity alarm.	
	Power failure.	
	Temporal alarm silencer.	

Heater power indicator

User Adjustable Parameters

Air temperature control from 23°C/73.4°F to 37°C/98.6°F

Patient temperature control from 34°C/93.2°F to 37°C/98.6°F

Humidity control from 40 to 80%

Oxygen input flow rate from 3 to 15 lpm

Components:

Transparent cabinet.

Double-wall with air circulation between the hood and the double wall.

One door with air curtain.

Mattress with washable and waterproof covers; removable and not smaller than 55 cm (length) x 34 cm (wide).

Accommodates shelves and I/V poles.

Mounted on stationary table, base of which is at least 80 cm high

At least four ports for tubes access to the interior of the hood.

At least four ports to access the patient.

At least one door or drawer or accessories base

Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes. Mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium.

Humidifier Water tank capacity not less than 1 liter.

5. System Configuration Accessories, spares, Consumables and other consumables:

Two extra mattresses

Two extra sets of skin temp sensors

Two extra sets of air temp sensors

Two extra sets of air filters

Two reusable temperature sensor probes.

A reusable or disposable skin temperature sensor probe.

Sticky reflective patches.

Sleeves

oxygen analyzer

Two extra sets of fuses

Mattress with washable and waterproof cover.

• Internal Quality control and calibration system and control material

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Document: Capital Medical Device Technical Specification

Shall meet IEC-60601(Or Equivalent BIS) General Requirements of electrical Safety

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsight technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling;

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part shall be configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Ccan-91		Laboratory
	1. Generic Name: Analyzer - Clinical Chemistry	
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: Chemistry Analyzer is required for the	
	detection and quantification of blood chemistry and other body fluids.	
	4. Technical Specification:	
	For analysis of serum, plasma, urine, cerebrospinal fluid (CSF), hemolysate and/or whole blood and other	
	A discrete patient prioritized automated random access clinical chemistry analyzer, For chemistries, immunoglobulins, drug assay etc. in blood/urine/fluid with ISE electrolyte module (Na+, K+, Cl ⁻). Independent calibration of photometer and electrolyte analysis and closed reagent system.	
	Operating Mode: End point, Kinetic, initial rate, monochromatic, bichromatic, turbidi metric, serum blanking (differential) and fixed time.	
	Wavelength range: 340 – 800nm	
	Through put: 400 test/hour with ISE module (Na ⁺ , K ⁺ , Cl ⁻).	
	Reagent/sample tray: Not less than 40 reagent position, 80 sample position	
	Reagent volume: 20 -350ul	
	Error Check: Automatic flagging for errors	
	Auto dilution Capability: For high value samples	
	Repeat Run Capability: Capable to check the results by repeat run on desired samples	
	Sample clot and Probe crash detection Capability: For excluding erroneous analysis	
	Self diagnosis and troubleshooting: For minor day-to-day problems	
	Calibration modes: Linear, Non-Linear and Multipoint	
	Reagent storage facility: Onboard refrigeration for not less than 40 reagent	

bottles

STAT mode

LAN interface facility: Online data transmission facility through LAN

Cuvette washing system: Inbuilt with automatic cuvette washing facility and/or disposal system for one time use.

OPTICAL SYSTEM:

Light Source: Halogen/ Xenon Lamp.

Wave Length Range: 340 – 800 nm with polychromatic correction

The Operational Requirements: should be with programmable memory -

The Processing mode: - patient by patient , Test by test and STATmode

Operating Mode: End point, Kinetic, initial rate, monochromatic, dichromatic, turbid metric, serum blank (differential), fixed time, optics and wavelength range

System: open system-able to work with reagents and supplies from other manufacturers

- Operating Mode: End point, Kinetic, initial rate, monochromatic dichromatic, turbid metric, serum blank (differential), fixed time and optics wavelength range
- Assay: End point, rate assay, fixed point assay
- Calibration: Linear, non-linear, with possibility of two and multi point calibration; multi point calibration for kinetic and fixed type modes.
- Light Source: long life halogen or equivalent lamp.
- resolution: 0.0001 Abs

