



ವೈದ್ಯಕೀಯ ಶಿಕ್ಷಣ ನಿರ್ದೇಶನಾಲಯ

DIRECTORATE OF MEDICAL EDUCATION
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No. ME/TENDER/41/2021-22.

Dt. 06.01.2022

“ನೋಟಿಸ್”

ಕೋವಿಡ್-19 ಸಂಬಂಧ ಕಲ್ಯಾಣ ಕರ್ನಾಟಕ ಅಭಿವೃದ್ಧಿ ಪ್ರದೇಶಾಭಿವೃದ್ಧಿ ಮಂಡಳಿಯ ಅನುದಾನದ ಅಡಿಯಲ್ಲಿ ಕಲ್ಯಾಣ ಕರ್ನಾಟಕ ಜಿಲ್ಲೆಗಳಿಗೆ ಅಗತ್ಯವಿರುವ ವೈದ್ಯಕೀಯ ಉಪಕರಣಗಳನ್ನು ಕೆಟಿಪಿಪಿ ಕಾಯ್ದೆಯ 4(ಎ) ಅಡಿಯಲ್ಲಿ ಖರೀದಿಸಲು ತೀರ್ಮಾನಿಸಲಾಗಿದೆ.

ವೈದ್ಯಕೀಯ ಉಪಕರಣಗಳ ವಿವರಗಳನ್ನು ಈ ನೋಟಿಸ್‌ನೊಂದಿಗೆ ಲಗತ್ತಿಸಿದ್ದು, ಸದರಿ ಉಪಕರಣಗಳಿಗೆ ಕೆಳಕಂಡ ಷರತ್ತು ಮತ್ತು ನಿಬಂಧನೆಗಳನ್ನು ಪೂರೈಸಿ ಅರ್ಹರಾದಲ್ಲಿ ಆದೇಶ ಪಡೆದ ನಂತರ ಕೂಡಲೇ ಸರಬರಾಜು ಮಾಡಲು ಸಾಧ್ಯವಾಗುವಂತಹ ಸರಬರಾಜುದಾರರು ದಿನಾಂಕ:- 07/01/2022 ರ 5.00 ಅಪಾರಾಹ್ನ ಒಳಗಾಗಿ ಅಗತ್ಯ ದಾಖಲೆಗಳೊಂದಿಗೆ ಈ ಕೆಳಕಂಡಂತೆ ಸಲ್ಲಿಸಲು ತಿಳಿಸಿದೆ.

Supplier shall fulfill the below mentioned Terms & Conditions and also should submit the required documents/proof without fail:

Sl No	Description	Remarks
1	Hard Copy Technical Documents	1. Shall be submitted on or before 07.01.2022 5.00 PM 2. Hard Copy Technical Documents shall be submitted to Personal Section, Directorate of Medical Education, Anandrao Circle Bangalore
2	Financial Bid	1. Shall be submitted through email to dmekarnataka@yahoo.com on or before 07.01.2022 5.00 PM only
3	Technical Documents to be submitted compulsorily, failing which bid will not considered.	1. Manufacturer License in case of manufacturer 2. Manufacturer Authorization in case of authorized distributor 3. Stock Availability Declaration 4. Service Center in Karnataka 5. Technical brochure 6. Technical Compliance Sheet 7. Warranty for 3 years undertaking letter from the manufacturer for the unit price quoted 8. List of items quoted. 9. Supply details of similar equipment in last three years 10. Atleast 5 purchase order copies received in last three years from other Govt or reputed pvt hospitals for the same equipment. 11. Warranty of all equipment shall be three years and CMC for 7 years shall be quoted seperately.


ನಿರ್ದೇಶಕರು, ವೈದ್ಯಕೀಯ ಶಿಕ್ಷಣ
Directorate of Medical Education
Anand Rao Circle, Bangalore

List of required Equipments to be purchased under KKRDB

S NO.	Name of Medical Equipments
1	LMO 6 KL
2	LMO 20 KL
3	X-Ray Machine (300MA)
4	X-Ray Machine (500MA)
5	Mobile X-ray machine 100 Ma
6	Oxygen Cylinders D Type
7	Revolving stools
8	Semi Auto Analyzer.
9	Dialysis Units.
10	ICU Cot Pediatrics.
11	Intubating Flexible Laryngoscope
12	16 slice CT scan machine
13	Video Larngoscope
14	Infrared Vien Viwer (Flex) for Neonatal & Pediatrics Patients
15	1000 LPH RO Plant for Dialysis Machine
16	Baby Incubator


ನಿರ್ದೇಶಕರು, ವೈದ್ಯಕೀಯ ಶಿಕ್ಷಣ,
Directorate of Medical Education
Anand Rao Circle, Bangalore

1. LMO-6 KL

- Supply of liquid medical oxygen in 06 kl 17 bar MAWP cryogenic storage tank. Medical oxygen conforming to IP-2018 (99.5% purity) .
- Space taken for installation should be as per regulations of Indian explosive controller and having easy access for LMO tank. • Should have compact unit including vessel, vaporizer, & incorporated with level gauge (analog) for low content and pressure.
- Should not cause any damage to gas pipeline, anaesthesia machine and ventilators. Should have level indicator and preferably low liquid level gauge (analog) with safety system in case of emergency / un-natural calamities.
- Storage tank Capacity o Vacuum insulated evaporator vessel should have a capacity of 06kl (KiloLitres). o The AV coil should have adequate capacity to handle the gas flow requirements of the hospital. o The storage tank and the vaporizer coil should be designed as per the standards, o The cryogenic vessel will be of Double walled, vertical & cylindrical shape with vaporizer and the pressure control system. o It should be provided with the essential components to fill the liquid, to build up pressure, to relieve pressure, to withdraw product and to evacuate the vessel. o All protective, safety and level gauge (analog) provisions mandatory to Liquid Medical Oxygen System o The fence, foundation, lighting, signage, approach gate, approach road etc are to be designed and installed by the vendor
- Barricade o Barricade to be fabricated; this barricade will be painted with alternate yellow and black strips of colour. All welding to be done as per standards.
- Earthing Pit o The earthing Pit is to be constructed. o The GI pipe used for earthing is to be drilled type, of size 40mm in diameter and 3meter in length. o Charcoal to be filled for 150mm and salt to be filled for 150mm. o The 550sq. chequered plate to be provided to cover the earthing plate. o GI flat of size 50mm width and 6mm thick of length 20meter to be connected from earthing pit to equipment.
- Emergency Gate o The emergency gate to be fabricated. o Suitable sizes of MS flats and MS rods to be selected. o Galvanised diamond mesh 11 of gauge 50x50 to be used. o Provide mechanical stopper to the gates such that gate cannot be opened inward
- Hard stand o Hard stand to be constructed. o The hard stand size to be 8m X 4m. o The hard stand comprised of 150mm soling, 150mm PCC 1:4:8, 150mm thick concrete.
- Fencing o Fencing to be fabricated. o Fencing comprises of 2" diameter pipe of length 2meters. o The bottom 500mm pipe portion to be placed in pcc. o These have to be paced 2000mm typical position. o The mesh to be used is to be of 50x50 GI, 9mm gauge. o All pole pipe to be painted with black paint. Mesh to be painted with white paint. o Space taken for installation should be as per regulation of Indian explosive controller and having easy access for LMO tank
- Main Gate o Gate to be fabricated. o Gate will be of 2meters height and 6meters in width. o Provide mechanical stoppers to the gate such that gate cannot be opened inward.

