DEPARTMENT OF HEALTH & FAMILY WELFARE, GOVERNMENT OF ODISHA

REQUEST FOR PROPOSAL (RFP) FOR COMMISSIONING, OPERATION, MAINTENANCE & MANAGEMENT OF CARDIAC CARE HOSPITAL AT JHARSUGUDA IN PPP MODE

Response to queries received and discussed during Pre-bid meeting held on 27June 2023

#	Clause Reference	Query	Response
1	Clause - 5.12 Article 5, Page - 16	Are we allowed to treat other specialties along with Cardiac?	Please refer to Schedule E of the draft concession agreement which specifies the minimum specialties to be provided by the Concessionaire. The Concessionaire is required to take prior approval from the authority to introduce new specialties in the hospital. However, the hospital should be operationalized as a Cardiac care super specialty hospital during the entire concession period. As per Clause 5.14 of the draft Concession Agreement, any new asset / equipment / furniture procured by the Concessionaire at its own cost shall be called the “Concessionaire’s Assets”.
2		Can we increase the no. of beds if required?	Yes. The Concessionaire is required to take prior approval from the authority to increase the number of beds in the hospital. If approved, Concessionaire may do so at its own cost. As per Clause 5.14 of the draft Concession Agreement, any new asset / equipment / furniture procured by the Concessionaire at its own cost shall be called the “Concessionaire’s Assets”.
3		Support money:Can we get aonetime grant of Rs. 10 crore or 5 crore per annum for 5 years for project operations?	The conditions of the RFP remain unchanged.
4		Concession period may please be extended to 30 yrs.	The conditions of the RFP remain unchanged. Please refer to clause 3.1.1 of the draft Concession Agreement as per which “Provided that in the event the Concessionaire shall have discharged its obligations without any material breach thereof for a period of 15 (fifteen) years

			from the Appointed Date, it may by notice to be given no later than the 14th (fourteenth) anniversary of the Appointed Date, seek extension of the Concession Period, and in such an event, it shall be entitled to an additional Concession Period of 15 (fifteen) years on the terms and conditions set out herein."
5	Clause - 2.1, Page- 8 Article – 2 **-** Project Site – Schedule – A	Request for a location plan	The Location Plan is attached as Annexure – A.
6		What is the timeline of completion of construction activities?	The construction of the Cardiac Care Hospital building has been completed. The staff quarters are under construction and the construction work is scheduled to be completed by December 2023.
7		Regarding upgrading and replacing medical equipment – Is there any pre- conditions?	Please refer to clause 5.14 of the draft Concession Agreement as per which the Concessionaire shall maintain record of Concessionaire's Assets with details including particulars of asset, specifications, date of replacement / refurbishment / renovation / procurement, value of asset and supporting documents towards creation / procurement / refurbishment / renovation and value of asset. The Concessionaire shall provide a report covering these details within 30 days of completion of replacement / refurbishment / renovation / procurement of Concessionaire's Asset(s). Upon submission of report by the Concessionaire, the Independent Panel shall have the right to inspect the Concessionaire's Assets. The Concessionaire's Assets shall become part of Project Asset.
8	Clause - 9.1.1 Page – 23	Performance security = Rs. 5.5 Cr should be omitted as we are depositing all other fees and with this security the project is not viable.	The conditions of the RFP remain unchanged.
9	Clause - 9.2 Page – 23	The 15 days' time to replenish may please be extended to 30days.	The conditions of the RFP remain unchanged.
10	Clause - 9.3 Page – 23	Can you please drop this 6-month extra time beyond the concession period?	The conditions of the RFP remain unchanged.
11	Clause - 11.1.7	If possible, in the last para the words "whichever is earlier"	The conditions of the RFP remain unchanged.

	Page – 26	may be deleted as 20% is covered in 200 days.	
12	Clause - 16.5 Page - 35	Accreditation -The two years period may please be revised to 4 yrs.	The conditions of the RFP remain unchanged.
13	Clause - 16.8 Page – 36	Penalty for shortfall in KPI (Schedule –H) P.117 The Penalty provision may please be reduced from 2% to 0.5%.	The conditions of the RFP remain unchanged.
14	Clause - 21.1.4 Page -41	The words “other patients” may please be clarified.	Please refer to clause 21.1.3 of the draft concession agreement which mentions any of the Patients other than Patients enrolled under the BSKY, Odisha or any substitute thereof are ‘Other Patients’.
15	Clause - 26.1 Page – 50	All the cure period to cure the default may please be extended. From 30 to 60 days(27.1.1.a) From 60 to 120 days(27.1.1.b)	The conditions of the RFP remain unchanged.
16	Clause - 29.1 Page - 58	Liability for defects after termination 1. The period 120 days after termination may please be reduced to 30 days. 2. The period to repair/rectify the deficits should be increased from 15 days to 30 days.	The conditions of the RFP remain unchanged.
17	Clause - 36.12 Page – 71	This may please be clarified if the persons identified by Govt. orders is for cardiac care only? If not, should we require to provide urgent/ emergency medical service to other patients also?	In case there is a need for providing urgent / emergency medical services not restricted to cardiac care, the govt will issue an order identifying the need for such medical services. The Concessionaire shall provide urgent / emergency medical services not restricted to cardiac care to people identified under suchorders.
18	Clause - 37.1.1 Page – 73 - Annual Concession Fee	a. The sum of (……..) has not been mentioned.	Annual Concession Fee is the bid parameter for selection of private hospital operator for the Project. Please refer to clause 1.1.5 (b) of the RFP as per which the term “Highest Bidder” shall mean the Bidder who is offering the highest Annual Concession Fee payable for the 1st Accounting Year commencing from the Operations Date in accordance with the provisions of the Concession Agreement. Subject to the provisions of Clause

			1.1.6 of the RFP, the Project will be awarded to the Highest Bidder.
19		The details of Bed Mix/ Bed distribution status not mentioned in RFP. Kindly share.	Please refer to Annexure – B of this document.
20		SICU/ ICCU and other ICU are mentioned, however in "Minimum clinical specialties" General Surgery is not mentioned.	Please refer to Schedule – B of the draft Concession Agreement (List of Medical equipment and medical furniture) wherein the equipment related to General Surgery have been included.
21		Can there be reduction of INR 5.5 crores security amount?	The conditions of the RFP remain unchanged.
22		Can there be reduction of eligibility from 5 years to 3 years?	Please refer to Corrigendum 1 of the RFP, that is issued by the Authority along with the responses to the pre-bid queries.
23	Clause - 2.1.1.3 (a) ii Minimum eligibility criteria	Requesting Authority to reconsider the eligibility criteria for wider participation in tender. For wider participation and competitive bidding request for amendment of the technical capacity of the bidder under point no. a (ii) of minimum eligibility criteria as "*The bidder should have performed Cardiac surgeries and Percutaneous transluminal coronary angioplasty (PTCA) procedures. In support of the statement bidder should submit letter of Consent from the Doctors associated with them*". As it will be difficult to ascertain the numbers, accordingly Consent letters from the associated doctors should solve the purpose.	Please refer to Corrigendum 1 of the RFP, that is issued by the Authority along with the responses to the pre-bid queries.
24	Clause - 1.1 10 Background & Scope of Work	Requesting Authority to increase the Concession Period to 20 years	Please refer to Response #4 above.
25	Clause - 1.1 5 b Background & Scope of Work	As this is a Greenfield project, requesting authority to start the Concession Fee after the completion of the 5th Accounting year from the commencing of the operation date of the project.	The conditions of the RFP remain unchanged.
26	10.1.3 Handover And Use Of Project	As per our understanding the ownership status of the License cannot be transferred, so require more clarity on the	The license will not be transferred. The Concessionaire will procure new license in its own name. The Authority shall use best efforts to facilitate securing of such applicable permits /

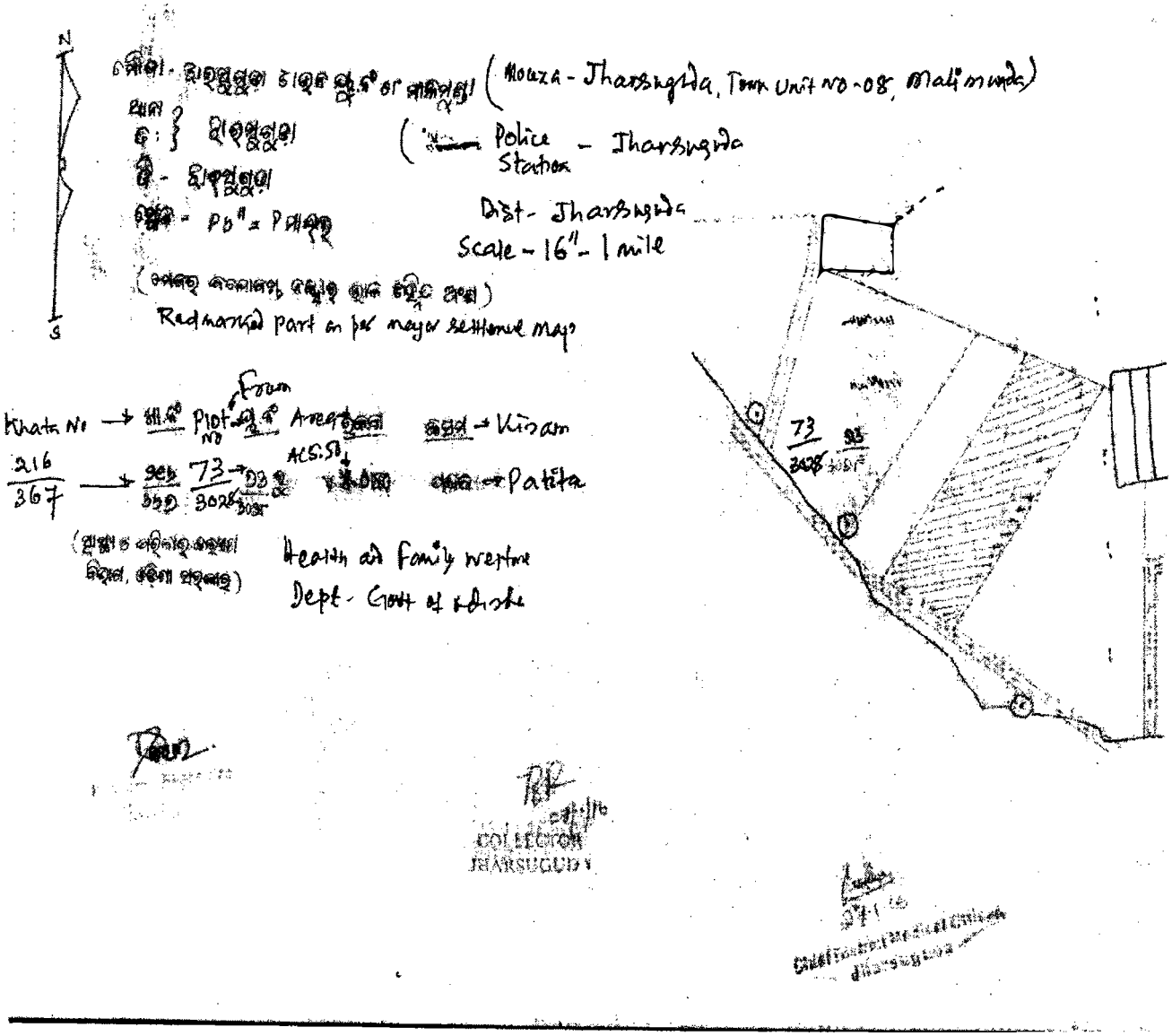
	Assets	various license to be handed over and for renewal of the same.	approvals from the relevant government authority. The Concessionaire is required to subsequently arrange for renewal procedure as and when required. Please refer to clause 5.3 of the draft concession agreement which mentions that: a) The Concessionaire shall procure and maintain at its cost all Applicable Permits for the Operation of the Project, including commissioning, managing, operating, and maintaining the Project Assets in accordance with the terms of the Concession Agreement. b) Subject to the Concessionaire complying with the applicable laws and good industry practices, the Authority shall use best efforts to facilitate securing of such applicable permits/approvals from the relevant government authority but is not obliged to do this and the Concessionaire shall remain solely responsible for securing such applicable permits / approvals.
27	SCHEDULE - B: List of Medical Equipment And Medical Furniture	As far the information received the purchased CT scan machine is of CT slice, for a cardiac hospital it required a min of 128 slice cardiac CT machine. Requesting authority for replacement.	The specifications of the critical medical equipment have been provided in Annexure – C of this document. As per the suggestion of the Concessionaire, specifications of biomedical equipment can be modified (subject to approval by the Technical Committee).
28		Please arrange to provide the total list of Bio-Medical & Non-Biomedical equipment list along with quantity, specification and make	The specifications of the critical medical equipment have been provided in Annexure – C of this document. As per the suggestion of the Concessionaire, specifications of biomedical equipment can be modified (subject to approval by the Technical Committee).
29		Please arrange to provide the AMC/ CAMC warranty period and commercial terms & conditions mentioned in the PO for our financial projections.	The warranty period will be the typical warranty period as provided by the manufacturer. It will be applicable from the date of installation of the equipment. Please refer to Clause 12.1.1 (p) of the draft concession agreement where it is mentioned that "The Concessionaire shall be responsible for maintenance, replacement and/or upgradation of the Project Assets as required during the Concession Period. The Concessionaire shall enter into Comprehensive Annual Maintenance Contracts (CAMCs) as required with the suppliers for medical equipment and medical furniture and other support equipment. The CAMCs shall be valid for the entire Concession Period and shall