Temperature control: cuvette heating (electrical) in caruousel and reading path: 37 0C

- **5.** System Configuration Accessories, Spares, Consumables and other components:
- 1- System as describes
- 2- Graphic printer- for printout of parameters, results, calibration curves, kinetic and statistics, facility to store data in PC through connecting data cable and related software must be provided.
- 3- Desktop PC (microprocessor with speed not less than 3.00 GHz, 512MB

RAM, 80 GB HDD,, 105 keys Board, scroll mouse,

multimedia kit, 56 kbps modem 32 MB AGP Card, 52xCD CD-RW Drive, with 17" TFT Digital Color Monitor) with compatible Operating system

must be provided along

4-Complete Start up kits consumables (reagents, kits, controls...),

accessories, and spares required for installation and standardization of the

System to be provided.

5- Reusable: cuvette block for 4 tests Each

: Reagent bottles

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

Federal Democratic Republic of Ethiopia Pharmaceuticals Supply Agency (EPSA)

Tender and Purchase Order No.

Name and Model of the product

PO Box 25-11-276-32-65

Tel: +251-11-276-32-65

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Addis Ababa

Base Code		Department
	Item Detail	_
Mibl-90	1. Generic Name: Microscope ,Binocular, LED	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description: To magnify and study specimens and small	
	objects by transmitted visible light	
	4. Technical Specification:	
	Microscope frame with revolving, 30 degree inclined binocular tube 360 degree	
	rotatable head illuminator LED light source with white light intensity control and	
	LED light life more than 10,000 Hrs. Fixed graduated mechanical stage approx. 200 x 150 mm, travelling approx. 80 x	
	50 mm	
	Double slide holder	
	Coarse focusing: approx. 3 mm per rotation	
	Fine focusing: approx. 0.3 mm per rotation	
	Range of magnification: 40 to 1000x	
	Reverse angle quadruple revolving nose-piece, with distinct click-stop, with rubber	
	grip for easy handling	
	Objectives, full plan achromatic: 4x (0.10 NA), 10x (0.25 NA), 40x (0.65 NA), 100x	
	(1.25 NA, oil) and 100X oil immersion	
	Condenser: Abbe with iris diaphragm aperture, 1.25 NA	
	Eyepieces: Focusable pair, 10x (FN 20), with inter-pupillary distance- and dioptre	
	Adjustment	
	Retractable eye guards	
	Filter: blue	
	All optics anti-fungus treated	
	Brightness control: 0 to 100 % (linear)	
	Detachable plano-concave mirror unit with adjustable convex and concave	
	mirror on alternate side	
	5. System Configuration Accessories, Spares, Consumables and other components:	
	Ø 1 x Pair eye shades	
	Ø 1 x Pair of tube caps	
	Ø 1 x Oil, immersion	
	Ø 1 x Lens cleaning kit consisting of lens cleaning tissue, 100 ml cleaning	
	solution,	
	dust blower	
	2 x Fuse	
	1 x Power cord	

dust cove and storage box

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature:+10 °C to + 30°C

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC +10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Addis Ababa

Base Code	Item Detail	Department
Hema-90	1. Generic Name: Analyzer-Hematology, 3 Differential	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	Used in clinical laboratory, Hematology tests can be used to indicate, diagnose, and evaluate many conditions, including infection, inflammation, and anemia. Hemoglobin (HgB) - the oxygen-carrying protein in red blood cell.	
	4. Technical Specification:	
	Principles: Electrical impedance method with advanced SRV technology for accurate & precise total count	
	Diode based LASER Technology for 3 part differential	
	Photometry – LED based technology for hemoglobin	
	Parameters: Not less than 20 parameters (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM#, MON#, Gran#, LYM%, MON%, Gran%, RDW-SD, RDW-CV, PDW-SD, PDW-CV, MPV, PCT)	
	Plus: 3 histograms –RBC, WBC & PLT	
	Throughput: Not less than 40 tests / hour	
	Sample mode: whole blood in open mode	
	Chambers: Dual chamber advanced system	_
	Auto Clean Modes: Available	_
	Automatic system	
	Sample volume: approx. 30 ul	
	• Determination of: Red blood cell (RBC), White blood cell (WBC), Hemoglobin (HGB),	
	Calibration: independent automated calibration and manual calibration	