- PC CaroundTank o This has to be to constructed asper the Requirement 2. PowerSupply
- Industry Standard Power Supply tobe provided by the Tenderer
- All Civil and Electrical works onsite is the responsibility of theTenderer and not the Purchaser.

3. Accessories

- Fire extinguisher o Twono'sfireextinguishersofDCPtype,of capacity 10kg each are required
- Fire and water buckets with stand o Two nos. of fire buckets and two nos. of water buckets fixed on metallic stand which.These buckets to be painted in red and stand to be painted in black. • Water tap o Water tap along with 10meters plastictube is required. o Pipe line work to be done as per the requirement from oxygen plant to existing Pipeline.
- Safety o The vendor should ensure that all international safety norms and standards applicable as implemented and certified by the CCE. Two safety valves for innervessel fitted on pipeline with flow divert valve. - Rupture disc for inner vessel. -Safety valve for inlet pipeline.- Safety valve forpipeline ofpressurizing evaporator.- One rupture disc/ safety device onouter vessel. 129 4. Certification

- USFDA and/orCE Approved and Certified • ISO and BISCertified
- All statutory requirements of the Chief Controller of Explosives of India and SMP Vrules and need to be followed; besides all regulations and guidelines put forward

bytheGovt.OfIndiafromtimetotimeshouldbefollowed.AndLicensesfromPESO. 5. Warranty

- Maintenance: All routine preventive maintenance and break-down maintenance of the liquid oxygen system should be done by the vendor. Experienced personnel should be readily available
- Warranty three(3)years and CMC for Five(5)years 6. General
- Erection &commissioning of complete storage system should be done.
- Transportationofcompletestoragesystemfromsuppliersworksoursiteandbackafterc on tract expiry shall be in bidder's scope and no extra charges will be paid.
- Satisfactory Training to be provided at site.

2. LMO 20 KL Specifications

- Supply of liquid medical oxygen in 20 kl 17 bar MAW Pcryogenic storage tank.MedicaloxygenconformingtoIP-2018(99.5%purity).
- Space taken for installation should be asper regulations of Indian explosive controller and having easy access for LMO tank. • Should have compact unit including vessel, vaporizer, & incorporated with level gauge (analog) for low content and pressure.
- Should not cause any damage to gas pipeline, anaesthesia machine and ventilators. Should have level indicator and preferably lowliquid levelgauge(analog) with safety system in case of emergency/ un-natural calamities.

- Storage tank Capacity o Vacuum insulated evaporator vessel should have a capacity of 06kl (KiloLitres). o The AV coil should have adequate capacity to handle the gas flow requirements of the hospital. o The storage tank and the vaporizer coil should be designed as per the standards, o The cryogenic vessel will be of Double walled, vertical & cylindrical shape with vaporizer and the pressure control system. o It should be provided with the essential components to fill the liquid, to build up pressure, to relieve pressure, to withdraw product and to evacuate the vessel. o All protective, safety and level gauge (analog) provisions mandatory to Liquid Medical Oxygen System o The fence, foundation, lighting, signage, approach gate, approach road etc are to be designed and installed by the vendor
- Barricade o Barricade to be fabricated; this barricade will be painted with alternate yellow and black strips of colour. All welding to be done as per IS standards.
- Earthing Pit o The earthing pit is to be constructed. o The GI pipe used for earthing is to be drilled type, of size 40mm in diameter and 3 meter in length. o Charcoal to be filled for 150mm and salt to be filled for 150mm. o The 550sq. chequered plate to be provided to cover the earthing plate. o GI flat of size 50mm width and 6mm thick of length 20 meter to be connected from earthing pit to equipment.
- Emergency Gate o The emergency gate to be fabricated. o Suitable sizes of MS flats and MS rods to be selected. o Galvanised diamond mesh of gauge 50x50 to be used. o Provide mechanical stopper to the gates such that gate cannot be opened inward
- Hardstand o Hardstand to be constructed. o The hardstand size to be 8m X 4m. o The hardstand comprised of 150mm soling, 150mm PCC 1:4:8, 150mm thick concrete.
- Fencing o Fencing to be fabricated. o Fencing comprises of 2" diameter pipe of length 2 meters. o The bottom 500mm pipe portion to be placed in pcc. o These have to be paced 2000mm typical position. o The mesh to be used is to be of 50X50 GI, 9mm gauge. o All pole pipe to be painted with black paint. Mesh to be painted with white paint. o Space taken for installations should be as per regulation of Indian explosive controller and having easy access for LMO tank
- Main Gate o Gate to be fabricated. o Gate will be of 2 meters height and 6 meters in width. o Provide mechanical stopper to the gates such that gate cannot be opened inward.
- PCC around Tank o This has to be constructed as per the Requirement 2. Power Supply
- Industry Standard Power Supply to be provided by the Tenderer
- All Civil and Electrical works on site is the responsibility of the Tenderer and not the Purchaser. 3. Accessories
- Fire extinguisher o Two no's fire extinguishers of DC type, of capacity 10kg each are required

- Fire and water buckets withstand o Two nos. of fire buckets and two nos. of water buckets fixed on metallic stand which. These buckets to be painted in red and stand to be painted in black. • Water tap o Water tap along with 10 meters plastic tube is required. o Pipe line work to be done as per the requirement from oxygen plant to existing pipeline.

- Safety o The vendor should ensure that all international safety norms and standards applicable as implemented and certified by the CCE. Two safety valves for inner vessel fitted on pipeline with flow divert valve. - Rupture disc for inner vessel. - Safety valve for inlet pipeline. - Safety valve for pipe line of pressurizing evaporator. - On rupture disc/ safety device on outer vessel. 129 4. Certification

- USFDA and/or CE Approved and Certified • ISO and BIS Certified

- All statutory requirements of the Chief Controller of Explosives of India and SMPV rules and need to be followed; besides all regulations and guidelines put forward by the Govt. Of India from time to time should be followed. And Licenses from PESO. 5. Warranty

- Maintenance: All routine preventive maintenance and break-down maintenance of the liquid oxygen system should be done by the vendor. Experienced personnel should be readily available

- Warranty three (3) years and CMC for Five (5) years 6. General

- Erection & commissioning of complete storage system should be done.