			cover each and every aspect of maintenance and pay the required CAMC charges to the CAMC services provider on regular basis."
30		Scope of work in case any structural modification is required as per concerned authorities guidelines, who will be responsible for the financial part.	Please refer to clause 12.7 of the draft concession agreement which mentions that the Concessionaire shall not carry out any material modifications to the Project Assets save and except where such modifications are necessary for the Project Assets to operate in conformity with the Service Level Specifications, Maintenance Requirements, Good Industry Practice and Applicable Laws; provided that the Concessionaire shall notify and take approval of the Independent Panel of the proposed modifications before commencing work on such modifications. For the avoidance of doubt, all modifications made hereunder shall be subject to the approval of the Independent Panel and comply with the Specifications, Applicable Laws and the provisions of this Agreement. The Concessionaire shall bear all costs for carrying out such modifications.
31		Is there provision for a dedicated blood bank within the facility?	The new District Headquarter Hospital (DHH), Jharsuguda located adjacent to the Cardiac Care Hospital has an existing Blood Bank facility. The Concessionaire can leverage this or can also arrange for setting up a blood bank at its own cost and this shall be part of "Concessionaire's Assets" as defined in the draft Concession Agreement.
32		During site visit on 23rd June 2023, we found that only 1 (one) number 750 KVA DG is available. There is no standby DG.	The request is noted. The Authority will decide on this in due course of time.
33		Who will arrange the renewal procedure for Fire, Pollution and other statutory licenses.	Please refer to Response #26 above.
34		When will the staff accommodation be constructed by the authority? What is the timeline?	Please refer to Response #6 above.
35		What is the usual timeline for reimbursement of raised invoices under BSKY?	As per current BSKY guidelines, minimum required documents need to be uploaded in the BSKY portal within 7 days of discharge of the patient. Payment is done by electronic transfer through Public Financial Management System (PFMS) of raising the claims (with complete documentation) in BSKY portal within 4 weeks.

			Please refer to www.bsky.odisha.gov.in for further details.
36		What is the scope for tele-radiology?	The Concessionaire can introduce tele-radiology upon prior approval from the Authority. As per Clause 5.14 of the draft Concession Agreement, any new asset / equipment / furniture procured by the Concessionaire at its own cost shall be called the "Concessionaire's Assets".
37		Clinical Establishment Act license will be procured under whose name?	Please refer to Response #26 above.
38		Regarding Concession Fee revision: Can 5% year-on-year increase be removed? Can there be an initial period of 2-3 years where Concessionaire will pay no fees, but will start payment from the 4th year onwards?	The conditions of the RFP remain unchanged.
39		Are BSKY patients entitled for free OPD?	As per the current BSKY guidelines, BSKY (Component – 2) covers in-patient (IPD) and day care treatment packages only. OPD Cases in private hospitals are not covered under BSKY. Please refer to www.bsky.odisha.gov.in for further details.
40		If a hospital has multiple single specialty units in various hospitals, where they are providing treatment to patients, will the number of beds in these units be eligible for calculating the total number of beds they have?	No. Please refer to clause 2.1.13 (i) of the RFP.
41		What will happen after end of the 15 years of Concession Period?	Please refer to clause 3.1.1 of the draft Concession Agreement.
42		Ownership of licenses usually cannot be transferred. If a license has been obtained in name of authority, how will the name be transferred to Concessionaire upon renewal?	Please refer to Response #26 above.
43		Is there scope for a liquid oxygen plant?	As per Clause 5.14 of the draft Concession Agreement, the Concessionaire can procure any new asset / equipment / furniture other than the Project Assets at its own cost and in accordance with Good Industry Practice, which shall be called the "Concessionaire's Assets".
44		What are the guidelines for Branding?	Please refer to clause 5.12 of the draft Concession Agreement.
45		Furnishing of staff accommodation will be whose	Please refer to clause 12.1.1 (b) of the draft Concession Agreement.

		responsibility?	
46		In the last 3 years, due to Covid, the number of cardiac surgeries carried out by hospitals might not have been a lot. Can there be any relaxation on the criteria considering this?	Please refer to Corrigendum 1 of the RFP, that is issued by the Authority along with the responses to the pre-bid queries.
47		Can modification possible in requirement of "300 surgeries annually for last three years" to " 3 years' experience in doing heart surgeries in last 3 years"	Please refer to Corrigendum 1 of the RFP, that is issued by the Authority along with the responses to the pre-bid queries.
48		What is the "start date of Warranty period" of the equipment and "No. of years of warranty"	Please refer to Response #29 above.
49		We request for extension of the bid due date for proposal submission	Please refer to Corrigendum 1 of the RFP, that is issued by the Authority along with the responses to the pre-bid queries.

ANNEXURE A – LAND DETAILS



ANNEXURE B

PROPOSED BED MIX – CARDIAC CARE JHARSUGUDA

Bed Mix	No. of beds
Census Beds	
Triple sharing	24
Twin sharing	12
Single	15
Deluxe	6
Critical care (CTVS)	8
ICU	10
Medical Step-down	8
Total census Beds	**83**
Non census Beds	
Dialysis	7
Pre & Post op beds	10
Total non-census beds	**17**
GRAND TOTAL HOSPITAL BEDS	**100**

ANNEXURE C - Technical Specification of the Critical Equipment		
S.No.	**Equipment name**	**Total Qty**
1	1 Dome Ceiling light	1
2	3D-Echo Machine	1
3	C arm Image Intensifier	1
4	Cath Lab	1
5	Double Arm Pendants	3
6	Portable Color u s 2 probes	2
7	Portable X-ray	3
8	Ventilator	10
9	Microtomes	1
10	Paraffin Embedding system	1
11	Electrosurgical Cautery	3
12	Horizontal High Pressure Rectangular Cylindrical Sterilizer	1
13	Infusion Pump (Volumetric)	52
14	OT Light	2
15	Syringe Infusion Pump	120
16	Pacemaker - DC	5
17	Video Bronchoscope with Processor	1
18	Heart lung machine	2
19	Hemotherm	2
20	Sternal saw	2
21	Blood cell counter - 5 part	1
22	Blood culture system wit ID/AST	1
23	Coagulation Analyzer 4 channel	1
24	Defibrillator with Ped, Neo Paddles	24
25	Direct Digital Flat panel Fluoroscopy Radiography System	1
26	ETO machine	1
27	Fixed X ray with Motorized Table 500mA High Frequency	1
28	Cryo Machine	1
29	Endo washer	1
30	Laparoscopic Surgical Set with all std. Accessories and harmonic	1
31	OT Table (Hydraulic Table)	2
32	3D-Echo Ultrasound With TEE	2
33	ABG Machine with Electrolytes	3
34	Anaesthesia Workstation	4
35	C R Digitizer	1
36	Color Doppler + Ultra Sound (4Probe)	2
37	Multiparameter Monitor ECG HR RR SPO2 and NIBP, IBP and ETCo2 – Modular with CMS &Wall mount.	22
38	ENT Treatment unit	1
39	Nasal Endoscope	1
40	Multipara monitor(Basic 5 parameter with Dual IBP,ETCO2)	2
41	Patient bed(Motorised)	26
42	Beside loacker	120
43	CT Scan	1
44	HPLC (For Hemoglobinopathis)	1
45	Multipara monitor(Basic 5 parameter with Dual IBP)	8

1. Single Dome OT LIGHT

A. Product & Manufacturer Quality Standards:

1. The quoted model should be "USFDA approved (Device listed with registration under valid FEI number /CFG)" **OR** "EU-CE certified. The EU-CE certificate should be issued from a notified body having notified body number" **OR** "BIS certified conforming to the standard BIS specification/ guideline specifically for 'Ultrasonic Cleaner' and ISI marked with valid CML number."
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" **OR** "IS/ ISO / IEC 80601 (Part 2)" **OR** "IS 13450 (Part 1)".
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification :

1. The quoted model should be single dome, flat, compact based on innovative multi color LED technology portable procedure light.
2. It should have headlamp of approximate 400mm or more diameter and should be made up of ABS.
3. It should have high fail safety through optical light system should consist of minimum 10-12LED's in the lamp head for low power consumption and less heat generation even after prolonged use.
4. It should have the following features:
    a) Intensity(Lux): 1,00,000 or more.
    b) Color Temperature: 3700 to 4500 k.
    c) Life of LED: 50,000 or more.
    d) Colour rendering index (CRI): 95 or more.
5. It should be non winged round shaped lamp head for easy maintenance and better sealing against dust and fumigation.
6. It should have cold, high intensity light through use of multi lens matrix technology or reflectors.
7. It should have intensity controller to offer different levels of light intensity.
8. It should have variable color temperature feature to offer different levels of color temperature.
9. It should be strobe free light and offer endo mode as well.
10. It should have the feature to adjust intensity, color temperature, Endo mode etc.
11. It should preferably have a digital control with LCD display for displaying important parameters like intensity, color temperature and mode of operation etc.
12. It should have spring balanced lamp-head with molded plastic sterilizable handle in the middle for manual focusing and lamp head movements.
13. It should work on power supply 220-240V AC, 50Hz frequency.

C. Warranty: 3 years of manufacture warranty on the equipment**.**

2 & 6. ULTRASOUND MACHINE (Portable For Bedside)

A. Product & Manufacturer Quality Standards:

1. The quoted model should be USFDA (510K/CFG) **AND** EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number".
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted model should comply with IEC 60601-2-37 or equivalent: Basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Clinical Use: Portable ultrasound scanners are commonly used for a wide range of point-of-care ultrasound (POCUS) applications. POCUS refers to the use of ultrasound by the treating physician or other care giver as opposed to the treating physician referring the patient to an ultrasound specialist. Unlike the comprehensive examinations performed by imaging professionals in radiology or cardiology settings, POCUS exams are typically performed to answer specific clinical questions. The use of ultrasound in the emergency department (ED) is a typical example of POCUS.

C. Technical Specification:

Performance Parameter:

1. Should be State of the Art fully digital portable ultrasound machine with provision for high resolution real time B mode, Color Doppler, Power Doppler and Pulsed Doppler scanning modes.
2. The unit should have a laptop type console design. The unit should be compact, lightweight and portable. Weight should not exceed 5kgs including battery (excluding cart and accessories).
3. It should be provided with high quality, compact stand with lockable wheels with epoxy powder coated trolley (rust free). Trolley should be have multiport adapter for attaching upto three imaging transducer from the same company.
4. It should be suitable for abdominal, Obstetrics, Gynecological, Cardiac, Vascular, Thoracic, Transcranial, Musculoskeletal, Urological, Small Parts, for adults, pediatric and neonatal patient.
5. Multiple preloaded as well as user configurable application presets should be available.
6. The system should have advanced measurement, manual and automatic for all applications.
7. The system should have minimum 2,00,000 or more digital processing channels and 256 or more grey shades.
8. Maximum scanning depth to be 30cm or more.
9. It should have capability to scan large organ (up to 60 cm) in a stretch.
10. The system to have a dynamic range of 250 decibels or more.
11. System should support transducer technologies like Phased array, Convex, Linear, Hockey stick, Micro convex, Endocavitary and 4D volume.
12. All transducer should be light weight digital phased array broadband type transducers.