for two test modes minimum

- Data storage approximately 40,000 sample results with Histogram WBC,RBC, and platelet
- Calibrator and control shelf life at least 3 months and reagent 1 year
- Operation by screen touch and key board
- Printer built in thermal printer (standard)and external printer optional
- Typical counting time: approx. 60 seconds for differential
- With self-test capability
- Display: LCD screen
- Indication of self-test failures and assistance messages
- Sample ID, date and time are reported with test results
- Supplied complete with dedicated data analysis and data management software
- Results are reported on external inkjet printer
- Casing, corrosion proof material such as plastic or epoxy coated steel
- With built-in RS232, USB 2.0 or equivalent, allowing data transfer

5. System Configuration Accessories, Spares, Consumables and other components:

- Supplied with: UPS and stabilizer as one unit
- Supplied with dust cover
- Bar code reader with handheld accessories

All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above

6. Operating Environment;

Operating Temperature: $+10 \,^{\circ}\text{C}$ to $+30 \,^{\circ}\text{C}$

Relative humidity: < 85%

7. Utility Requirements:

Electrical Power Supply: 220VAC ±10%

8. Standards and Safety Requirements:

Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility

Shall meet ISO 13485 Medical Device Quality Management system (Or Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

11. Documentation:

User and service manual in English

12. Packaging and Labeling:

Packing of all the goods clearly marked and securely packed.

Each goods will be further packed in separate package with all its standard accessories of distinct identification and numbers consecutively.

Additional packing and labeling requirements should bear in each package

Each item with all accessories /spare part configured and packed in one unit.

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Name and Model of the product

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Addis Ababa

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Base Code	Item Detail	Departmen
Afcc-90	1. Generic Name: Analyzer – CD4	Laboratory
	2. GMDN/UMDN Code/Name:	
	3. Clinical Purpose/Description:	
	CD4 [abs] counter, provide absolute and percentage results of CD4 T lymphocytes) concentration in whole blood samples.	-
	4. Technical Specification:	
	Output: Quantitative CD4 Absolute count, CD4 %	
	Sample type: Capillary or venous whole blood	
	Sample volume: 20 - 25 μL	
	Reading time to results: 20 - 22 min for first sample. Then 4 minutes per sample	
	Throughput (per 8 hrs working day/operator):90 - 110 tests	
	System Batching capabilities	
	System Built-in printer and optional external printer ,USB, RS232 connectivity	
	Number of tests results printed with 1 paper roll: 100 - 120	
	Data storage: Approx. 10,000 test results	
	Connectivity	
	System Built-in voltage surge protection	
	Capacity battery life (in hours and test runs): 8 hours	
	System Factory calibrated	
	System Internal quality control (IQC)	
	System Compatible with external quality control scheme(s)	
	5. System Configuration Accessories, Consumables and other components:	
	probes, different types of tubes, with all standard accessories and consumables must be provided.	
	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials including items not specified above	
	6. Operating Environment;	
	Operating Temperature:+10 °C to + 30°C	
	Relative humidity: < 85%	
	7. Utility Requirements:	1
	Electrical Power Supply: 220VAC ±10%	1
	8. Standards and Safety Requirements:	1
	Shall meet IEC-60601(Or Equivalent) General Requirements of Safety for Electromagnetic Compatibility	
	Shall meet ISO 13485 Medical Device Quality Management system (Or]

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Equivalent)

9. Installation, Training and Commissioning:

The supplier must provide installation, and commissioning of the device at health Facility

The supplier must provide onsite technical and end user training

10. Warranty and After Sale service:

The supplier must be provide minimum of Two years warranty including labor and spare part from the date of commissioning.