- Transportation of complete storage system from suppliers works our site and back after contract expiry shall be in bidder's scope and no extra charges will be paid.

- Satisfactory Training to be provided at site.

03. X-Ray Machine (300MA)

Name	300 mA Hf X-ray machine
general	
1. use	
1.1 Clinical purpose	Radiography of the bones and fractures and other arthropathies. X-Ray Chest for the supportive diagnosis of the Pulmonary Tuberculosis X-Ray Pelvis (KUB) for renal disorders and stones. Sinusitis, Fractures of the Skull Cardiac diseases and cardiac enlargement Silicosis and other respiratory conditions, like Pleural effusion, hydrothorax, Pneumothorax Peritonitis by X-Ray abdomen.
1.2 used by clinical department/ward	
technical	

2. technical CHARACTERISTICS

- 2.1 **technical characteristics (specific to this type of device)** High Frequency X-Ray machine suitable for general Radiography.
- X-ray generator**
- High Frequency X-Ray generator having Frequency of 40 KHz more suitable for Radiography should be provided.
 - Power output of generator should be 25 KW or more.
 - Radiography KV range should be 40 to 110 KV or more.
 - mA range (Rad.): 300mA or more • Exposure time (Rad.): 1 ms to 2 sec. with maximum numbers of steps.
- Control:**
- A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with Spill Proof design. Following features should be available on the control panel.
 - Machine ON/OFF switch • Digital Display of KV & mAs. • KV & mAs increase and decrease switches.
 - Tube focal spot selection switch. • Ready and x-ray on switch with indicators.
 - Bucky Selection switch.
 - Self diagnostic Programme with Indicators for Earth fault error, KV error, filament error & Tube's Thermal Overload.
- X-ray tube**
- One No Dual focus Rotating Anode BEL/Toshiba/Imported X-ray tube thermally protected having focal spot:
 - 1mm or less small Focus, 2mm or less large Focus.
- Anode heat storage capacity of tube should be more than 140 KHU.
 - One no manual collimator with aluminum filter & for adjustment of exposure area.
- Column Stand:**
- It should have floor to ceiling stand with vertical counter balanced travel.
 - It should have 360 deg. Rotation.
 - It should be provided one vertical bucky stand with machine.
 - Table.
 - Five position manual tilt table having buky grid ration of 8:1 with 85 lines per inches should be provided.
 - The bucky tray should accept cassette of 8"x10", 10"x12" and 14"x17" size.

2.2 **user's interface** Manual

2.3 **Software and/or standard of communication (where ever required)**

3. pHySiCAI CHArACTeriStiCS

3.1 **dimensions (metric)** NA

3.2 **Weight (lbs, kg)** NA

3.3 **Configuration** NA

3.4 **noise (in dBA)** Noise-free system

3.5 **Heat dissipation** Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism

3.6 **mobility, portability** Certified Room Installation

4. energy SourCe (electricity, upS, solar, gas, water, Co2)

4.1 **power requirements** Power unit: Input voltage- 400V-440V AC, 50Hz ;3 -phase

4.2 **Battery operated** No

4.3 **tolerance (to variations, shutdowns)** NA

4.4 **protection** Stabliser of appropriate capacity to be installed.

4.5 **power consumption** 25 to 30 KW.

5. ACCeSSorieS, SpAre pArtS, ConSumABLES

- 5.1 **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** Machine should be supplied with following transducers:
 2 No. BARC Approved whole body lead aprons with all attachments.
 One Pair of 8 meter H. V. Cable.

Bidding/procurement terms/conditions/requirements

6. Environmental And departmental Considerations

- 6.1 **Atmosphere/Ambiance (air conditioning, humidity, dust ...)**
- 1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances.
 - 2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
- 6.2 **user's care, Cleaning, disinfection & Sterility issues**
- 1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
 - 2) Sterilization not required.

7. Standards And Safety

- 7.1 **Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**
1. Should be FDA/European CE/BIS approved product.
 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.
 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-1 (General requirements or equivalent BIS Standard)

4. Shall meet internationally recognised for Electromagnetic Compatibility (EMI/EMC) for electromedical equipment: 61326-1.
 5. Certified to be compliant with IEC 61010-1, IEC 61010-2-40 for safety.
 6. AERB type approved
- 7.2 **local and/or international** Manufacturer/supplier should have ISO 13485 certificate for quality standard.

8. trAining And inStAllAtion

- 8.1 **pre-installation requirements: nature, values, quality, tolerance**
- 1) Availability of three phase uniform power supply.
 - 2) Safety and operation check before handover.
 - 3) To be installed in a separate room.
 - 4) Facility for dark room should be available.
- 8.2 **requirements for sign-off** Certificate of calibration and inspection of parts from the manufacturer.
- 8.3 **training of staff (medical, paramedical, technicians)**
- 1) Training of users on operation and basic maintenance;
 - 2) Advanced maintenance tasks required shall be documented;

9. WArrAnty And mAintenAnCe

- 9.1 **Warranty** 3 years
- 9.2 **maintenance tasks** CMC 5 years 2 PM Visits Annually.
All Breakdown calls to be attended within 24 hrs of registration.
- 9.3 **Service contract clauses, including prices** The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. doCumentAtion

- 10.1 **operating manuals, service manuals, other manuals**
- 1) Should provide 2 sets (hardcopy and soft-copy) of: User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams;
 - 2) List of equipment and procedures required for local calibration and routine maintenance;
 - 3) Service and operation manuals (original and copy) to be provided;
 - 4) Advanced maintenance tasks documentation;
 - 5) Certificate of calibration and inspection.
 - 6) Satisfactory certificate for any existing installation from government hospital.
- 10.2 **other accompanying documents** List of essential spares and accessories, with their part numbers and cost;

11. noteS

- 11.1 **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** Contact details of manufacturer, supplier and local service agent to be provided;
Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;
- 11.2 **recommendations or warnings** Any warning signs would be adequately displayed.

4. X-Ray Machine (500MA)

Name And Coding	
Name	500 mA X-Ray Machine(HF)
General	
1. uSe	
1.1 Clinical purpose	<p>Radiography of the bones and fractures and other arthropathies. X- Ray Chest for the supportive diagnosis of the Pulmonary Tuberculosis. X - Ray Pelvis (KUB) for renal disorders and stones. Sinusitis, Fractures of the Skull. Cardiac diseases and cardiac enlargement. Silicosis and other respiratory conditions, like Pleuall effusion,, hydrothorax, Pneumothorax. Peritonitis by X-Ray abdomen.</p>
1.2 used by clinical department/ward	Radiology Department

teCHniCAI	
2. teCHniCAI CHArACTeriStiCS	
2.1 technical characteristics (specific to this type of device)	<p>High frequency X-Ray machine suitable for general radiography.</p> <p>X-rAy generAtor:</p> <ul style="list-style-type: none"> - High Frequency X-Ray Generator having frequency of 50KHz or more should be provided. - Power output of generator should be 50KW. - Radiographic KV Range should be 40 to 125KV. - mA Range (Rad.): 500mA or more. - Exposure time (Rad.): 1ms to 3Sec. - mAs Range (Rad.): 1 to 200mAs. <p>Control:</p> <p>A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in Floor or Wall mount with Spill Proof design.</p> <p>Following features should be available on the control panel.</p> <ul style="list-style-type: none"> • Machine ON/OFF Switch. • Digital Display of KV & mAs. • KV & mAs increase and decrease switches. • Tube focal spot selection Switch.