13. Provision for inter-switch ability between the transducers without the need of manual disconnection.
14. Display screen should be more than 15 inches in size with high resolution colour LCD. The system should an integrated high resolution TFT/LCD/LED of more than 15 inches (flicker free images).
15. Should be supplied with four transducers (mentioned below).
16. Convex and linear transducers shall have detachable reusable biopsy guides for different gauge needles.
17. The system should have a frame rate more than 1400 fps.
18. The system should have an ergonomic full alphanumeric soft keys keyboard with easy access scans control and trackball or touchpad.
19. The Systems should have cine loop review facility of not less than 60 sec/1000 frames.
20. System should have 200 GB or higher capacity internal HDD.
21. The system should have the facility of digital storage and retrieval of B/W and colour image data.
22. Provision for USB port and LAN transfer of data should also be present.
23. The system shall support the all DICOM functionality, Storage, Print, and Work List, also ready to connect to PACS. Should have DICOM 3.0 connectivity.
24. Imaging modes of Real time 2D, Colour, Pulsed wave, Continuous Wave, Quad imaging, Steer M, M mode color, TDI, Surface 3D Rendering, Speckle Reduction IMT, Panoramic, Trapezoidal and Power (energy) Doppler, Anatomical M-Mode should be available.
25. Controls for 2D mode: Total gain, depth, TCG, dynamic range, acoustic power output.
26. Controls for Color Doppler: PRF, Color gain, position and size of ROI, steering of ROI, colour maps and colour invert.
27. Controls for pushed Doppler: variable sample volume size from 1 to 5mm or more, steer, PRF, baseline, gain angle correction, spectral invert duplex on/off.
28. Measurements for 2D mode: Multiple distances, area and volume.
29. Measurement for Doppler modes: Stenosis quantification in area percentage, Diameter, PSV, EDV, means, PI, RI, acceleration time and index. Automatic and manual measurements and display of pulsed Doppler calculations should be possible.
30. Unit should function with 200-240 VAC, 50 Hz, and 5-amp power outlet power requirement to be specified.
31. In built battery backup, should be at least 45 minutes or more.
32. System should have both Triplex and Duplex display and a wide range of probes, increases system versatility and adaptability to our clinical needs.
33. System should be upgradable to Enhanced Needle Tracking, Panoramic Imaging and 3D software in future.
34. System should be ready to upgrade Real-time to 3D/ 4D imaging.
35. System should have capability to compare the current exam to the previous exam.
36. System should have stain elastography.
37. System should have continuous optimization the images when scanning different tissues.
38. System should have onboard contextual reference tool.
39. System should have capability for auto EF.

Transducer Probes: All probes should be provided with dedicated probe cover,

1. Broadband Curvilinear transducer: 2-8 MHz +/-1 for abdominal imaging, OB&G, lung ultrasound application.
2. Linear array transducer: 5-13 MHz +/-1 with color, power & spectral doppler capabilities for vascular and small part Imaging.
3. Phased array transducer upto 8 MHz suitable for Pediatric cardiac applications.
4. Phased array transducer 2-8 MHz +/-1 suitable for Adult cardiac & lung studies.

D. Accessories:

1. The machine should supply with 1 no. of thermal printer with 10 roll of printing paper which should be compatible with the quoted model of the ultrasound machine.
2. The machine should supply with ultrasound transmission gel for approximately 500 patient's exam.

E. Warranty: The quoted model should have 5 years comprehensive warranty on the entire system along with Online UPS**.**

3. C-ARM FLUOROSCOPE X RAY MACHINE

Product Quality standard certification:

1. The quoted model should be either "USFDA approved (510K/CFG)" or "EU-CE certified and the EU-CE certificate should be issued from notified body having notified body number or IS 7620 (Latest) Certificate .
2. The quoted model should have IEC 60601 certified or Certificate issued from BIS conforming to IS 13450 or IS /ISO 80601.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.
5. The model should have Type test approval certificate from AERB.

Technical Specification:

- Carm fluoroscopy should use in variety of general surgical, cardiac, and neurological applications, including aneurysm repair, pacemaker implantation, hip replacement, fracture reduction, foreign-body location, needle biopsy, catheter placement, pain management, per-cutaneous lithotripsy, and brachytherapy.
- The system should have following features:

A) Gantry:

i. Should have sturdy & vibration free self-balanced C-Arm stand
ii. Should have C-Arm Rotation of 270 degree or more in both side
iii. Should have orbital travel of 140 degree or more
iv. Should have motorized vertical travel of 430mm or more
v. Should have horizontal travel of 220mm or more
vi. Should have C-Arc depth of 700mm or more
Vii. Should have free space of 800mm or more
Viii. Should have Source to image distance of 1000mm or more
IX. Should have foot print/total width of 800 mm or less.
X. Should have double steering wheel system for easy steering.

B. X-Ray Generator:

i . Should have generator output of 5 kw or more
ii. Should have Generator frequency of 220KHz or more
iii. Should have mA range of 0.2mA to 6 mA or more in continuous fluoroscopy mode
iv. Should have mA range of 0.1 to 2.5mA or less in low dose paediatric fluoroscopy mode
V. Should have mA range of 0.8 to 12mA or more in high dose fluoroscopy mode
Vi. Should have mA range 0.8 to 35 mA or more in Pulse Fluoroscopy mode.
vii. Should have mAs selection range 0.5mAs to 300mAs or more
Viii. Should have KV range of 40 to 100 KV or more in fluoroscopy & radiography mode.
IX. Should have KV rise time of 40KV/sec or more in Auto Dose rate control mode for lesser radiation in auto mode.
X. Should have Digital Spot mA range up to 20mA or more

C. Control Panel:

i. It should have 15" or more touch screen LCD control panel for exposure parameters selection and display of live image.
ii. Should have Automatic Dose Rate Control (ADRC) mode for automatic selection of KV & mAs with KV rise time of 40KV/sec or more.
iii. Should have following exposure modes and selection from control panel:
   a) Continuous fluoroscopy mode,
   b) Boosted/High dose Fluoroscopy mode,
   c) Low Dose Paediatric Fluoroscopy mode,
   d) Single snap shot fluoroscopy mode
   e) Pulse fluoroscopy mode
   f) Automatic Dose Rate Control (ADRC) mode
iv. Should have 5 min cumulative timer with buzzer and re-initiate switch
v. Should have exposures through foot switch as well as hand switch.
vi. Should have laser centering device with switching from control panel.

D. X-Ray Tube:

i. Should have dual focus Rotating anode X-Ray tube
ii. Should have small focus of 0.4 mm^2 or less and Large focus of 0.8 mm^2 or less
iii. Should have Anode Heat storage capacity of 300KHU or more.

E. Dynamic Flat Panel Detector:

i. Should have Dynamic Flat Panel Detector of Amorphous silicon with caesium iodide scintillator material.
ii. Should have size of 22cm x22cm or more
iii. Should have Pixel Pitch of 160µm or less
iv. Should have image resolution of 1.5K x 1.5K or more.
v. Should have Spatial resolution of 3lp/mm or more
vi. Should have 16 bit or more A/D conversion

F. Monitor:

i. Should have single 30 inch or more High Resolution, flicker free Flat Screen Monitor with split screen display of Live image & Saved Memory Image
ii. It should be mounted on modular design mobile trolley having caster wheels & locking system.

G. Image Processing:

i. Should have Digital Image Memory PC based with storage of more than 10000 images in 1.5K x 1.5K format.
ii. Should have User selectable pre-set programs.
iii. Should have real time endless Digital Image Rotation (CW/CCW)
iv. Should have Recursive filter for noise reduction
v. Should have Image Mirror (Horizontal and Vertical) & Image Negative
vi. Should have Contrast & Brightness Enhancement (WW/WL adjustment)
vii. Should have Digital Zoom/Magnification of image
viii. Should have image annotation and text marking on image
ix. Should have USB Pen drive provision for external image storage
x. Should be DICOM ready, DICOM Work list, DICOM Print provision

H. **DSA with Roadmap with following features:-**

i. Should have DSA Frame rate up to 15FPS
ii. Should have selection of mask 1-9 odd numbers, land marking from 0 to 100%, Random angle rotation
iii. Should have Stenosis and aneurysm measurement
iv. Should have patient dose rate calculation and display on screen.

I) Each machine should supply with the following accessories:
   i. Light weight lead apron- 5Nos.
   ii. Thyroid shields -5 Nos
   iii. Gonad shield - 5 Nos
   iv. Lead Goggles – 05 Nos,
   v. Lead apron wall stand with hangers- 1No.
   (Note that Radiation Protection accessories should be ICMED 13485 certified and must be of reputed brand only)

J. **Warranty:**

3 years Comprehensive warranty on the complete system.

4. CARDIAC CATH LAB

Product & Manufacturer Quality Standards:

a) Should be CE (Notified) and USFDA approved product.

b) Electrical safety conforms to standards for electrical safety IEC 60601-General Requirements.

c) Manufacturer should have ISO 13485 certification for quality standards.

d) Shall comply with AERB and BARC guidelines.

e) Should have model type approval for the quoted product issued from AERB.

Operational Requirements It shall operate on AC power supply 3phase System should have 100% power backup of at least 30 minutes for the entire system. System Configurations

1. Gantry
2. Patient Angiography table
3. X-ray Generator
4. X-ray tube
5. Collimator
6. Flat Panel Detector
7. Image Display Monitors
8. Digital Imaging Processing System & Workstation.
9. System Operation
10. Radiation Protection
11. Software
12. DICOM compatibility.
13. Hemo-dynamic Recorder
14. Pressure Injector
15. Lead glass 100cm X 150 cm of 2mm Lead equivalence with suitable frame-1 piece.
16. Lead-free apron: 6 pieces.
17. Thyroid shield: 6 pieces.
18. Lead goggles: 6 pieces.
19. Other accessories as specified

Gantry:

1) Ceiling / Floor mounted gantry providing full body coverage without repositioning of patient.

2) Gantry must have three working positions for easy operation.

3) Facility for motorized positioning/rotation of stand from the ceiling or floor pivot by +/-90 degrees for improved workflow.

4) Patient access must be possible from left, right and head side.

5) Rotation speed should be 15 deg. /sec or higher for Cranial to Caudal and LAO to RAO positions with non-contact sensing mechanism or collision protection switches.

6) Gantry rotation for Cranial-to-caudal angulation of atleast +/- 45deg. and atleast +/- 90 deg. for both LAO and RAO.

7) The system must have capability of memorizing at least 3 positions for easy recall of gantry positions for PTAs (Percutaneous transluminal angioplasty or intervention).

8) The throat depth of the gantry must be 89cm or more for better groin access.

Table:

1) The table should have longitudinal, horizontal and vertical travel.

2) Table should allow head to toe coverage of adult patients without repositioning

3) Floor-mounted patient table for all angiographic examinations and interventions

4) Large unobstructed cantilevered table top and wide range of rotations enables access to patient from all sides and easy transfer and positioning.

5) Should have table control module for operation of all table functions.

6) Should have extendable arm rest both sides and elbow guard, motorized up/down, free floating 4way table top, atleast radiation attenuation, at least 200 kg + at least 100kgs of additional weight for resuscitation in the metal free overhang area without having to retract the table back on its base.

7) Table should have tilt facility of atleast +/- 12deg. to enhance the accuracy and efficiency of gravity-oriented procedures.

8) Motorized longitudinal travel 110cm or more and manual transverse travel +/-14cm or more

9) Should be provided with following accessories with table and mattress:

a) Accessory clamps

b) Arm supports

c) Drip stand

d) Peripheral filter set or equivalent techniques

e) Catheterization arm support

f) Foot support

g) Head end holder

h) Handles with support

i) Articulating arm support

j) IV set holder

Detector:

1) Should be 30 x 40cm rectangular or atleast 48cm diagonal flat detector that can berotated by 90 degrees for better flexibility and projection angles depending upon area of interest.

2) Latest generation of digital output of the flat detector must be of 2K image matrix at 14 bit or higher depth for the largest mode.

3) System must have at least four imaging modes.

4) DQE of the entire detector must be atleast 75%

5) Pixel pitch of 200 micron or less for better resolution.

6) Control room should have antiglare provision with high resolution display in the control room.

Image Processing & Storage:

1) System must have a fully digital 2K image processing for improved detailed visualization of small structures.

2) System must have storage capability of at least 1,00,000 images at matrix size of 1024 x 1024.

3) Advanced image processing technique for: • Real time edge enhancement • Real time Harmonisation • Real time noise reduction and dose correction algorithms

4) Availability of Vascular analysis software both in examination room and console room.

5) System must be capable of virtual collimation of the shutters and wedges in the last image to reduce the x-ray dose.

6) Grab function to allow storage and archiving of fluoro image.

X- ray Generator:

1) Generator should be microprocessor controlled high frequency for constant output with automatic dose rate control.