After basic warranty the supplier must agree for after sales service

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Addis Ababa

General Reminder

Ethiopian Pharmaceutical Supply Agency in collaboration with EFMOH categorized medical device into 87 capital and 358 routine groups based on their complexity. This document has 83 capital medical equipment technical specifications based on Ethiopian Health Tier system.

- From 358 Routine medical devices; 10 medical Equipment are considered as capital medical equipment in this document b/c of their complex technical requirement and TWG consensus.
- Despite predefined 87 capital medical devices, 14 medical devices are not included in this document due to item redundancy, incorporation of features in one machine and non-advanced technical requirement.
- Ethiopian Health Tier system categorize health facilities into Health Post, Health Center, Primary, General, Referral/Specialized Hospital but in this document Health post is not incorporated b/c from 87 capital medical equipment there is no item which belongs to Health post.
- The Item code used in this document is taken from EPSA pharmaceuticals procurement list first edition.

REFERENCES

- ❖ Ethiopian List of Medical Instrument with Minimum Specification. (2013), EFDA
- Registration of Manufacturers and other Parties and Listing of Medical Equipment. (2010), Global Harmonization Task Force.
- ❖ UNFPA Technical requirements for medical devices.
- ❖ USER GUIDE: WHO technical specification for medical devices, (2014) Version 1.1.
- ❖ Federal Public Procurement Directive. (2010), Ministry of Finance & Economic Development.
- ❖ Health Center Medical Equipment Standard List and Specification. (2014), FMOH in collaboration with FMHAC.
- ❖ Primary Hospital Medical Equipment Standard List and Specification. (2014), FMOH in collaboration with FMHAC.
- ❖ General Hospital Medical Equipment Standard List and Specification. (2014), FMOH in collaboration with FMHAC.

Annex 1 Technical Working Group

S.No	Full Name	Organization/Position	Remark
1	Eng. Abel Solomon	EPSA, MDCMO	
2	Eng. Abenezer Asegid	EPSA, MDQMSO	
3	Eng. Abrehaley Beyene	EPSA, MDTMO	
4	Eng. Addisu Fayera	EFMOH, HTMO	
5	Eng. Addisu Taso	EFMOH, HTMO	
6	Eng. Alemu Abibi	EFMOH, HTMO	
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10	Eng. Dawit Getahun	EPSA, MDCMO	
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23	Eng. Walta Tekle	EPSA, MDTMC	
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Annex 2 Workshop Participant

S.No	Full Name	Organization	Remark \
1	Abera Merga	TASH	
2	Akili Alemu	Ghandi Hospital	
3	Amina Bushir		
4	Atilaw Zenebe	Arert Hospital	
5	Befekadu Mekonene	TASH	
6	Birhane Tekie	Pharmaceuticals Product Importers Association	
7	Daniel Demissie	ЕРНІ	
8	Dawud Ahmed	Afar RHB	
9	Demeru Yeshitla	EFDA	
10	Desalegn Fekadu	TASH	
11	Dr. Abel Debela	Yekatit 12 Hospital	
12	Dr. Abel Debla	Yekatit 12 Hospital	
13	Dr. Ephrem Birhanu	St.Paul	
14	Dr. Etenesh Tewolde	St. Paul	
15	Dr. Fikadu	St. Paul	
16	Dr. Fikadu Girma	St.Paul	
17	Dr. G/Medhin Kidane	Minilik Hospital	
18	Dr. Gebreamlak Atirsaw		
19	Dr. Gesit Metaferia	St. Paul	
20	Dr. Habtom Hagos		
21	Dr. Hailemariam Takele		
22	Dr. Hiwot Zelalem	TASH	
23	Dr. Kasech Ayalew	Yekati 12 Hospital	
24	Dr. Kasech Ayalew	Yekatit 12 Hospital	
25	DR. Mamo Beksisa		
26	Dr. Mengistu G/Yohannis	TASH	
27	Dr. Mihada Hashim	Yekatit 12 Hospital	
28	Dr. Mikias Mekonin	Jimma University Hospital	
29	Dr. Mulugeta Na		
30	Dr. Rahel Tufa	Zewditu Memmorial Hopsital	
31	Dr. Tesfamickaele Buzuayehu		
32	Dr. Tesfaye Tadesse	Minilik Hospital	