- Ready and X-Ray on switch with Indicators
- Bucky Selection Switch.
- Self diagnostic Programme with Indicators for Earth fault error, KV error, filament error & Tube's Thermal Overload.
- Anatomical Programming Radiography (i.e. APR) should have Preprogrammed parameters of human Anatomy Up to 216 programs which helps the user to select exposure parameters based on body part, examination view and size of the patient.

2.1 **technical characteristics (specific to this type of device)**

A dual action hand switch with retractable cord should be provided for Radiation Protection of Operator. There should be provision for a cordless Exposure switch also.

There should be provision of auto shut off of Control if no key is pressed for 10 Min.

X-ray tube:

- Two Nos. Dual focus Rotating Anode X-Ray tube thermally protected
- Anode heat storage capacity of tube should be more than 140KHU.
- Two Pair of 8 meter H.V. Cable.
- Two Nos. Collimator with auto shut off facility should be provided.

HV tank:

A very compact H.V. Tank filled with high dielectric transformer oil should be provided. The H.V. Tank should contain H.V. transformer, Filament Transformers, H.V. Rectifiers & H.V. Cable receptacles.

Tube Stand:

- Floor to Ceiling Stand with Counter Balanced Tube Head (Rotatable ± 180 Degree), 360 Degree Rotatable; mounted on Floor Ceiling Rails for convenient movements should be provided.

2.1 **technical characteristics (specific to this type of device)**

TABLE:

- Motorized table should have motorized bucky consisting of bucky grid of size 17 1/4" x 18 7/8" ratio 8:1, 85 lines/inch. Spot Film Device (semi automatic) capable of doing all routine spot filming (4 on 1, 2 on 1, 1 on 1) for use with 8" x 10", 10" x 12", 14" x 14" cassettes. Grid size 15" x 15", 6:1 ratio, 103 lines per inch. Compression movement of spot film device is motorized. The fluoroscopic parameters (fluoro KV, fluoro mA and fluoro time) should be digitally displayed on the SFD. Control of fluoro KV should be available on SFD.

VERTICAL BUCKY STAND:

- Vertical Bucky Stand with oscillating Grid of Ratio 8:1, 85 lines/inch is provided.
- The Bucky moves up & down & is equipped with a stainless steel cassette tray.
- The stand is floor-mounted type & can accommodate cassettes up to 14" X 17". The Bucky is tilted in 6 steps of 15 degree Angle each for various Radiographs.

2.2 **user's interface**

manual

2.3 **Software and/or standard of communication (where ever required)**

In built

3. pHySiCAI CHArACteriStiCS

3.1 **dimensions (metric)**

NA

3.2 **Weight (lbs, kg)**

NA

3.3	Configuration	NA
3.4	noise (in dBA)	Noise-free system
3.5	Heat dissipation	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism
3.6	mobility, portability	Stationary Installation

4. energy Source (electricity, upS, solar, gas, water, Co2)

4.1	power requirements	Power supply: 230V, AC, 50Hz. 15 Amps ,three phase, Line resistance < 0.4 ohms
4.2	Battery operated	no
4.3	tolerance (to variations, shutdowns)	line regulation of ±10%.
4.4	protection	NA
4.5	power consumption	??????

5. ACCeSSorieS, SpAre pArtS, ConSumABleS

5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Machine should be supplied with following transducers:- I. 2 No. BARC Approved whole body lead apporns with all attachements.
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Bidding / proCurement termS / donAtion reQUIREmentS

6. enVironmentAl And depArtmentAl ConSiderAtionS

6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
6.2	user's care, Cleaning, disinfection & Sterility issues	1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2) Sterilization not required.

7. StAndArD S And SAFety

7.1	Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international	1. Should be FDA/ European CE/BIS approved product. 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard) 5. Shall meet internationally recognised standard for Electromagnetic Compatibility (EMI/EMC) for electromedical equipment: 61326-1. 6. Certified to be compliant with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304 7. AERB type approved
7.2	local and/or international	Manufacturer / supplier should have ISO 13485 certificate for quality standard.

8. trAining And inStAlliAtion

8.1	pre-installation requirements: nature, values, quality, tolerance	Three phase stable power supply
8.2	requirements for sign-off	Certificate of calibration and inspection of parts from the manufacturer

- 8.3 **training of staff (medical, paramedical, technicians)**
- 1) Training of users on operation and basic maintenance;
 - 2) Advanced maintenance tasks required shall be documented

9. WarrantY And mAintenAnCe

- 9.1 **Warranty** 3 years
- 9.2 **maintenance tasks** CMC 5 years
2 PM Visits Annually.
All Breakdown calls to be attended within 24 hrs of registration.
- 9.3 **Service contract clauses, including prices** The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;

10. doCumentAtion

- 10.1 **operating manuals, service manuals, other manuals** Should provide 2 sets (hardcopy and soft-copy) of:-
- 1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams;
 - 2) List of equipment and procedures required for local calibration and routine maintenance;
 - 3) Service and operation manuals (original and copy) to be provided;
 - 4) Advanced maintenance tasks documentation;
 - 5) Certificate of calibration and inspection
- 10.2 **other accompanying documents** List of essential spares and accessories, with their part numbers and cost;

11. noteS

- 11.1 **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** Contact details of manufacturer, supplier and local service agent to be provided;
Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;
- 11.2 **recommendations or warnings** Any warning signs would be adequately displayed

05. Portable X ray 100 ma

Specifications for 100 mA High Frequency Portable / Mobile X Ray Unit

High frequency, microprocessor controlled, High Frequency Mobile X Ray unit having following features:

Compact, lightweight, easily transportable mobile X Ray unit suitable for bedside x-rays, trauma, Intensive care units, Operation theatre and Radiology department.

The unit should be fully counterbalanced and can be positioned to suit different bed heights. The unit should have facility of vertical swing and horizontal rotation of the tube head to ensure X Ray of any anatomy even within limited space.

The unit must have an effective braking system for parking and transport.

The tube stand must be fully counterbalanced with rotation in all directions.

The unit must have intelligent graphical LCD display with at least 60 user-configurable anatomy presets for ease of operation to the operator.