2) Voltage range: 50 to 125KV

3) Nominal Power: at least 100KW.

4) Pulsed X-ray for (subtracted) acquisition up to 6 frames/sec. for vascular applications.

5) Fluoroscopy must be possible in low frame rates up to 3fps or high frame rate of 25 fps or higher.

X-ray Tube:

1) A noise-free, dual/triple focus rotating anode x-ray tube with spiral groove bearing technology and fluid lubricant for faster cooling must be provided.

2) Minimum Anode Heat Capacity: 3.7 MHU or more.

3) Cooling rate or Anode Heat Dissipation of x-ray tube must be 500 kHU/min. or more.

4) X-ray tube should have secondary grid switching.

5) System must be capable of delivering minimum 2200W continuous fluoro power.

6) Additional beam filtration of at least 1.0 mm Cu/Al equivalent. Different filter sizes and types to be freely selectable or auto selectable at the table side for any patient weight for maximum radiation safety to staff and patients.

7) Virtual collimation of shutters and filters on the last image to reduce extra radiation for positioning of shutters.

Image Display Monitors: A) Examination Room:
1) Single large medial grade high resolution color monitor of atleast 52 inch with wide -viewing angle, high luminance, high contrast, flicker free, distortion-free should be available.

2) Two additional back up color monitors should also be provided.

3) Monitors in the examination room should be ceiling-suspended with height adjustment and longitudinal travel to either side of table & Swivel capabilities

4) Monitor brightness should be 600 cd/m2 or more.

5) Any additional feature to switch various video signals from various sources such as MRI, CT and ECHO in a single monitor should be offered as standard.

6) Should have inbuilt CT imaging facility inside the cathlab for structural heart and valve disease guidance.

B) Control/Console Room:
1)Two LCD/TFT flat 19 inch color monitors with wide viewing angle, high luminance high contrast, flicker free, distortion free: One for Patient Data / RIS information and One display for Live/Ref Display. 1) Additional One monitor with workstation for Special 3D applications should be provided.
2) All the image display monitors to be supplied for examination room and console room as asked in the technical specification should be of high-resolution medical grade color monitor. **Quantification Software:**
a) Quantification

b) Vascular analysis with stenosis quantification

c) Quantitative Coronary analysis

d) LV analysis

e) Advanced and latest Real time stent enhancement tool in relation to vessel with provision of necessary hardware and software.

f) DICOM COMPATIBILITY (DICOM 3 Compatible)

g) Archiving / recording in DICOM modes

h) DICOM storage commitment for archiving on CD.

i) DICOM print of image through laser printer.

Additional Software Feature to be offered:
1) System must have road mapping facility wherein subtracted roadmap should be superimposed on live fluoroscopy. It must be possible to select different roadmap protocols depending upon the anatomy and procedure type.

2) Should be provided with stent enhancement software with feature of live fluoroscopy image over reference image with fade-in and fade-out capability.

3) Should have inbuilt Angiographic FFR and Conventional FFR software.

4) The Cath lab should be compatible with IVUS and OCT system.

5) System should be provided with latest dose saving features.

6) The workstation should be provided from the same company of cathlab machine.

Hemodynamic Recorder:
a) 12 channel ECG waveform display
b) 2 or more invasive pressure display and necessary transducers, connectors.
c) FFR License
d) SpO2, Non-invasive BP display and necessary equipment
e) Storage of ECG/pressure recording on CD
f) Storage on hard disk: specify storage capacity
g) One LCD/TFT monitor in examination room with ceiling suspension and one in console.
h) Conversion of homodynamic reports into DICOM3 Compatible image data format
The following minimum features should be available in the supplied hemodynamic recorder as follows,
1) Pressure calculations

2) Gradient calculations

3) Rate of pressure change (dP/dt max)

4) Shunt calculation

5) Cardiac output

6) Valve area

7) Cardiac index, flow & stroke volume

8) Systolic area index that provides a very efficient method for diagnosing and documented constructive pericarditis.

9) Resistance

10) Regurgitation

Pressure Injector: a) Should be of stand-alone type and single channel. b) High pressure injector for contrast delivery. c) Disposable syringes and 100 numbers of disposable syringes should be provided. **ACCESSORIES:**

a) Lead window 150x100 cms (imported good quality)

b) UPS with 30 Min back up for the whole system

c) Ceiling suspended lead partition

d) Focused ceiling mounted cool light of high quality

e) Console room chairs 4 and tables (as per user)

f) Console room and review station in the cath lab with computer and DVD/CD writing facility and DICOM print output

g) Wireless remote communication with operators from outside

h) Lead goggles for vision protection .

5.MOTORIZED DOUBLE ARM MOVABLE PENDANT FOR ANESTHESIST & SURGEON

Product Quality Standard certification:

i) The quoted model should be either "USFDA approved (Device listed with registration under valid FEI number /CFG)" or "European CE certified " or equivalent BIS.

ii) The Pendants should comply with safety standard NFPA 99C/HTM 02-01/DIN or"IEC 60601" or"IS/ ISO / IEC 80601 (Part 2)" or "IS 13450 (Part 1)

Manufacturer Quality standard certification:

i)The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.

ii)The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

(A) Motorized Double Arm Moveable Pendant For Anaesthetist:
Technical Specifications:

The support arms should be extremely robust and revolve on high quality bearings, so that the pendant head glides smoothly and quickly to any desired position. The Pendant should have the following specification:
i. Moveable arms (any combination) with total coverage of 1800mm ± 10% and 330 deg. horizontal movements for each arm.

ii. Vertical movement should be motorized with air braking system and the arm height should remain to a height greater than 6.5 feet above floor level.

iii. Weight carrying capacity of the arm should not be less than 125 Kgs.

iv. Should have electromagnetic brakes.

v. Each arm should be capable of 300-340 degrees of rotation, which can be easily adjusted to suit the desired mode of operation.

vi. The Pendant Service Heads should be modular with minimum 400mm head. The heads should be capable of accepting a range of shelves, and infusion poles or other accessories. The Pendant Heads should support the range of Physiological Monitor Mounting Solutions.

vii. The Pendant Service Heads should be supplied with medical gas terminal units and 15/5 Amp. Sockets.

viii. Each pendant should have:

1. Oxygen Outlets – 2 nos.
2. Vacuum Outlets – 2 nos.
3. Nitrous oxide – 2 nos.
4. Air (4 bars) Outlets - 2 nos.
5. AGSS outlet - 1 no.
6. Electrical sockets - 6 nos.
7. Shelf with two rails one on each side – 3 nos.
8. Data socket RJ-45 -2 nos.

(B) Motorized Double Arm Moveable Pendant For Surgeon.

Technical Specifications:-
i. Moveable arms (any combination) with total coverage of 1800mm ± 10% and 330 deg. Horizontal movements for each arm.

ii. Vertical movement should be motorized and the arm height should remain to a height greater than 6.5 feet above floor level.

iii. Weight carrying capacity of the arm should not be less than 200 Kgs.

iv. Should have electromagnetic brakes.

v. Each arm should be capable of 300-340 degrees of rotation, which can be easily adjusted to suit the desired mode of operation.

vi. The Pendant Service Heads should be modular with minimum 400mm head. The heads should be capable of accepting a range of shelves and infusion poles or other accessories.

vii. The Pendant Heads should support the range of Physiological Monitor Mounting Solutions.
viii. The Pendant Service Heads should be supplied with medical gas terminal units and 15/5 Amps. Sockets.
ix. Each pendant should have:
1. Oxygen Outlets – 2 nos.
2. Vacuum Outlets: 02nos.
3. Air (7bar) Outlet: 02nos.
4. CO2 Outlet: 02 nos.
5. Electrical sockets: 6 nos.
6. Expandable shelf (minimum width: 70cm & Depth min. 45cm) with two rails one on each side: 5 nos.
7. Data socket RJ-45:2 nos.

Warranty: The Complete system should have 3 years of comprehensive warranty from the date of installation excluding consumables.

7. PORTABLE X-RAY

A. Product & Manufacturer Quality Standards:

1. The quoted model should have "USFDA (510K/CFG)" certified **OR** "EU-CE certified and the EU-CE certificate should be issued from notified body having notified body number **OR** IS 7620 or latest certified".
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted product must comply with or certified as per "IEC 60601-2-54" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601" for electrical safety standard.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.
5. The quoted model should have AERB type approval certificate.

B. Technical Specification:

Performance parameter: -

1. X-RAY GENERATOR:

a) Should be Microprocessor controlled High Frequency X-Ray Generator.
b) Should have output power of 4 KW or more.
c) Should have high frequency out-put of 110 KHz or more.
d) Should have KV Range of 40 - 120 KVp or more.
e) Should have MA range up to 100 mA.
f) Should have mAs range of 250mAs or more.
g) Should have Exposure Timer of 1ms to 5 sec.

2. X-RAY TUBE

a) Should have dual focus Stationary Anode X-Ray Tube.
b) Should have Focal Spot: 2 mm x 2 mm or less.
c) Should have Anode Heat storage capacity of 40KHU or more.

3. CONTROL PANEL:

a) Should be Microprocessor controlled High Frequency Mobile x ray machine.
b) Should be Micro Controller based control Panel with touch/feather touch switches for various operations and LCD disply.
c) Should have LCD display : KV, mAs, APR Program selection and indicators for error display.
d) Should have 2Point Technique (KV & mAs selection) for exposure
e) Should have Status and error display, Self-diagnostic program with LCD display of earth fault error, KV error, filament error and tube head thermal overload.

f) Should have LCD display and option of 120 or more A.P.R. parameters of human Anatomy, which helps the user to select exposure parameters based on body part, examination view and size of the patient.

g) Should have Dual action hand switch with retractable cord.

4. COLLIMATOR:

a) Should have double slot manual collimator for adjustment of exposure area

b) Should have Auto cut-off provision after 50 sec.

5. SPRING BALANCED MOBILE STAND:

a) Should have Spring Balanced Mobile (SBM) stand with 4 wheel design ensures easy mobility.

b) Should be Light weight design, easy to maneuver with smooth movement of tube head.

c) Should have integrated cassette storage box.

d) Should have light vehicle wheels for easy mobility.

e) Should have manual locks for all mechanical movements & Parking Lock.

f) Should be Light weight of less than 150kg.

g) Should have minimum Height of 150cm or less in parking position.

6. Accessories:

1) Lead Aprons (Full body and Skirt type 0.5 pb)-4 nos, Thyroid shield-4 nos. and Gonald Shield-4 nos. should be supply with each portable X-Ray machine. 2) Hand switch for X-ray exposure command control.

3) Power Cable having length 3 meter or more.

7. POWER SUPPLY:

Should work on Single phase 230 VAC, ± 15%, Frequency 50 Hz, 15Amp.

8. WARRANTY:

5 Years of Comprehensive manufacturer warranty on the equipment.

8. ICU VENTILATOR (Adult, Paediatric and Neonatal Use)

Product Quality and Safety standard certification:

1. The quoted model of ventilator along with the air compressor should have USFDA (510K/CFG) and EU-CE certified. The EU-CE certificate should be issued from a notified body having notified body number.
2. The quoted model should be certified to the electrical safety standard ISO 80601-2-12 particular requirement for basic safety and essential performance of critical care ventilator.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

- **Scope of the Equipment:** Intensive care ventilators are defined as mechanical ventilators that can be configured to provide invasive ventilation (e.g., with an endotracheal tube or tracheostomy tube) or noninvasive ventilation (eg, with a face mask).
- **Clinical application:** Mechanical ventilators are life support devices that move gas (e.g., air and/or oxygen) to and from a patient's lungs. These devices may provide temporary or permanent respiration for patients who cannot breathe on their own, or who require assistance maintaining adequate ventilation.