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35	Dr. Yoseph Zekarias		
36	Ejigu Kebede	St. Paul	
37	Ekrahm Mahfuz		
38	Eng. Abebe Bekele	ЕРНІ	
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40	Eng. Ashenafi H/Wolde	ЕРНІ	
41	Eng. Bantie Tsegaye	EFDA	
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45	Eng. Biruk Mekuria	Harar RHB	
46	Eng. Demoz Kebede	EFDA	
47	Eng. Henock Yohanis	SNNPR RHB	
48	Eng. Imad Aliyi	Dire Dawa RHB	
49	Eng. Kedir Yilma	National Blood Bank	
50	Eng. Kehulubelay Hussen	Tigray RHB	
51	Eng. Keneni Benti	EFDA	
52	Eng. Lemma Kumbi	TASH	
53	Eng. Mahder Sintayehu	St Paul	
54	Eng. Melese Bunkula	Hawassa University Referal Hospital	
55	Eng. Mulugeta Achame	TASH	
56	Eng. Nigist Amdetsion	EFDA	
57	Eng. Nuru Kassa	Yekatit Hospital	
58	Eng. Nuru Kassa	Yekatit 12 Hospital	
59	Eng. Rahel Beyene	ЕРНІ	
60	Eng. Samuel Debebe	SNNRHB	
61	Eng. Selamawit Asfaw	EFDA	
62	Eng. Solomon Mossie	Gambilla RHB	
63	Eng. Yared Eshetu	ALERT	
64	Eng. Yonas Kebede	TASH	
65	Eng. Zelalem Kekab	ЕРНІ	
66	Eng. Zelalem Yigzaw	Benishangul RHB	
67	Ephrem Hassen	St Paul	

S.No	Full Name	Organization	Remark
68	Eyuel Ber	Ethiopian Radition Association	
69	G/Medhin Kidanu	Minilik Hospital	
70	Gemechis Benti	Felege Melese Health Center	
71	Gemechu Solomon	Oromia RHB	
72	Gemechu Solomon	Oromia RHB	
73	Getachew Alem	TASH	
74	Habtamu Mohamed		
75	Ketsena Leulseged	TASH	
76	Lencho Mekonnen	TASH	
77	Lulit Hailu	ЕРНІ	
78	Mesfin Girma	TASH	
79	Michel Teklu	TASH	
80	Misrak W/Yohannes	Ethiopian Anesthetist Association	
81	Mohamed Eid	Somale RHB	
82	Molalign Gebresenbet	TASH	
83	Molalign Gebresenbet	TASH	
84	Molalign W/ Mariam	TASH	
85	Nebat Mohammed	St. Paul	
86	Rahel Tilahun	TASH	
87	Retalign Geletu	Lab. Association	
88	Retalign Getahun	Ethiopizan Medical Laboratory Association	
89	Samuel Wondweson	EPSA	
90	Sirak Gugsa	TASH	
91	Tadele Negash	Ethiopian Radition Authority	
92	Tafesse Bekele	TASH	
93	Takele Berhe		
94	Tewodros Assefa	TASH	
95	Tilahun Alemu	St Paul	
96	Workineh Merga	TASH	
97	Yohannes Jorge	TASH	
98	Yusuf Gerada	TASH	
99	Zelalem Fekedu		
100	Zerihun Geresu	St.Paul	