The exposure release switch should be detachable with a cord of sufficient length (at least 3 m)

The unit should have integrated cassette box of size 542 mm (W) x 420 mm(H)

The Generator:

- a. Microprocessor controlled high frequency / inverter type of high frequency 200 KHz or more for constant output. Generator with higher switching Frequency of will be preferred.
- b. It should have power rating of 4 kW or more
- c. It should have a digital display of mAs and kV.
- d. KV range : 40 kv to 100kV or more
- e. mA range: 10 mA to 100 mA or more
mAS selection: 0.1 to 250 mAS or more

X-Ray Tube and Collimator:

- a. Stationary / Rotating anode having focal spot size 1.8 mm or less.
 - b. The X-Ray tube should be Toshiba or BEL or CEI make
 - c. Light Beam diaphragm / Double layer Collimator with auto cut off switch. The light intensity must be at least 160 lux at 1 mtr distance from focal spot.
 - d. Collimator rotation - 90° to +90° must be possible
- The unit should operate on single phase power supply and should have plugin facility to any standard wall outlet with automatic adaptation to line voltage 200 to 240 volts, 15 Amp plug.

The Leakage radiation level at 1 meter from the focus should be less than 50 mR. Products having minimal leakage radiation level will be preferred. (Please attach relevant test report)

The weight of complete unit should be less than 100 kg

Manufacturer / supplier should have ISO 13485 certification

The product offered must have European CE certification.

Should be an AERB approved product.

User/Technical/Maintenance manuals to be supplied in English.

06. Oxygen Cylinder D type with applicable certificates

07. Revolving Stools:

Stainless Steel top and MS understructure.

Height adjusted through Threaded Screws

Four Legged base made up of 25 mm Steel tube mounted on rubber shoes

Diameter of top to be 300mm.

Height Adjustment should be 450 - 650 mm

08. Semi Auto Analyzer:

- It should be micro processor controlled, programmable ,semi autoanalyser to perform routine biochemistry tests with 10 modes including
 - 1-point Linear(End–point),
 - 2-point Linear(Fixed Time),
 - Rate A Linear(Kinetic),
 - 1-pointNon-linear(End-Point),
 - 2-PointNon-Linear(Fixed Time),
 - Rate A non-linear(differential),
 - Absorbance,
 - (Coagulation),
 - Enzyme immunoassays(withmultistandardcurveblank&sixstandardscalibration & memorization) etc.
 - All modes can work with monochromatic as well as bi- chromaticfilterselections.
- It should offer a minimumof200 user definble chemistry parameters
- Instrument should have keys toaccess56Chemistry directly.
- It should have a peltier controlled reading block and below 20ul flow cell with temperature
- Programmable for off 25,30&37 C
- Flow cell with peristaltic pump should be part of the main unit.
- It should have facility to use both 6mm glass cuvettes and 10mm plastic cuvettes additionally.
- It should have minimum 8 narrow band staticinterferencefilter(notfilterwheel) with wave length selectable from340–700nm.
- It should have a large 8 lines LCD display alphanumericdisplayandbuilt-infullgraphicprinterforprintingreactioncurvesandtestresults.
- Itshouldrequireminimumreagentpertesttypicallynotmorethan500ul / test
- Itshouldhavethefacilitytodisplaytheactualtemperatureonscreen
- ThesoftwareshouldbeuserfriendlyandguidetheprogrammerstepwithspecialHELP& CALIB key.
- TheinstrumentshouldalsobecapableofdoingcoagulatingassayswithprogrammableSI value & INR can beprinted.
- The manufacturer / supplier should have a full– fledged service for ce and installation base for the quoted equipment.
- The manufacturer should be able to supply kits locally against orders.

2. **Power Supply**

- Standard Industry Power Supply

3. **Certification**

- BIS and ISO Certified as applicable
- CE/FDA Certified as applicable

4. **Warranty**

- Three(3)ManufacturerWarrantyandadditionalFive(5)yearsCMCfromthefort h year onwards to the eighth year.

09. Dialysis Unit:

- The Hemodialysis machines should meet following criteria.
- It should have facility for bicarbonate / acetate dialysis.
- It should have facility for single needle / SN click clack.
- It should have facility for ultrafiltration and sodium, UF & Bi-carb profiles.
- It should have facility for ISO isolated Ultrafiltration.
- It should have facility for online Hemo DiaFiltration: Optional
- It should have colour ATLEAST 10.4" LCD screen display of all parameters
- It should have Intelligent monitoring of set alarm limits (free false alarm)
- Should be suitable for adult and pediatric dialysis.
- Should have traffic light status indicator.
- Should have easy software upgrading by SD card.
- The online clearance measurement enables continuous monitoring of Kt/V, plasma sodium concentration by a non-invasive technique which runs automatically and requires additional disposable, labor staff effort.
- The blood volume measurement is based on ultrasound technology to permit exact online acquisition of relative changes in blood volumes, hemotocrit.
- There should be facility for blood pressure monitoring.
- Dialysis fluid flow range should be 0-300-500-800 ml / min.
- There should be facility for concentrate supply in all 3 forms i.e. constant / central concentrated delivery system and on line dry concentrate.
- In heparin pump – should have processor controlled syringe pump with bolus capability.
- Machines should be capable of doing UF at rate 0-4 Lt. / hour.
- Blood leak detector with high sensitivity of <0.5 ml blood / min at flow of 800 ml / min.
- Facility for heat, chemical disinfection with auto timer function.
- Water inlet pressure 1.5-6.0 bar
- Water inlet temp 50C – 300C
- Max. drain height 1m
- Should have modern monolithic design,

- automated self test.
- Should have optional capability to be connected with patient therapy data management system.
- Easy cleaning of all surface.
- Arterial pressure monitoring -300mmHg to +280mmHg
- Venous pressure monitor -60 mm Hg to + 520mm Hg.
- Transmembrane pressure monitoring -60 mmHg to +520mmHg.
- Arterial blood pump 10ml/350ml / min
- Single needle system facility with 2- blood pumps internal pressure / pressure control.
- Air bubble detector.
- All the hydraulic circuit should have electrodes for monitoring the correct function.
- User friendly setting for all parameters of individual hospital paramedical staff.
- Blood pressure monitor (NIBP) in built for patients BP.
- Suitable RO system including plumbing and storage tank with minimum maintain should be supplied if needed.

2. Power Supply

- Power supply 230 V -10% to 6% 50Hz, 1A.
- Should have internal battery power backup for at least 15 min.
- Suitable servostabilizer for each machine should be supplied.

3. Certification

- BIS and ISI Certified as applicable
- CE / FDA and ISO Certified

4. Warranty

- Three (3) Manufacturer Warranty and additional Five (5) years CMC from the forth year onwards to the eighth year.
- Should have excellent quality
- PROMT 24hrs local service facility.