1. The ventilator should be use for Adult, Paediatric and Neonatal patients.
2. Ventilator should have Turbine based/ Compressor based technology.
3. Tidal volume range : 2 ml or less to 1500 ml or more.
4. Respiration rate or breaths/min should be 0-150 or more.
5. Should have both pressure and flow trigger mechanism.
6. Fi02 range should be 21 to 100 %.
7. Inspiratory flow rate - up to 180 L/min or more.
8. Inspiratory pressure – up to 80 cm H2O or more.
9. IE ratio : 1:10 to 4:1
10. Should have Sigh breath function .
11. should have PEEP/CPAP –upto 40 cm H2O or more.
12. Should have Pressure support 0-40 cm H2O or more.
13. Should have leak compensation technology.
14. Should have Auto 100%/Increase O2 button.
15. Should have Control panel lock.
16. Maximum wave forms displayed: 3 (Pressure and time, volume and time , flow and time).
17. Number of loops : minimum 2 loops (P-V, F-V) with facility of saving of 2 Loops for reference.
18. Maximum trending time in hrs : ≥24 hr
19. Should have Lung mechanics visualization tool.
20. Should have Volumetric Capnography /CO2 monitoring .
21. Modes of ventilation: Volume controlled, Pressure Controlled, Pressure Support, SIMV with Pressure support ,SIMV with volume control with pressure support, ,CPAP/PEEP, Inverse Ratio Ventilation, Non invasive ventilation, Apnea /back up ventilation, SIMV (VC) with Pressure support; SIMV (PC) with Pressure Support; SIMV (PRVC) with Pressure Support.
22. Should have Adaptive support ventilation ,APRV/Bivent/Bi Level , PRVC/Auto flow ventilation , High flow oxygen therapy , Automatic weaning system ,volume support tools.
23. The Ventilator is a Microprocessor Controlled ventilator with integrated facility for Ventilation monitoring.
24. Ventilator should display Peak inspiratory pressure , Mean airway pressure, PEEP pressure, Tidal volume, Minute volume, Spontaneous minute volume, FiO2 (analyzed %), Respiratory rate , Inspiratory time, Expiratory time, IE ratio, Plateau Pressure parameters.
25. Ventilator should have status indicator for Ventilator mode, Battery life, patient data, alarm settings, clock on display.

26. Ventilator should have patient alarms for Low/high FiO2, Low/high minute volume , Low inspiratory pressure , High pressure, Low PEEP , High PEEP , Apnea, Continuous high pressure/occlusion, Inverse IE, High respiratory rate, Breathing circuit disconnect.
27. Ventilator should give alarms for Gas-supply failure , Power failure, Ventilator inoperative, Low battery, Self-diagnostic.
28. Ventilator should have facility to measure Rapid shallow breathing index, static compliance, dynamic compliance, Inspired and expired resistance , Occlusion pressure, Inspiratory and expiratory hold , Spontaneous frequency, Total peep, intrinsic peep, extrinsic peep .
29. Expiratory block is autoclavable and no routine calibration required.
30. Should have facility for auto compensation for ET Tube. automatic compliance & Leakage compensation for circuit.
31. Ventilator should have RS 232 port for communication with Hospital and other network.
32. Should have LED or LCD or TFT touch screen colored display of size 12 inch or more.
33. NIV (Non Invasive Ventilation) to be possible in all modes of ventilation available.
34. Graphic display have automatic scaling facility for waves.
35. Machine should work with the Power supply 220-240 V , 50 Hz AC single phase.
36. In compressor based ventilator, Should supply compatible external air compressor having oil free Medical grade air, with Peak output flow should be 150 LPM or more and Air quality complying with ISO compressed air purity class. In Turbine based ventilator, The Turbine should be inbuilt and it should provide adequate Air to the ventilator.
37. Should be supplied with one ultrasonic nebulizer (inbuilt or external type) with particle size of less than 3 micron Along with each Ventilator.
38. **Warranty:** 3 years of comprehensive warranty on both ventilator (Complete Unit) and Compressor/Turbine from the date of installation excluding consumables.

39 .**Accessories supplied along with the machine:**

i. Reusable silicon breathing circuits for Adult, Paediatric and Neonatal : 2 each
ii. NIV mask(Re usable)-Small, medium and large : 2 each
iii. 3 mtr or more power cord -1 no.
iv. Reusable flow sensor-2 no. each for Adult, Paediatric and Neonatal.
v. Disposable flow sensor: 5 no. each for Adult, paediatric and Neonatal.
vi. Autoclavable exhalation valve/expiratory cassette / filter: 2 no.
vii. Humidifier: Should be supplied with one servo controlled humidifier with digital monitoring of inspired gas temperature with heating wire (Along with each ventilator). -1 no.
viii. Trolley for ventilator with circuit holding arm -1 set

9. FULLY AUTOMATIC ROTARY MICROTOME

Product & Manufacturer Quality Standards:

1. The quoted model should be "USFDA approved (Device listed with registration under valid FEI number /CFG)" **OR** "EU-CE approved and CE Marked" **OR** "BIS certified conforming to the standard BIS specification/ guideline specifically for 'Fully Automatic Rotary Microtome' and ISI marked with valid CML number."
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" or "IS/ ISO / IEC 80601 (Part 2)" or "IS 13450 (Part 1)".
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

- Fully Automatic Rotary Microtome should be Programmable.
- Vertical guidance should be by zero-backlash and maintenance free Cross Roller Bearings.
- Electronic precision feed & cutting mechanisms with Microprocessor Control and stepping motor technology.
- Automatic Specimen Retraction varying with Sectioning Speed.
- Special smooth running hand wheel. One hand quick clamp change.
- Hand Wheel option for Right sides
- Fine orientation with one hand operation and zero positioning, Easy exchange of specimens.
- Indication of cutting parameters.
- Communication display incorporated in instrument housing enclosed micrometer mechanism.
- Large section waste tray, covering the entire working area.
- Easy shift between trimming and sectioning operation should be available.
- Two motorized forward specimen coarse feed speeds must be available.
- Two separate programs for trimming and sectioning must be available.
- Section thickness range: 0.5 µm to 99 µm
  from 0.5 µm - 1 µm in 0.5 µm increments
  from 1 µm - 99 µm in 1 µm increments
- Trimming Section thickness range: 0.5 µm to 99 µm
  from 0.5 µm - 1 µm in 0.5 µm increments
  from 1 µm - 99 µm in 1 µm increments
- Horizontal Specimen Feed range must be 30mm.
- Vertical Specimen Feed range must be 70mm.
- Maximum Specimen Size: 50mm(L) x 60mm(H) x 40mm(W)
- Specimen orientation: x - and y – axes with 8° and Rotation: up to 360°
- Cutting drive: Automatic & Manual.
- 3 Sectioning Modes:
  - 1 Manual Mode
  - 1 Motorized Mode (Continuous)
  - 1 Motorized Mode (Single Stroke)
- Availability of Rock Mode.
- Cutting Speed adjustable.
- Operating conditions: +5°C up to +40°C for indoor use only.

- The equipment should be supplied Complete with: Universal Cassette holder, Knife holder base, Object orientation unit & Section waste tray.
- The equipment should be supplied with Disposable Blade Holder common for both High and Low Profile Blades. The machine should supply with 2 packets of disposable blades.
- Should be a Table top device.
- Nominal Voltage Supply: 230V, 50 Hz, Single Phase.

10. TISSUE EMBEDDING STATION

Product & Manufacturer Quality Standards:

5. The quoted model should be "USFDA approved (Device listed with registration under valid FEI number /CFG)" **OR** "EU-CE approved as per Annex-III of IVD 98/79/EC Directive or latest" and CE Marked" **OR** "BIS certified conforming to the standard BIS specification/ guideline specifically for 'Tissue Embedding Station' and ISI marked with valid CML number."
6. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
7. The quoted model should confirm to "IEC 61010" or "IS/ ISO / IEC 80601 (Part 2)" or "IS 13450 (Part 1)".
8. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

Should be in 3 part modular system with separate fully programmable automatic On/Off control for each of them.

Paraffin Dispensing Unit

1) Capacity of Paraffin Tank: should be minimum 3-5 litres.
2) Capacity of Thermal Chambers for storage of moulds: min 1.8 liters.
3) Temp. range of Paraffin tank: 50-70^{0}C.
4) Temp. range of Thermal Chamber: 50- 70^{0}C.
5) Temp. range of Hot plates & forceps wells: 50-70^{0}C.
6) Should have connection for electrically heated forceps .
7) Should have six heated wells for normal forceps, 3 on either side of the wax dispensing line.
8) Should have precisely metered and adjustable gravity feed paraffin dispenser to deliver the right amount of paraffin.
9) Should have both finger touch plate and foot switch for control of paraffin flow.
10) Should have large warm working surface on either side for min 10 cassettes on each side.
11) Should have digital display.
12) Should have a Magnifying lens adjustable in any position, large

Cold spot & illumination for specimen orientation.

Cold Console

1) Capacity of freezing up to 60 or more blocks at a time.
2) Temp. range of cold plate: 0-12^{0}C, adjustable in steps of 1^{0}C.
3) Compressor to be extra quite to reduce noise fatigue.
4) Cold console can work independently without switch-on dispensing console.
5) The system should work on 220-240 V, 50 Hz. Should use CFC free gas.
6) 3 years of comprehensive warranty.
7) To be supplied with 1000 nos. Plastic Embedding Rings for making paraffin Blocks and 100 nos. reusable Metallic Base moulds.

11.Electro Surgical Generator

Product Quality standard certification:

1) The quoted model should have "USFDA approved (510K/CFG)" and "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
2) The quoted model should have IEC 60601-2-2 Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Manufacturer Quality standard certification:

3) The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4) The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specification:

1.The system should be a microprocessor controlled surgical generator having Monopolar and Bipolar outputs designed for all surgical procedures including general surgery, gynecology, minimal invasive surgery, Orthopedic and ENT surgery.

2. Machine should be able to monitor changes in tissue impedance continuously and adjusts power.

3.Should have facility to connect two mono-polar electrodes.

4. Should have LED orLCD or TFT display of power settings for bipolar and mono-polar cut and coagulation modes. Display should be 3 or more segment.

5. Should have return electrode contact safety.

6. Should have different audible alarm for cut and coagulation modes.

7. Should have maximum range mono-polar cut power of at least 300 Watts variable in steps.

8. Should have Low cut mode having monopolar power 300 watt or more, Pure cut mode having monopolar power 200 watt or more and blend mode having monopolar power 200 watt or more.

9. Should have mono-polar coagulation power 120 Watt variable in steps.

10. Should have 3 or more bipolar modes having coagulation power of 80 watts or more.

11. Should have facility to set power through display or membrane key board.

12. Should have Patient plate monitoring facility.

13. Power efficiency of the device should be 98 % or more.

14. Should have advanced cutting modes for skin incision.

15. Should have a volume control for the audible alarm.

16. The performance of the unit should not be affected by electro-magnetic interference radiated or conducted through power lines from another device.

17. The working of the equipment should not interfere with the functions of other devices.

18. Should have alarm facility if contact between patient and patient plate is not proper.

19. Should supply compatible trolley with castor for mounting the device.

20. Warraty: 3 years comprehensive warranty on complete system.

21: Each machine should supplied with :

i. Foot paddle for Monopolar and bipolar(waterproof) – 1 No. Each

ii.Monopolar pencil switch : 50 No,s

iii. Disposable Patient return electrode/Pad: 50 Nos.

iv.Monopolar cable and bipolar cable for Laproscopy surgery – 5 No.s Each.

v.Universal adaptor- 1 no.

VI. Reusable Bipolar forceps-

Bayonet (Blunt tip1mm-0.7 mm) : 2 nos.

Straight (Blunt tip1mm-0.7mm): 2 nos

12. Steam sterilizer(High Pressure)

Product Quality standard certification:

5) The quoted model should have "USFDA approved (510K/CFG)" and "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
6) The quoted model should have IEC 60601-2-40 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

Manufacturer Quality standard certification:

7) The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
8) The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specification:

It should be fully automatically controlled double door Steam Sterilizer and should be horizontal in size with pre and post-vacuum treatment having chamber capacity of approx. 750 - 800 liters carrying 10 or more STU's per cycle.
The sterilizer should have inbuilt electric Steam Generator and vacuum pump.
It should be ergonomic and user-friendly design and loading height should not be more than 800 mm, in-built to use touchscreen at ergonomic height for user.
The sterilizer should have double door pneumatically operated vertical sliding doors. Pneumatic door cylinder should in stainless steel for eliminating the risk for particles which can be a problem when the door is operated via chains that has been lubricated.

Door Safety Systems:

1. Pressure monitoring system should be available in the chamber to monitor the chamber pressure before opening of the door. Chamber should be completely depressurized before the door seal is retracted by vacuum. Should have an essential safety feature that when the door seal is retracted the chamber is completely vented to atmosphere while the door is still retained in the fully closed and mechanically locked position.
2. Door chamber cannot be opened when chamber is pressurized.
3. A cycle should not start if the door is open or not properly locked.
4. Emergency stop should be there for extra door safety mechanism to protect staff from force of the door
5. The door seal should be made of silicon rubber gasket & on commencement of the process the door gasket is pressed against the rear face of the door by Air to ensure the door remains closed during the process.