Annex 3
Referral/Specialized Hospital Capital Medical Equipment Technical Specification

S.No	Base Code	Item Detail
1	Ctsc-90	CT Scan Machine - 64 Slice
2	Mrim-90	MRI 1.5 Tesla
3	Enbr-90	Endoscope - Video Bronchoscope
4	Eneu-90	Endo-Urology Set
5	Enhy-90	Endoscope - Hysteroscope
6	Engi-90	Endoscope - Video Gastro Intestinal
7	Envl-90	Endoscope - Video Laryngoscope
8	Enco-90	Endoscope - Colposcope
9	Denu-90	Dental Unit
10	Xrd-90	X-Ray- Dental
11	Uran-90	Analyzer -Urine
12	Ccan-91	Analyzer - Clinical Chemistry, Fully Automated
13	Mibl-90	Microscope Binocular, LED
14	Hema-91	Analyzer - Hematology 5 diff
15	Anbg -90	Analyzer - Blood Gas
16	Anac-90	Analyzer - Couagulation
17	Mcil-90	Microscope Inverted
18	Inst-90	Inspissator - TB Culture
19	Mira - 90	Microtome - Autoamatic
20	Mirm -90	Microtome - Manual
21	Mivc-90	Microscope - with Video Camera
22	Aeli-90	Analyzer - ELISA
23	Afcc-90	Analyzer - CD4
24	Pcrm-90	PCR Machine - Thermocycler
25	Staa - 90	Slider Stainer - Histology /Cystology
26	Cenb - 90	Centrifuge - Blood Bank, Refrigerated
27	Mitm-90	Microscope - Fluoresence
28	Refb 90	Refrigerator - Blood bank
29	FreP-90	Freezer - Plazma
30	Frev-90	Freezer - Vaccine
31	Seal-90	Tube Sealer
32	Perk-90	Perimetry/ Automated Visual Field Analyzer
33	Ulto-90	Ultrasound - Ophthalmic
34	Yagl-90	YAG Laser

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S.No	Base Code	Item Detail
35	Refa -90	Refractometer - Automated
36	Octm - 90	Optical Coherence Tomography
37	Arga-90	Argon Laser
38	Func-90	Fundus Camera
39	Cryo-90	Cryo Unit Opthalmic
40	Pham-90	Phaco + Vitrectomy Machine
41	Meto-90	Microscope - Operating, Ophthalmic
42	Slla-90	Slit Lamp
43	Refg-90	Refrigerator - General Purpose, 300L/500L/700L
44	Eegm-90	EEG Machine
45	Wari-90	Warmer - Radiant, Infant
46	Incn-90	Incubator - New born
47	Venm-90	Ventilator - ICU, Mechanical
48	Femo-90	Monitor - Fetal
49	Pamo-90	Monitor - Patient
50	Mopc-90	Monitor - Patient, Central
51	Xfcd-90	C-arm Fluoroscopy
52	Xrad -90	Radiography - X ray, Digital
53	Xrrd 90	Radiography - X ray with Fluoroscopy, Digital
54	Xrmd-91	Radiography - X ray, Digital, mobile
55	Xrmd-90	Radiography - X ray, Mammography, Digital
56	Ultg-90	Ultrasound - Ob/Gyn
57	Ugcd-90	Ultrasound - General Purpose, Color Doppler, Portable
58	Ugcd-90	Ultrasound - General Purpose, Color Doppler, Mobile
59	Sttm-90	Stress Test Machine
60	Trea-90	Treadmill
	Ultec-90	Electrotherapy Modality (TENS, Ultrasound therapy & Combination
61		therapy)
62	Diam-90	Dialysis Machine
63	Laum-90	Laundry Machine
64	Rala - 90	Radiotherapy - Linear Accelerator
65	Stel-90	Sterilizer - Chemical, H ₂ O ₂ , Low Temperature
66	Steh-90	Instrument - Sterilizer Hot Air 60L
67	Stds-90	Instrument - Washer/Disinfector
68	Stes- 90	Sterilizer - Steam, 300/500L
69	Toeh-90	Table – Operating, Electro hydraulic
70	Mioe-90	Operating Microscope