10. Pediatrics ICU Cot:

11. Intubating Flexible Laryngoscope

- **A Full High Definition NBI Set should consist of the following items:**

- Rhino – Laryngo Videoscope (Chip on Tip) with early cancer detection capability
- Full HD Video Image Processor With Powerful Inbuilt LED Light Source
- Equivalent to 300W Xenon -OI
- 26" Full HD Medical Grade Monitor -OI
- HD Recording Device -OI
- Surgical Trolley -OI

- **Rhino – Laryngo Videoscope (Chip on Tip) with early cancer detection capability**

- Distal end & Insertion tube outer diameter should be 2.6mm or less
- Field of view should be 90 degree or more
- Depth of field should be 3.5 mm or less
- Angulation range should be approx. Up 130deg & Dn 130deg
- Working length should be around 300–400mm
- Early Cancer Detection capability
- Remote Switches should be Max 4 nos on Scope
- Should be Compatible with Stroboscopic Light source
- Should be supplied with compatible Leakage Tester
- Should have close focus for accuracy

- **Full HD Video Image Processor:**

- Should be of latest series / model and have following specifications:
- Should have Integrated Light Source to make system a simple box compact Endovision system
- A full high definition processor should have resolution of 1920x1080 pixels with 16:9 aspect ratio.
- Should have provision of Optical image enhancement of capillary vessels and fine patterns in the superficial layer of mucosa for early detection of lesions.
- Should be upgradable or compatible with IR (ICG) visualization
- Should have 5 or more Default User Preset for different surgical disciplines including IR
- Should have touch panel for easy access of system functions & settings
- Should have built-in-Fibre mode for Flexible Scopes
- Should have Laser mode for maintaining uniform Brightness during LASER use with Flexible scopes

- Should have Cysto Color adjustment mode for proper visualization of enhance vessels under special light observation
- Automatic Shutter and microprocessor controlled Automatic Gain Control
- Should have modes for maintaining uniform brightness and brightening of dark areas in Endoscopic Image
- Should have modes for False color overlay Image & Fluorescence black and white image for ICG Visualization
- Should have USB slot for capturing HD / SD Endoscopic Still Images
- Should have provision of storing 20 users settings & 50 Patient data
- Should have one output each for DVI / HD-SDI and S- Video / Composite for HD & SD videos
- **Powerful LED Light Source:**
 - A Powerful LED (equivalent to 300W Xenon) Light Source to keep Laparoscopy field brighten by providing adequate white light intensity
 - Automatically adjust light intensity to achieve ideal illumination
 - Should have special filter light for observation of capillary vessels and fine patterns in the superficial layer of mucosa for early detection of lesions.
 - Preferably Integrated Light Source with Camera Processor to make system as a single box compact system for Camera & light source
- **26" Full HD Medical Grade Monitor:** Should have following specifications:
 - 26 inch full HD monitor with TFT / LCD Screen with LED backlit having resolution of 1920 X 1080
 - Aspect Ratio 16:9
 - Should have multi-modality display compatibility, including Picture-in-Picture, Picture-out-Picture and preferably clone out for various image sizes combinations.
 - Should have at least one input and output terminals each including 3G / HD / SD-SDI, DVI, HD15, Y / C and Video.
 - Should be eco-friendly, having various power saving modes, lightweight and thin body.
 - Should have preferably provision of Clone o / p for recording 2 Channel simultaneously in one.
- **HD Recording Device:** Should have following specifications:
 - A high definition video recorder system with real time recording facility for videos & still images
 - Should have internal hard disk drive of 300GB or more and should have facility of recording on Blu Ray Disc / DVD Disc or USB memory stick if required by user.
 - The recorder should have following input of HD-SDI, Composite video

&S-video inputs for recording from various sources.

- The recorder should have one output each for HD-SDI, Composite video & S-video for routing the image if required
- Should also have a facility for one channel audio recording in real time with Endoscopy image
- The recording should be MPEG 4 AVC / H.264 format with a maximum native resolution of 1920x1080 pixels depending on the input selected.
- A good Quality Trolley should be supplied to accommodate all equipment's.
- All above mentioned items should be from the same manufacturer
-

2. **Power Supply**

- Standard Industry Power Supply

3. **Certification**

- CE / FDA Certified
- BIS and ISO as applicable

4. **Warranty**

- Three (3) Manufacturer Warranty and additional Five (5) years CMC from the forth year onwards to the eighth year.

12. 16 Slice CT Scan:

1. Specifications

- **Gantry**
 - Minimum scantime for one gantry rotation of complete 360 degrees should be in 0.75sec or less
 - Size of gantry aperture – 70 cms or more
 - Should have Gantry physical Tilt: $\pm 30^\circ$
 - The CT is capable of acquiring 32 slices
- **X-Ray Tube**
 - The X-Ray tube should have capacity of at least 3.5MHU or above
 - The X-Ray generator should be 40 kW or above
 - Tube voltage should be variable from 80 to 140 kV A or better
 - mA – 10 to 350 or above
- **Patient Table**
 - Minimum Table Load – 175 kg and higher
 - Minimum floating table top width should be at least 40 cm
- **Spiral/Helical Section (Sub-MM acquisition & Reconstruction)**
 - The stem should have spiral capability of at least 100 seconds or above
 - Min slice thickness 0.625 mm or less and maximum 10 mm or more
- **Detector**
 - the detector should have minimum 16 or more rows of elements.
 - Should have minimum detector width of 17 mm or more
- **Resolution**
 - Low contrast resolution should be 2.5 mm at 0.25% or better
 - Specify the CT dose index
- **Main Console Computer Section**
 - It should have latest flat colour screen 19 inches or above in size
 - There should be a console with one monitor
 - The display matrix should be at least 1024 x 1024
 - CPU offered should be latest multi-tasking processor and a menu driver platform with RAM size of at least 8GB
 - Hard disk capacity for both image and raw data should be 150GB or more
 - The main console should have standard software like 3D volume rendering, MIP, 3D artefact suppression, colour angio display, auto bone removal, endoscopy vascular assessment
 - The following software should be offered as standard (MPR, ROI, VOLUME CALCULATION, CT NUMBER Measurement of between -10,000 to +25,000, WINDOW WIDTH, WINDOW LEVEL TO POGRAM DISPLAY, CINE DISPLAY, HRCT LUNG, DYNAMIC SCAN)
 - It should have facilities to store at least 2,00,000 images
- **Other Feature**
 - Scanning capability: High resolution scan package to be available as standard.
 - Slice thickness should be freely selectable
 - Suitable UPS with 15 minutes backup to handle the CT computer

2. **PowerSupply**

- Suitable stabilizer to be provided
- Suitable power infrastructure to be provided as required at the installation site.
- All civil and electrical infrastructure from power source and the location of installation is the responsibility of the Tenderer.

3. **Accessories**

- Single head contrast injector of reputed make with 50 nos. syringes and tubing
- All standard accessories including adequate Lead Glass 2FT.X4ft. etc. to be provided
- Multi size DICOM Laser camera for Film printing

4. **Certification**

- The equipment must be AERB approved. AERB certificate to be produced for Radiation standard. Necessary certificates to be enclosed.
- Equipment must have CE, FDA (USA), or equivalent (other than AERB) certificate. Necessary certificates to be enclosed.