Construction:

The chamber, doors and steam generator should be made of solid, high quality 316L Stainless steel. Water level indicator should be made of Stainless Steel and jacket should be made of hi graded SS .
The chamber should be jacketed to ensure the temperature uniformity in chamber. The chamber floor should be slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer protects the drain port from blockage by debris. The chamber should be mounted on a stainless steel framework with height adjustable feet.
The sterilizer jacket and doors should be completely insulated with 50 to 80 mm chloride free mineral wool thereby keeping the autoclave cool on the outside. The insulation should be completely encased in removable rigid aluminium sheet housing.
Steam Generator: The sterilizer should have an inbuilt steam generator of adequate capacity. It should be mounted under the sterilizer chamber & should be made of SS316L. The steam generator pressure vessel should be made of stainless steel. The sterilizer should be equipped with dual water connections for different water quality for cooling water and steam generator. All connecting pipes and valves shall be made of good quality stainless steel. Process valves are should be pneumatic. Chamber should be mounted on a framework which should have adjustable feet.

Vacuum Pump:

The Sterilizers should have a high capacity efficient liquid ring vacuum pump. It should be mounted on vibration isolator for quiet operation. It should be connected to condensers to assist air removal. It should also have low water level alarm to protect it from dry run. Disposable air filter (HEPA) should be provided for filtering the atmospheric

air before entering in the chamber. The filter separation efficiency should be higher than 99.99% H14 for particle size less than 0.3µm

(e) CONTROL SYSTEM & OPERATING PANEL:

1. The Sterilizer should be equipped with Microprocessor PLC control system which is dedicated to control the sterilizer including Digital Input Output for Sterilizer control Analog measuring Inputs COM ports for printer & PC communications. The Control System is operated via approx.

2. 8 to 10" Color touch screen, as a default the operator should have access to select cycle, start cycle & to close door. Digital display of Chamber Pressure, temperature, cycle no., Batch no., Time & date, alarm indicator, Low water indicator. Remaining cycle time also should be visible.

3. The operator should be able to run only type tested cycles. It should have visual and audible alertsfor the operator of program malfunctions and provides visual indication of process status.

4. Access to other functions such as setting parameters, calibration servicing and maintenance is controlled using pre-defined access level which prevents unauthorized access.

5. The Control system should have built in Linearization to correct the individual characteristics of each type of sensors.

6. Control system should have built in battery backup so that it can support the controller and operator panel for up in case of power loss.

7. The sterilizer shall be fitted with suitable PLC (Microprocessor) for fully automatic cycle operation instead of manual operation with 2''Fascia panel printer (mounted on control side)

8. The Control System should have comprehensive alarm/alert systems which automatically trigger pre-programmed information alerts.

9. In the event of any deviation in the type tested cycle, the control system should register an alarm

10. The system should give alarm for

i. Temperature & pressure sensor failure
ii. Phase time-outs
iii. Door(s) not properly closed
iv. Power failure (less than 10 seconds will be ignored)
v. Continuous self-checking of all safety devices
vi. Low water level (seal water to vacuum pump)

11.The Sterilizer should be equipped with following Pre-programmed cycles Programs should include:

i. Wrapped solid and hollow instruments, textiles, porous load (134°C). Type tested program for sterilization of medical devices, e.g. textiles, utensils.
ii. Wrapped, heat sensitive solid and hollow goods, rubber, plastic, porous load (121°C).
iii. Bowie & Dick test,
iv. Automatic Leak rate test,
v. Heavy load (134°C),
vi. Specific goods (134°C)

12. Each machine should supply with

i. sealing machine Packaging the items for sterilization- 01 No.
ii. Packaging material for 100 sterilization Cycles.
iii. Chemical and biological indicator for validation- 50 Cycles

13. **Warranty:** 5 years comprehensive warranty on complete system.

13. INFUSION PUMP

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG) Or EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.
2. The quoted model should be certified to the electrical safety standard IEC 60601-2-24, Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

1. Volumetric Infusion pump which can be use for Adult and Paediatric patient and can be run on all commonly used pressure IV Lines.
2. Should have facility to store up to 8 IV set brands for better accuracy.
3. Should have programmable Infusion modes such as Rate, Time, Volume, Micro and Macro mode of operation.
4. Flow rate range should be 1.0ml/hr to 999 ml/hr or more with increment start from 0.1ml/hr.
5. Flow rate accuracy should be ± 5 %.
6. The pump Should have programmable mode of Infusion having Units as :ng/kg/min, ug/kg/min, mg/kg/min, g/kg/min, U/kg/min, IU/kg/min, ng/kg/h, ug/kg/ h, mg/kg/ h, g/kg/ h, U/kg/h, IU/kg/h, ng/min, ug/min, mg/ min, g/min, U/min, IU/min, ng/h, ug/ h, mg/ h, g / h, U/h, IU/h , ml/h.
7. Should have inbuilt drug library of 1000 or more drugs.
8. Bolus rate of the infusion pump should be start from 1ml/hr to 999 ml/hr or more.
9. KVO(Keep vein open) Rate should be up to 5 ml/hr.
10. Should have Anti-bolus system for sudden release of occlusion with Selectable occlusion pressures and the device should have minimum 3 pre set level pressure mode (High, Medium, Low).
11. Display type should be LCD/TFT/Touch screen having good visibility and Contents of Display should be Flow Rate, Accumulated Volume, Battery Life, Power status, Drug Name& Lib, Syringe Size, KVO& Bolus, Dynamic pressure and alarms etc.
12. Should have Alphanumeric Programming Key Board.
13. The Machine should have built in feature for Anti free flow protection.
14. The device should have the Comprehensive Alarm package and should have audible & visual alarm with automatic pump stop function. alarm options include Occlusion pressure drop alarm, end of infusion alarm, air bubble alarm, rate error alarm, empty bag alarm, Door open alarm, low battery alarm, technical fault alarm etc.
15. The device should have Rechargeable Li-ion battery having minimum 6hr backup on full charge.
16. The model should have Protection against Solid and Liquid ingress (Ie. IP X4 or above

certified).

17. The device should have Capable to communicate via LAN/ RS232 Serial port and upgradable Wireless interface to connect any PDMS or HIS system.
18. Should have versatile clamp for fixation of pumps on a bed site rail or on a pole.
19. **Warranty:** The complete system should have 3 years of comprehensive warranty from the date of installation.
20. **<u>Accessories to be supplied with each machine:</u>**

    i) One Power cord in each pump,
    ii) One Clamp for mounting each pump at bed site rail or on a pole.

14. Double Dome OT light with Camera

Product & Manufacturer Quality Standards:

1. The quoted model should be "USFDA approved (Device listed with registration under valid FEI number /CFG)" **OR** "EU-CE certified. The EU-CE certificate should be issued from a notified body having notified body number" **OR** "BIS certified conforming to the standard BIS specification/ guideline specifically for "Double dome OT light" .
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" **OR** "IS/ ISO / IEC 80601 (Part 2)" **OR** "IS 13450 (Part 1)".
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid

Technical Specification:

1.The double dome OT light having LED technology of light emission.

2. The lamp head should be round shaped/petal shaped/winged having diameter of 550 mm to 700 mm .Material of the lamp head should be ABS.

3.No of LED mounted on lamp head should be 10 to 100 .

4. Light Intensity range of both the primary and auxiliary dome should be 160000 Luminous at 1 meter distance.

5. Should have color temperature range 3800-5000 k.

6. Life span of LED should be 60000 hours or more.

7. Should have illuminated field diameter of150-400 mm or better.

8. Should have Color rendering index of 96 or more.

9. Should have manual or touch screen control panel.

10. Should have User selectable intensity variation with digital display from 30 to 100% in 6 or more steps.

11.The light head should be so constructedas to provide optimum conditions for laminar flow.

12.The lamp head should have sterilizable handle at the center of the lamp head.

13. Should have illumination depth of 60 to 180 cm or more of OT light.

14. The Lens of the domes should be interchangeable and removable; the glass should be scratch proof to optimize light penetration.

15. OT light should be provided with drip free spring arms for easy maneuverability, total lateral viewing of the patient as well as 360^{o} rotation in main arm and light head.

16.The system should have Full HD Camera system from same OEM with Auto focus, autoiris camera, auto brightness control, freeze the image, rotation controlfacility, Resolution: Minimum 1080 horizontal lines, Minimum 20X Opticalzoom & minimum 12X of Digital zoom, Minimum illumination intensity of12.0 lux, Anti-flicker, Auto & Manual focus, video output of 1080i/50, Auto white balance,360 degree continuous rotation. The main lamp head should be camera preparation with full HD for present use and 4K preparation for future use.

17.should have full HD display LED monitor (minimum 24inches or more diagonally) compatible with the HD camera system .TheMonitor should mountable on 3rd arm .The quoted model shouldhave Multimedia Digital recording system for recording on internal hard diskof 1TB and DVD writer.

18. Should supply 3 numbers of sterilization handle.

19. Should supply online UPS having 1 hour battery backup.

20. **Warranty:** 3 years comprehensive warranty on complete system.Demo Should be the part of technical evaluation

15. SYRINGE PUMP

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG) Or EU-CE certified.
   The EU-CE certificate should be issued from notified body having notified body number.
2. The quoted model should be certified to the electrical safety standard IEC 60601-2-24, Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

1. The syringe pump should have Flow rate range from 0.1ml/hr to 999.9 ml/hr or more with increment start from 0.1 ml/hr or less and accuracy should be ≤2% on mechanism.
2. Should work on the following syringe capacities 5, 10, 20, 30/35, 50/60 ml. and should be Compatible with min 100 types of syringe.
3. Should have programmable mode of Infusion having Units as ml/hr, Volume / time, mg/ hr, µg/ hr, mg/ kg/ hr etc.
4. Should have inbuilt drug library of minimum 3000 drugs categorized in minimum 18 profile/ categories with facility to set all infusion parameters like soft limit, hard limit, bolus dose etc.
5. Pump should be equipped with drug error reduction software, which allows to configure drug dose soft & hard limit, to check over and under infusion of drug for patient safety.
6. Should have Auto bolus/Direct bolus option with flow rate up to 1200ml/hr or more (in 50 ml syringe) along with programmable bolus with settable volume/time and the bolus volume range should be 0.1 to 5ml or more in 0.1 ml increment .
7. Should have settable KVO (Keep vein open) option (ranging from 0.1 to 5ml/hr with feature to keep it off.
8. Should have Night mode programmed manually or automatically to decrease the brightness of the screen.
9. Should have The Dynamic Pressure System with maximum and minimum threshold setting for Fast start option.
10. Should have Anti-bolus system for sudden release of occlusion with Selectable occlusion pressures from 75 mmHG or lower to 900mmHg with at least 3 occlusion levels.
11. Display type should be LCD/TFT/Touch screen having good visibility and Contents of Display should be VTBI, Flow Rate, VI, Drug Name, Syringe Size, Dynamic pressure etc.
12. Should have Alphanumeric Programming Key Board.
13. Should save 1000 data log events in real time and should have graphical history of Volume/ dose infused, pressure and flow rate.
14. The device should have the Comprehensive Alarm package such as: occlusion pressure alarm, patient line disconnection, end of infusion pre-alarm, end of infusion alarm, volume limit pre-alarm, volume limit alarm, keypad manual locking or keypad lock, hard and soft flow rate limits, start infusion at pause end, plunger disconnect alarm, low battery pre-alarm, technical malfunction alarm, communication connection failure, preventive maintenance etc.
15. The model should have Protection against solid and Liquid ingress (Ie. IP 22 or above certified).

16. The device should have Rechargeable Li-ion battery having Battery run time at normal delivery rate (when fully charged): > 6 hrs at 5 mL/h and >2 hrs at highest delivery rate.
17. The device should have Capable to communicate via LAN/ RS232 Serial port and upgradable Wireless interface to connect any PDMS or HIS system.
18. Should have option of self stackability of minimum 3 pumps.
19. The device should have option of Docking station to fit in 4 or 6 pumps and Docking station should be able to communicate to HIS and should be HL7 compliant.
20. Should have versatile clamp for fixation of pumps on a bed site rail or on a pole.
21. **Warranty:** The complete system should have 3 years of comprehensive warranty from the date of installation.

22. **<u>Accessories to be supplied with Syringe pumps:</u>**

i) One Power cord in each pump,
ii) One Clamp for mounting each pump at bed site rail or on a pole,
iii) Docking station to connect multiple syringe pumps on a single patient.(4 or 6 pumps in a single dock)

(NB: Docking station shall NOT be Ordered with each Syringe pump and it shall not be supplied to all institutions but the same shall be Ordered and supplied to only the institutions where it is required now and as or when required by other institutions. Price for the "Docking station" should be quoted separately in the price bid (BOQ Format-B) which will be taken into price evaluation.)