S.No	Base Code	Item Detail
71	Mins-90	Microscope - Neuro surgical
72	Lith-90	Lithotripter
73	Lioc-90	Light-Operating, Ceiling
74	Liom-90	Light-Operating, Mobile
75	Cryu-90	Cryo Therapy Unit - Gynecology
76	Anem-90	Anesthesia Machine
77	Elsu-90	Electrosurgical unit
78	Sucm-90	Suction Machine
79	Pulo-90	Pulse Oximetry
80	Oxyc-90	Oxygen Concentrator
81	Defi-90	Defibrillator
82	Carg-90	ECG Machine

Annex 4
General Hospital Capital Medical Equipment Technical Specification

S.No	Base Code	Item Detail
1	Ctsc-90	CT Scan Machine - 64 Slice
2	Mrim-90	MRI 1.5 Tesla
3	Enbr-90	Endoscope - Video Bronchoscope
4	Eneu-90	Endo-Urology Set
5	Enhy-90	Endoscope - Hysteroscope
6	Engi-90	Endoscope - Video Gastro Intestinal
7	Envl-90	Endoscope - Video Laryngoscope
8	Enco-90	Endoscope - Colposcope
9	Denu-90	Dental Unit
10	Xrd-90	X-Ray- Dental
11	Uran-90	Analyzer - Urine
12	Ccan-91	Analyzer - Clinical Chemistry
13	Mibl-90	Microscope Binocular
14	Hema-91	Analyzer - Hematology, 5 diff
15	Anbg -90	Analyzer - Blood gas
16	Anac-90	Analyzer - Coagulation
17	Mcil-90	Microscope Inverted
18	Inst-90	Inspissator - TB Culture
19	Mira - 90	Microtome - Autoamatic
20	Mirm -90	Microtome - Manual
21	Mivc-90	Microscope - Video Camera
22	Aeli-90	Analyzer - ELISA
23	Afcc-90	Analyzer - CD4
24	Pcrm-90	PCR Machine - Thermocycler
25	Staa - 90	Slider Stainer- Histology /cystology
26	Cenb - 90	Centrifuge Blood Bank Refrigerated
27	Mitm-90	Microscope - Fluoresence
28	Refb 90	Refrigerator - Blood Bank
29	FreP-90	Plazma - Freezer
30	Seal-90	Tube Sealer
31	Perk-90	Perimetry
32	Ulto-90	Ultrasound - Ophthalmic
33	Yagl-90	YAG Laser
34	Refa -90	Refractometer - Automated