5. **Warranty**

- Three (3) Manufacturer Warranty and additional Seven (7) years CMC

6. **General(Essential)**

- The company must have local service centre. Must be able to provide maintenance service on all the days.
- Detailed technical data sheet for offered make / models to be attached
- Make & Model of offered item to be mentioned by bidder
- Bidder should have past experience of supplying similar machine to other users and should submit the Performance letter issued by the user for such similar machine
- Bidders should visit the site, in consultation with HOD and do the necessary works like Granite flooring, false ceiling for CT room & Console Room⁹⁵

including internal electrical & lighting fitting works. Sidewalls should be covered with Granite up to 6 feet and Suitable split Air Conditioners should be supplied.

- Adequate on-site clinical training to be provided
- All turnkey works shall be carried out by the vendor and cost should be included in the equipment cost

13. Video Laryngoscope

1. Should be a portable video laryngoscope for intubations with minimal manipulation of head & neck dedicated features for teaching, training & learning in the specialty
2. Minimum 1 megapixel camera should be available
3. Should have a free fog optical polymer material / poly carbonate material blades
4. Should have a suitable view angle to visualize glottis without much head & neck manipulation, ergonomically
5. The system should have portable colour video display LCD of at least 2.3" or above size for the real time clear view
6. Weight of handle should be light and not be more than 250 g
7. Should have passed the drop test for one meters
8. Light sources should be high-intensity LED
9. Should have facility to run independently on a battery and back up should have minimum four hours. The rate for the battery shall be offered in the BOQ and the same will be fixed for 5 years from the date of price bid opening. The rate will be taken for evaluation.
The system should be supplied with a set of different sizes of disposable blade size 1,2,3,4 and one additional blade for difficult intubation
11. Should be immersible for complete disinfection (without battery)
12. Should supply the following blades free of cost along with the machine - 25 nos. of size 1, size 2, size 3, size 4 and 10 numbers of 'additional blade for difficult intubation'
13. The rate for the 5 types of blades shall be mentioned in the BOQ (taken for evaluation) and the rate will be freeze for 5 years from the date of price bid opening.
14. Device should have durable medical grade thermoplastics
15. Should have safety certificate from a competent authority CE issued by a notified body registered in European commission / FDA (US). Copy of the certificate / test report shall be produced along with the technical bid.

14. Infrared Vien Viwer (Flex) for Neonatal & Pediatrics Patients

15. 1000 LPH RO Plant for Dialysis Machine:

Equipment :R.O Plant a. Sand Filter – Capacity – 2000 lph, Media – Sand / Pebbles, MOC – FRP / Composite, Backwash : Automatic, Multiport valve : Timer based with 3 cycle backwash sequence, Pressure gauge and fittings – 1 set. b. Activated Carbon Filter – Capacity : 2000 lph, Media : Carbon ID 900, MOC : FRP / Composite, Make: Pentair / equal, Backwash : Automatic, Multiport valve : Timer based with 3 cycle backwash sequence, Pressure gauge and settings : 1 set c. Water softner / High Definition Carbon / Ion Remove(As per feedwater quality) – Capacity : 2000 lph, Media : Ion exchange resins (ion exchange / thermax or equivalent) / High Definition Carbon / Ion Remove, Regeneration: Automatic, Multiport valve : Timer based with 3 cycle backwash / regeneration sequence, Pressure gauge and settings : 1 set d. MEMBRANE ELEMENTS – Sufficient quantity and arrays to satisfy the output condition of 1000 LPH at 50-75% rejection for the given water quality. e. Antiscalent dosing system : Capacity : 3 lph, MOC : PP, Dosing tank : 50 ltrs, Level switch and fittings – 1 set. f. UV Lamp with SS 304 Housing with quartz reflectors. Flow rate 1000 LPH g. The vessel size shall be at least 13” X 54” II. WATER STORAGE TANK a. Raw water storage tank sintex or equivalent capacity 2000 Litres. b. Softened water tank sintex or equivalent, capacity 1000 Litres. c. RO Water storage tank should be stainless steel SS304 Grade – 2000 Litres. III. PUMP. a. Raw water pump – 1 HP (1+1) – Crompton / Grundfos or equivalent. b. Softened water booster pump – 1 HP (1+1) – Crompton / Grundfos or equivalent. c. SS RO Distribution Pump – 1 HP (1+1) – Crompton / Grundfos or equivalent.

I. OTHERS

- a. Should have 1 Micron pre-filter, 20 inch height and 4” diameter.
- b. Should have automatic inlet shut-off valve
- c. Should have Permeate and Concentrate flow meters.
- d. Should have Digital display of critical parameters through range of sensors.
- e. Should have User friendly RO controller and ensure automatic trouble free operations.
- f. RO controller should have automatic and manual mode.
- g. Should have automated pre treatment for RO.
- h. Should have Salt rejection around 96 – 98%.
- i. RO recovery range shall be 50-75%
- j. Permeate Rate : 1000 LPH, Concentrate Rate : 1000-1200 LPH
- k. Should have P.E flexible tubing used to collect permeate into RO tank.
- l. Should have Thermal motor protection.
- m. Should have Pre-filter, post filter, primary and final pressure gauges.
- n. Should have Flow control centre including concentrate and recycle valves.
- o. Should have Auto flush valve in reject line.
- p. Should have Low inlet pressure switch before HPP
- q. 3 way Solenoid valve in feed before HPP
- r. Inlet shutoff solenoid valve in smaller system 250 to 1000lph.
- s. Glycerin filled SS pressure

gauges at feed / high pressure / reject lines. t. Panel mounted Rotameter in reject / re-circulate and permeate lines. u. Ball check valve in recirculation line, Spring check valve in permeate line & Conductivity meter in permeate line & Globe / needle valves in re-circulate and reject lines. v. Should have 5 micron cartridge filters big blue in feed line. w. Should have Digital conductivity meter with programmable relay x. Should have Alarms for Low Inlet pressure & Motor starter overload. y. Frame shall be made of stainless steel – 304 grade z. Membrane housing shall be made of stainless steel 304 grade or FRP. aa. Inlet plumbing shall be Sch 80 PVC. bb. High pressure plumbing shall be CPVC. cc. Permeate / concentrate tubing shall be Polyethylen / NSF approved wet parts. dd. CPVC Piping with SS push pull connectors. Should operate on mains 220-240Vac, 50 Hz single phase power supply. ff. All wetted parts should be INERT, SS or compatible to Haemodialysis procedure. gg. Control enclosures should be NEMA 1 & Motor starters should be NEMA 4 X hh. The outlet of the RO system must conform to AAMI standards both in terms of chemical contamination and bacterial contamination. The endotoxin limit for the RO water is 1 Eu/ml and the limit of bacterial growth shall be not more than 200 CFU/ml. The Certificate / test report shall be obtained after installation and shall be produced alongwith invoice for payment. ii. Should supply Test kit for checking hardness of water / portable TDS Meter. jj. Replacement of all necessary filters including 1 micron & 5 micron, Replacement of Sand / Pebbles / Carbon, resins, UV Lamps, Antiscalent chemical, and Acetic acid cleaning whenever requires should be done free of cost during the warranty period and also in the CMC period. kk. RO Membrane shall be replaced at free of cost during the warranty period whenever required. The replacement charge for RO Membrane replacement during CMC period shall be included in the CAMC rates.