16. **Dual Chamber Pacemaker**

Product Quality standard certification:

1. The quoted model should be USFDA (510k/CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.
2. The quoted model should have IEC 60601 certified for Electrical safety standard or equivalent BIS standards.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

5. 1. Compact, Easy to operate, Automatic lead and battery check, Continuous monitoring of the battery voltage, Shock and water resistant housing, Backup pacing during battery change.
6. Application: To be used to regulate the contractility of myocardiocytes to maintain adequate heart rate
7. Should have both Permanent Stimulation, Burst Stimulation
8. should have pacing Modes : DDD,VVI,AAI,DOO,VOO,AOO
9. Should have auto function AV Delay, PVARP, Sensitivity
10. Should have Atrial Sensitivity range of 0.4 mV or less to 10 mV or more and ventricular Sensitivity range of 1 mV or less to 20 mV or more.
11. Should have Stimulation Amplitude range 0.1 v to 18v or more
12. Should have Refractory period PVARP range of 150 ms or less to 500 ms or more
13. Should have Maximum/Upper tracking Rate (MTR) 80 ... 230 ppm or more,Basic pacing rate Rate 30 - 200 ppm or more and Rapid/high atrial pacing rate 80 – 800 ppm or more.
14. Should have AV delay 50 to 300 ms or more.
15. Should have alkaline batteries having battery life : 220 Hours or more
16. Weight of the machine should be 700 gm or less.
17. Should be safe against cross talk and defibrillator shock.
18. 3 years comprehensive warranty on complete system
19. Each machine should be supplied with two numbers of extension cables and two numbers of pacing cable.

17. FLEXIBLE FIBER OPTIC VIDEO BRONCHOSCOPE SET FOR ADULT AND PEDIATRIC

Product Quality standard certification:

- The quoted models should be USFDA (510k/CFG) Or EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.
- The quoted models should be certified to the electrical safety standard IEC 60601.

Manufacturer Quality standard certification:

- The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
- The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

System should Includes:

i) Adult HD Video Bronchoscope (1No.)
ii) Pediatric Video Bronchoscope-Slim (1No.)
iii) HD Video Processor Module – (1No.)
iv) Xenon/Multi LED (3 or more) Light source -(1No.)
v) High resolution Medical grade Full HD Monitor – (1No.)
vi) Online UPS- 1 nos
vii) Recording System and reporting software
viii) Trolley to mount complete system (1No.) Along with Standard accessories and consumable as mentioned below.

i) Adult Video Bronchoscope (1No.)

Should have following specifications:

- Lighter and possess High Definition image quality .
- Fully immerssible in disinfectant solution.
- Should have High Definition image(Full HD Endoscopy) with Chip on tip CCD/CMOS camera.
- Two or more no. of remote control switches on control body.
- Compatible with leakage testing device/ leakage tester.
- The Scope should have Digital Image enhancement technology for detailed diagnosis of mucosal.
- Should be Compatible with electro surgical and Laser device.

Field of view	:	120 degree or more
Direction of view	:	0-degree, forward viewing
Depth of field	:	3 to 100 mm or better
Distal end outer diameter	:	4 to 6.1 mm or less
Insertion tube outer diameter	:	6.0 mm or less

Tip Bending rage	:	Up 180 deg & more, Down 130 deg & more
Working length	:	600 mm or more
Channel inner diameter	:	2.8 mm or more

ii) <u>Pediatric Video Bronchoscope-Slim (1No.)</u>

Should have following specifications:

- Lighter and possess high Definition image quality .
- Fully immerssible in disinfectant solution.
- Should have High Definition image(Full HD Endoscopy) with Chip on tip CCD/CMOS camera.
- Two or more no. of remote control switches on control body.
- Compatible with leakage testing device/leakage tester.
- The Scope should have Digital Image enhancement technology for detailed diagnosis of mucosal.
- Should be Compatible with electro surgical and Laser device.

Field of view	:	90 degree or more
Direction of view	:	0 degree, forward viewing
Depth of field	:	3 to 100 mm or better
Distal end outer diameter	:	3.6 to 3.8 mm or less
Insertion tube outer diameter	:	4.0 mm or less
Tip Bending rage	:	Up 180 deg & more, Down 130 deg & more
Working length	:	540 to 600 mm or more
Channel inner diameter	:	1.2 to 1.5 mm or more

iii) <u>Video Processor:</u>

- Should have Full HD video Output with Analog, DVI-D x 2, RGB-TV x 1, S VIDEO x 1, VIDEO x 1 Full HD.
- Should contain the electronic Multi optical zoom for clear visibility of near & far objects
- Should have Digital Image enhancement technology for detailed diagnosis of mucosal.
- Compact, light weight and ergonomically designed
- Recording of both still & moving images
- Equipped with one touch connection of scopes and system should have Contact free technology.
- Portable Memory & USB Slot for image recording with 4 GB External memory USB (2GB)
- Automatic IRIS control & automatic white balance
- Electronic Zoom upto 2.0 X.

iv) Light Source:

- Light source should be 300 Watt xenon or LED equivalent to 300 watt having 3 or more LED & minimum average lamp life more than 5000 hours of continuous use. Should have special filter technology for real time optical Image enhancement technology

- Compatible for waterproof one touch connector.

- Backlit front panel indicators.

- Equipped with automatic light adjustment forced air cooling, regulated air feeding pump and fan with low noise**.**

v) High-Definition Monitor, Trolley and Leakage tester:

Minimum 24" High resolution full HD medical grade LCD color monitor with DVI input is must and system should be supplied with a movable trolley to mount the complete system and hand the scope along with leakage tester.

vi) Online UPS:

Online UPS (01 No) of rating 2 KVA with suitable trolley , with back up time of 30 minutes or more

Vii) Recording System and reporting software:

Should be supply with One complete set of Recording system(inbuilt/external) for still image and Video with standard computer system , Reporting software and laser jet color printer for Recording and reporting purpose. Memory of the system should be 2TB or more.

Viii) Required accessories and consumables compatible with Adult and Pediatric video scopes

i)Mouth piece Bite block for oral intubation - 20 Nos each, ii) TBNA needle - 02 Nos each for both the scope, iii) Cytology brush - 2 Nos each for both the scope,iv) Dormia basket -01 Nos each for both the scope , v)Alligator forceps - 2 Nos each for both the scope, vi)Cupped forceps -2 Nos each for both the scope, vii)Biopsy Forceps- 2 Nos each for both the scope ,viii) Grasping Forceps - 2 Nos each for both the scope ,ix) Mouthpiece - 01 No each for both the scope, x) Disposable Biopsy valve - 10 Nos each for both the scope, xi) Disposable suction valve-10 Nos each for both the scope ,xii)Gas sterlization Ventilation cap/valve-01 No each for both the scope , xiii)Cleaning Brush for working channel (Nos) - 2 Nos each for both the scope, xiv)Leakage tester- 1 nos each for both the scope.xv) Epoxy powder coated Rust free Trolley to mount complete system (1No.), Cidex Tray with lid for sterilization of both the scopes- 1 nos,

Warranty: The Complete system should have 3 years of comprehensive warranty from the date of installation excluding Instrument and consumables.

18. HEART LUNG MACHINE WITH HEATER COOLING UNIT

(a) Product Quality & Manufacturing Standard for Heart Lung machine & Heater Cooler Unit:

i. The quoted model should have "USFDA (510K/CFG/PMA)" **AND** "EU-CE certified where the EU-CE certificate should be issued from a notified body having notified body number".

ii. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".

iii. The quoted product must comply with or certified as per "IEC 60601" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601".

(b) Technical Specification of Heart Lung Unit:

1) The Heart Lung Machine should have direct drive pump mechanism to prevent noise, vibrations, wear and tear. Less down time and prolonged lifetime.
2) Heart Lung Machine Should has Incremental encoder with both Fine tuning and course adjustment for high flow (v/s potentiometers).
3) Heart Lung Machine should have Individual processors (CAN bus connection) for every pump starts in less than 10sec with no possible total system breakdown.
4) Heart Lung Machine should have Individual screens for every pump, which can easily be replaced.
5) Heart Lung Machine should have UPS battery back up to 90 minutes in normal working condition. (It shows time remaining, Charging conditions & Battery conditions).
6) Heart Lung Machine should have Horse Shoe pump head
7) Heart Lung Machine should have smallest foot print.
8) Heart Lung Machine should have Rotatable Heads.
9) Heart Lung Machine should have complete text message for warnings and alarms with different tones and with different color coding.
10) Heart Lung Machine should have Thumbwheel Locking Mechanism (Occlusion settings will not be drift and accuracy is 0.015mm).
11) Heart Lung Machine should have Touch Screen. BSA Factor can be set.
12) Heart Lung Machine should have Facility of making all the pumps pulsatile with master slave control.
13) Heart Lung Machine should have Mast Pump Available (Reduces tubing length and priming volume and can be taken close to the patient).
14) Should be modular / compact in design and the basic console should have a spill proof base which shall accommodate minimum 4 pumps with provision to attach an additional pumps as mast pumps. The console shall have (preferably) telescopic masts and cross arm, side guard where ever possible.
15) In all 5 numbers of direct driven roller pumps should be provided which should operate independently and should have controls such as power on-off, forward, reverse, pulsatile flow, etc. Of the 5 pumps 3 should be rated for flow capacity 0 -10 l/m and the other 2 pumps shall have flow capacity 0-1.5 l/m. At least one pump shall have pulsatile flow facility. One pump may be given as a mast pump with necessary fittings. Should have easy access connectors for interchanging the pump.

16) Each pump should be provided with tube clamp assembly and non-reversing hand crank. Each pump should have convenient hand occlusion setting. Each pump must display flow rates for various tubing sizes. Individual pump heads should have Harvey roller pumps with facility for tubing to be used adjustable from 3/16", 1/4" to 5/8" through 3/8" & ½" by easily changeable mechanism.
17) Individual pump heads should have display in digital- the total infusion volume in liters and delivery time, the flow rate in LPM and in RPM. Each pump should have easy mechanism for occlusion setting for different thickness of tunes available in the market, 1/32" to 3/32".
18) Should be provided with air bubble detection and oxygenator blood level detection facility. The system should provide both audible and visual alerts and alarms on detection, the arterial pump should stop in case low blood level is sensed, or air is detected.
19) The console should have a compact base mount for the entire pump heads together with pole and handles.
20) Should have variable changeable tubing holder in each pump head: 3/16", ¼", 3/8", 1/2", 5/8"& double ¼".
21) Should have a venous control module with single pole mast with electronic venous line occlude.
22) Should have movable oxygenator holder.
23) Should have a monitor mount with adjustable monitoring arm. Instrument tray position should be available with long monitoring arm. Light weight surface table; writing surface.
24) There should be provision for monitoring arterial line pressure and cardioplegia line pressure. Facility for monitoring minimum 4 temperature viz. core i.e. nasopharyngeal, rectal, arterial blood and cardioplegia shall be there with all required sensors, probes, transducers, etc. Timer should be provided for measuring total bypass time, ischemia time and elapsed time from cardioplegia and total duration of cardioplegia delivery. 4 temperature display

for patient monitoring and for cardioplegia monitoring with digital display in Celsius with 4 necessary compatible temperature probe and 6 additional probes(6x2=12 probes) with 3x2=6 of them for nasal, rectal & esophageal use.
25) Facility for 4 time display- 2 for arterial & 2 for cardioplegia delivery. With stop, reset and start function.
26) Pump should have self diagnostic circuit with provision to detect and display the following alarm conditions i.e Over speed, Pump jams & Over occlusion. It should have provision of feeding the flow constantly while using a tube of unknown internal diameter.
27) Should have computer interface capability.
28) Suitable line UPS with voltage regulation & spike protection for 2 hours & battery backup to provide power to minimum two higher flow pumps, all safety monitors and the console LED/halogen lamp for minimum two hour. Switch over from main power to battery backup should be automatic and immediate. The battery unit should be built in to the pump base and it should be recharged automatically when the system is operating with main power supply.
29) Should have a suitable flexible high intensity halogen/LED lamp assembly with adequate length and maneuverability duly mounted.
30) The unit should be provided with blender for air and oxygen to work at 50 to 60 PSI for membrane oxygenator with water trap attached with necessary hoses & connector of minimum of 5 meter length & with triple flow glass flow meter.
31) It should have suitable gas flow meter.
32) Should be provided with electronic or mechanical occlude for controlling venous occlusion.
33) The central control monitor shall preferably have a high resolution TFT/LED touch screen display.
34) Should be provided with suitable poles and arms for mounting sensors and monitors.
35) Should be provided with holders for mounting pressure transducers.
36) Should be provided with hoses and hose adapters and connectors for connecting to local gas supplies O2 & Air. (As per site).
37) Safety monitor should have capability for computer interface to retrieve perfusion data ultrasonic air sensor. Ultrasonic air sensor to detect bubbles to work equally well with crystalloid and blood; should be possible to fit anywhere in the circuit easily. Level sensor system: Ultrasonic transducers to work with crystalloid and blood with adhesive pads, with alarm settings.
38) Remote control module for the temperature control monitor optional remote control unit should be capable of taking 9 temp. Probes and display temperature in digital readouts. Alarm limits setting for at least probes at crucial sites.
39) Occlusion: - Should have thumb wheel locking mechanism
40) Pressure sensor should have 2 modes: - Stop & control mode.
41) Level sensor should be with 2 modes: - Normal & control mode

19. Hemotherm

1) Simultaneous delivery of water for arterial and cardio-plegia heat exchangers and to thermal blankets to be available from suitable ports. Pressure regulated blanket ports maintaining the temperature of the atrial port.