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S.No	Base Code	Item Detail
35	Octm - 90	Optical Coherence Tomography
36	Arga-90	Argon Laser
37	Func-90	Fundus Camera
38	Cryo-90	Cryo Unit Opthalmic
39	Pham-90	Phaco Machine
40	Meto-90	Operating Microscope
41	Slla-90	Slit Lamp
42	Eegm-90	EEG Machine
43	Wari-90	Warmer - Radiant, Infant
44	Incn-90	Incubator - New born
45	Venm-90	Ventilator - ICU, Mechanical
46	Femo-90	Monitor - Fetal
47	Pamo-90	Monitor - Patient
48	Морс-90	Monitor - Patient, Central
49	Xfcd-90	C-Arm Fluoroscopy
50	Xrad -90	Radiography - X Ray, Digital
51	Xrrd 90	Radiography - X Ray with Fluoroscopy, Digital
52	Xrmd-91	Radiography - X ray, Digital, mobile
53	Xrmd-90	Radiography - X ray, Mammography, Digital
54	Ultg-90	Ultrasound - Ob/Gyn
55	Ugcd-90	Ultrasound - General Purpose, Color Doppler, Portable
56	Ugcd-90	Ultrasound - General Purpose, Color Doppler, Mobile
57	Trea-90	Treadmill
58	Ultec-90	Electrotherapy Modality (TENS, Ultrasound therapy & Combination therapy)
59	Diam-90	Dialysis Machine
60	Laum-90	Laundry Machine
61	Stel-90	Sterilizer - Chemical, H ₂ O ₂ , Low Temperature
62	Steh-90	Instrument - Sterilizer Hot Air 60L
63	Stds-90	Instrument - Washer/Disinfector
64	Stes- 90	Sterilizer - Steam, 300/500L
65	Toeh-90	Table – Operating, Electro hydraulic
66	Mioe-90	Operating microscope
67	Lioc-90	Light-Operating, Ceiling
68	Liom-90	Light-Operating, Mobile
69	Cryu-90	Cryo Therapy Unit - Gynecology
70	Anem-90	Anesthesia Machine

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S.No	Base Code	Item Detail
71	Elsu-90	Electrosurgical unit
72	Sucm-90	Suction Machine
73	Pulo-90	Pulse Oximetry
74	Oxyc-90	Oxygen concentrator

Annex 5 Primary Hospital Capital Medical Equipment Technical Specification

S.No	Base Code	Item Detail
1	Denu-90	Dental Unit
2	Xrayd-90	X-Ray- Dental
3	Ccan-91	Analyzer - Clinical Chemistry
4	Mibl-90	Microscope Binocular
5	Hema-90	Analyzer - Hematology 3 diff
6	Afcc-90	Analyzer - CD4
7	Wari-90	Warmer - Radiant, Infant
8	Incn-90	Incubator - New born
9	Pamo-90	Monitor - Patient
10	Xrad -90	Radiography - X Ray, Digital
11	Xrmd-91	Radiography – XRay, Digital, mobile
12	Ultg-90	Ultrasound – Ob/Gyn
13	Ugcd-90	Ultrasound – General Purpose, Color Doppler, Portable
14	Ultec-90	Electrotherapy Modality (TENS, Ultrasound therapy & Combination therapy)
15	Laum-90	Laundry Machine
16	Stds-90	Instrument - Washer/Disinfector
17	Steh-90	Instrument - Sterilizer Hot Air 25L
18	Stes- 90	Sterilizer - Steam, 45/100L
19	Anem-90	Anesthesia Machine
20	Toeh-90	Table – Operating, Electro hydraulic
21	Liom-90	Light-Operating, Mobile
22	Cryu-90	Cryotherapy unit – Gynecology
23	Elsu-90	Electrosurgical unit
24	Sucm-90	Suction Machine
25	Pulo-90	Pulse Oximetry
26	Oxyc-90	Oxygen concentrator

Annex 6 Health Center Capital Medical Equipment Technical Specification

S.No	Base Code	Item Detail
1	Ccan-91	Analyzer - Clinical Chemistry
2	Mibl-90	Microscope Binocular
3	Hema-90	Analyzer - Hematology 3 Diff
4	Afcc-90	Analyzer - CD4
5	Wari-90	Warmer - Radiant, Infant
6	Incn-90	Incubator - New born
7	Xrmd-91	Radiography – X ray, Digital, Mobile
8	Ultg-90	Ultrasound – Ob/Gyn
9	Stds-90	Instrument - Washer/Disinfector
10	Steh-90	Instrument - Sterilizer Hot Air 25L
11	Stes- 90	Sterilizer - Steam, 45/100L
12	Cryu-90	Cryotherapy unit – Gynecology
13	Elsu-90	Electrosurgical unit
14	Sucm-90	Suction Machine
15	Sucm-90	Suction Machine
16	Pulo-90	Pulse Oximetry
17	Oxyc-90	Oxygen concentrator