16. Baby Incubator:

<p>GMDNname GMDNcode(s) Definition</p>	<p>infantincubator CT1432 An electrically-powered unit designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature; it is typically on wheels and also designed for transporting infant either outside or within the healthcare facility. It typically consists of a clear removable plastic hood with a mattress and operates using main electricity (AC-powered) when not in use for transportation. During transport, it is connected to an ambulance electrical outlet or is battery-powered from a battery pack.</p>
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GENERAL

		1. USE
1.1	Clinical purpose	designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature
1.2	Used by clinical department/ward	(Ex : Intensive care unit (ICU), radiology department, orthopaedics, emergencies,...)
1.3	Overview of functional requirements	Control of air temperature and infant skin temperature. Clear, hard cabinet for infant viewing Easy access control panel, with light touch operation switches. Facility to elevate base, adjustable range. Self-test functions are performed. Built for transport of infants between wards or health facilities, including by vehicle Must have skin temperature display

TECHNICAL

2. TECHNICAL CHARACTERISTICS

2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> 1. Visual and audible alarms for: <ol style="list-style-type: none"> (i) Patient and air high/low temperature alarm. (ii) Air circulation/probe/system/power failure alarm. 2. Heater power indicator. 3. Air velocity 0.35m/sec. 4. Oxygen input flow rate 5 to 15 litres/min or oxygen concentration range 25 to 70%. 5. Maximum CO2 concentration inside incubator 0.2%. 6. Internal noise level < 60dB. 7. Mode of operation should be properly displayed. 8. Green indicator light should be provided for its ready to be in normal use. 9. Infants strap should be provided to restrict the baby movement.
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		<ol style="list-style-type: none"> 10. skin temperature probe should be small in size not more than 10mm diameter and 4mm in height to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. 11. Infant bed should be draw able. Mattress foam density should be minimum 25kg./cm³ and infant bed mattress cover should be biocompatible material. 12. Examination light should be provided for inspection. 13. Should have heater power indicator. 14. Warm up time 30-40 minutes and shall not differ by more than 20%. 15. Shall be equipped with a thermal cut-out. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at an incubator temperature which does not exceed 40degC. 16. Should have elbow operable ports and head access door. 17. It should not topple over at 10deg in inclined plane. 18. Patient skin temperature range: 35degC to 37.5degC. override upto 39degC. 19. Air temperature range: 30degC to 39degC; Temperature resolution ± 0.1 degC; Temperature accuracy less than ± 0.2 degC. Patient skin temperature range: 35degC to 37.5degC. override upto 39degC. Air temperature range: 30degC to 39degC. humidity: 40-80%.
2.2	Settings	
2.3	User's interface	Display is to be backlit and allow easy viewing in all ambient light levels.
2.4	Software and/or standard of communication	In built
2.5	Others	<ol style="list-style-type: none"> 1. Patient leakage current should be less than 100μ. 2. Temperature on the baby mattress should not exceed 40degC and 43degC for other materials. 3. Uniformity of temperature on the horizontal mattress shall not exceed 1.5degC and tilted mattress not exceed 2deg C. 4. The overshoot temperature shall not exceed 2degC. 5. The stability of temperature during steady temperature shall not differ from the average temperature by more than 1degC.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Baby bed should be at least 60X30cm and the canopy should be at least 80X40cm.
3.2	Weight (lbs, kg)	not exceeding 40kg. (without cylinders).

3.3	Configuration	Oxygen port with tubing, also mount for oxygen cylinder of 5 litre size. Accommodates shelves, suction unit and I/V poles. Double-walled cabinet with at least two hand ports. Should have collapsible trolley with lockable castors. Mounted on mobile base, lowest height setting of which is at least 80 cm high. Minimum castor diameter 12cm. At least two castors must be fitted with brake facility. Castors must be made of conductive material and rotate (swivel) freely around the vertical axis. The canopy and infant bed should be crevice free for ease of cleaning.
3.4	Noise (in dBA)	<60 dBA. Audible sound level should be at least 65 dBA at 3 meter distance from the device; the alarm sound level in the compartment shall not exceed dBA.
3.5	heat dissipation	Should maintain up to 37 deg temp.
3.6	Mobility, portability	Yes, on castors.
4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2)		
4.1	Voltage (value, AC or DC, monophas e or triphase)	220 to 240V, 50Hz
4.2	Battery operated	Battery charger to be integral to main power supply, and to charge battery during mains power operation of unit. Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines. Battery backup of 2 hours for equipment operation. The battery should be protected from overcharging.
4.3	Tolerance (to variations, shutdowns)	Voltage corrector/stabilizer to allow operation at $\pm 30\%$ of local rated voltage.
4.4	Protection	Internal, replaceable, rechargeable battery allows operation for at least two hours in the event of power failure.
4.5	Power consumption	
4.6	Other energy supplies	Main cable to be at least 3m length.

5 ACCESSORIES, SPARE PARTS, CONSUMABLES

5.1	Accessories (mandatory, standard, optional)	With washable and removable straps and binders.
5.2	Spare parts (main ones)	Two extra set of fall sensors.
5.3	Consumables / reagents (open, closed system)	Two extra set of filters, two extra set of fuses (if replaceable fuses used).

6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS

6.1	Atmosphere/Ambiance(air conditioning, humidity, dust...)	Operating condition: — Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. — an ambient air velocity is less than 0.3m/s.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Unit layout to enable easy cleaning and sterilization of all surfaces, with non-reachable fluid traps. The case is to be cleanable with alcohol or chlorine wipes.
6.3	Others	
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,...); Performance and safety standards (specific to the device type); Local and/or international	Should be FDA/CE approved product. Manufacturer/suppliers should have ISO 13485 certificate for quality standard. Electrical safety conform to standards for electrical safety IEC-60601-1. Shall meet IEC-60601-1-2 (General requirements for safety-electromagnetic compatibility) Shall comply with IEC 60601-2-20 transport incubator standard requirement.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	Advanced maintenance tasks required shall be documented.
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manual to be supplied in English language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of important spares and accessories, with their part numbers and cost.
10.2	Other accompanying documents	User/Technical/Maintenance manual to be supplied in English
11. NOTES		
11.1	Other information	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warnings for safety should be declared