2) Temperature display should range from 2 to 41 degree Celsius remote accuracy of 0.3 degree Celsius & remote temperature display unit module with 3-temperature display.

3) Should be microprocessor based unit to control, cool, re-warm & maintain temperature.

4) Water outlet temperature of heat exchanger and blanket should range from 0-42 degree Celsius.

5) Should have separate tank for Cardio-plegia and Patient.

6) Should have feature to restrict ICE formation.

7) Should be 3 or more different tanks for fast and accurate temperature adjustment.

8) Should have independent outlet for cardio-plegia delivery system and exchanger.

9) Three Tanks with three circuits to ensure fast cooling and heating will be preferred.

10) Should have provision for connecting patient blanket.

11) Should have two adult and two pediatric heating cooling blankets of standard sizes.

20. STERNAL SAW & REDO SAW WITH BATTERY CHARGER

(a) Product Quality & Manufacturing Standard:

20. i. The quoted model should have "USFDA (510K/CFG/PMA)" AND "EU-CE certified where the EU-CE certificate should be issued from a notified body having notified body number".
21.
22. ii. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" OR "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" OR "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".
23.
24. iii. The quoted product must comply with or certified as per "IEC 60601" OR certificate issued from BIS conforming to "IS 13450" OR "IS/ISO 80601".
25.
26. (b) Technical Specification of Sternal Saw:
27. 1) Should have Safe Mode.
28. 2) Should have two speed controls with standard and fast mode. Free speed of 1000 to 13000 cycles per minute.
29. 3) Weight of hand piece with battery should be not more than 3.0 lbs.
30. 4) Microprocessor controlled Hand piece can be calibrated for the consistence Performance.
31. 5) Should have DC brush less motor for low maintenance.
32. 6) No lubrication require for lifetime.
33. 7) Should have Pistol grip Hand piece.
34. 8) Should have tool less mounting of accessories for all blades or attachments.
35. 9) Saw noise level should not more than 84db.
36. 10) Should be autoclavable.
37. 11) With different blades it should have maximum speed of 13000CPM
38. 12) Should be quoted with Two Sternum Guards.
39. 13) Accessory- Should be supplied with Sterilization case (2 nos.) and should accommodate all hand pieces, attachment and accessories can be autoclaved.
40. 14) Accessory- Supplied with Vertical Reciprocating Sternum blades free of cost (30 nos).
41. (c) Technical Specification of Redo Saw:
42. 1) Should have two speed controls with standard and fast mode. Free speed of 10000 - 12000 cycles per minute.
43. 2) Microprocessor controlled Hand piece can be calibrated for the consistence Performance.
44. 3) Saw Noise level should not be more than 84db.
45. 4) Weight of hand piece with battery should not be more than 3 lbs.
46. 5) Blade mount should be adjustable to different angles with 360 degree rotation.
47. 6) Should have tool less mounting of accessories.
48. 7) Should have DC brush less motor for low maintenance.
49. 8) No lubrication require for lifetime.
50. 9) Should be autoclavable.
51. 10) Should have safe mode.
52. 11) Blade arc of excursion should be up to 5 degree.
53. 12) Accessory-Supplied with Redo Oscillating saw blades free of cost (30 nos).
54. 13) Accessory- Should be supplied with Sterilization case (2 nos.) and should accommodate all hand pieces, attachment and accessories can be autoclaved.
55. (d) Technical Specification of Battery charger:
56. 1) Should be 220-240 volts charger with feature to count the charging cycle for a particular battery.
57. 2) Should have capability to identify the worn out battery.
58. 3) Should be able to charge four batteries at a time without any module or modification need.
59. 4) Should have an indicator to provide battery status for charging.
60. 5) Should be able to check over autoclaved battery cycles (Number of Time and Total Time).
61. 6) Should have reconditioning futures for Ni-cd battery.
62. 7) Should be able to charge different batteries with same charger.

63. 8) Charger should be of Li-ion Cell chemistry and should also be compatible with Ni-Mh & Ni-Cd batteries with low Internal impedance to deliver higher current than other battery type.
64. 9) Should be 9.9 volts with capacity of 2.2 Ah.
65. 10) Weight should be not more than 0.9 lbs.
66. 11) Li-ion cell with capacity to produce more torque.
67. 12) Should have 200 approximate & average charging cycles.
68. 13) Should have a run time of minimum 21 minutes.
69. 14) Should be autoclavable batteries.
70. 15) No need for re-conditioned with no memory effect.
71. 16) Should have Indicator light to inform user of low battery life.
72. 17) Should have capability to regulate Voltage to prevent battery energy level from being drained below a safety threshold where cells could potentially be damaged.
73. 18) Should have capability to measures and Store Autoclave Abuse.
74. 19) Should have safety features like Shuts off current to battery terminals when hand piece is not connected.

21.FIVE PART FULLY AUTOMATED CELL COUNTER

A) STANDARD QUALITY CERTIFICATION (Supporting document shall have to be submitted for below mentioned standards)

1. **Product:**The quoted model should have USFDA (510K/CFG) approved and EU-CE certified as per Annexure-III of IVD Directives 98/79 EC or latest.

2. **Manufacturer:**The manufacturer should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.

3. **Electrical Safety:** The quoted model should conform to "IEC 60601" **OR**" IEC 61010" **OR** " IS/ ISO / IEC 80601 (Part 2)" **OR** "IS 13450 (Part 1)".

4. **CDSCO Registration:**The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B) TECHNICAL SPECIFICATION:

Performance parameters:

1. The Instrument offered should be a closed system.

2. The Instrument should be based on LASER based scatter analysis principal.

3. The equipment should be 5-part WBC differential with Retics and NBRC enumeration capability.

4. The Instrument should have following reporting parameters**: WBC, RBC, HGB, HCT, MCV, MCH,MCHC, PLT, RDW-SD, RDW-CV, PDW, MPV, P-LCR, PCT, NEUT#, LYMPH#, MONO#, EO#, BASO#, NEUT%, LYMPH%, MONO%, EO%, BASO%, IG#, IG%, RET#, RET%,IRF, PLT-O, WBC-BF, RBC -BF, MN#,PMN#, MN%, PMN%.**

5. Following Discrete analysis modes should be available in the Instrument: **CBC, CBC+DIFF, CBC+RETIC, CBC+RETIC+DIFF, CBC+NRBC, CBC+Diff+NRBC, BF Analysis.**

6. Precision (CV) value for various Haematologic parameters measured should be less than equal to 3%.

7. The Instrument should have Tri Angle Laser Flow Cytometry analysis method for WBC.

8. Dual angle light scatter/fluorescent dye base method for platelet measurement should be available.

9. Light scatter measuring technique method should be used for RBC measurement.

10. HB measurement should be based on cyanide free colorimetry.

11. On board light scatter (fluorescent dye/retic stain based) for reticulocytes should be available.

12. The Instrument should have at least 4no of sample racks to cater to different tube sizes.

13. The instrument should have auto loader facility.

14. Maximum sample Aspiration volume needed in all modes should be 300ul or less.

15. Minimum sample volume required in all modes should be 30ul or less

16. Throughput capacity in CBC/Differential should be at least 100 samples or more.

17. Throughput capacity in Retic mode should be 45 or more.

18. The instrument should have closed vial mode for sample running.

19. Hemoglobin linearity of the equipment should be 0 to 22.5 gm/litre or higher &Rectic linearity should be 0 to 23 or higher.

20. The instrument should have option of Auto dilution or Predilution& should have Platelet clot detection facility.

21. The equipment should have both manual and automatic type of calibration.

22. The instrument may have facility for direct aspiration for capillary blood.

23. The equipment should have an option for Separate diluting nozzles for RBC and WBC.

24. The equipment should have Double bathing mechanism.

25. The equipment should have option to be integrated with "Fully automated Slide Maker & Slide Strainer" and also can be integrated with similar units in future during increase of workload.

26. Type of data management of the equipment should be Inbuilt/PC based.

27. The equipment shall be supplied with PC having the following features:

    a) Display option in the equipment should LCD/LED/TFT.

    b) PC hard disk space should be >500 GB

    c) Processor should be I5 or more.

    d) RAM should be 8GB

e) HDD should be 500GB

f) Monitor size of PC based should be more than 17 Inches or more/ Inbuilt Monitor size should be more than 5 Inches or more

g) HIS/LIS Interface should be RS232

h) Should provide with bar code reader.

i) Type of external storage option should be USB

j) No of USB Port provided with the equipment should be 4 or more.

28. The equipment should have additional External color Laser Printer.

29. Database capability of storing sets of results and graphics should be >= 25000.

30. The equipment should have L J Plot facility and Delta check for cumulative review.

31. On line QC option should be available with the Instrument along with patient moving average.

32. QC File management should be available with the Instrument.

33. 3 KVA UPS should be provided with the Instrument having backup time of 60mins.

34. The equipment should be supplied with start-up kit for 1000 samples.

35. The Instrument should come with Network integration with lab information system feature.

Note: The bidder shall have to quote the cost of all type of reagents required to be procured of same OEM of the equipment as Close System in the separate price bid format (i.e Format-A) of the price bid in pdf format which shall taken into account of price evaluation along with the cost of the equipment and same shall be approved for 5 yrsfrom the date of signing and acceptance of the contract.Non-submission of format A as well as not specifying the cost of all reagents required for performing the tests as described, shall lead to rejection of bid during financial evaluation.

22.i. AUTOMATED BLOOD CULTURE SYSTEM

A. Product Quality Standards:

1. The quoted model should be "USFDA approved (510k/CFG)" **AND** "EU-CE approved as per Annex-III of IVD 98/79/EC Directive or latest".
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" OR "IS/ ISO / IEC 80601 (Part 2)" OR "IS 13450 (Part 1)". Additionally, should also conform to IEC 61010-2-81 (Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes).
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification:

1. Fully automated system capable of culture of blood and sterile body fluids for bacteria (aerobes and anaerobes), fungi in the same system with 200 or more samples vial capacity with facility of adding more samples vials in future as up-gradation option. **(The cost of the up-gradation option of additional sample vials should be quoted in Format-C which shall NOT be taken into price evaluation).**
2. During the warranty period whenever any software up-gradation is available, it should be intimated to the end user within 1 month of its availability and it should be given by the company free of cost.
3. System should be based on sensitive fluorescence/colorimetric/nephelometry technology for interpretation of results.
4. Should have in built calibration check/facilitate calibration. Calibration process should not incur any additional cost in form of and not limited to calibration kit or consumables.
5. Quality control measures should be clearly defined.
6. System should have specific algorithms for detection of growing microorganisms and should be capable of continuous monitoring of all samples for growth of microorganisms.
7. System should be having continuous agitation and incubation facility to provide optimal growth of microorganisms.
8. The bottled media should be capable of neutralizing effect of antibiotics.

9. System should be capable of processing both adult and pediatric samples.
10. System should have interface for lab information system (LIS).
11. System should have an external computer/touch screen monitor and laser desk jet printer and barcode reader.
12. Should be capable of exporting data to external drive for long term storage.
13. Should work at an Operating ambient temperature range 20 to 30 degree Celsius (the operating temperature mentioned at the GENERAL REQUIREMENT is not applicable for this equipment).
14. Should be compatible with the Automated Microbial Identification/AST System along with the software and other accessories to run the system synchronously.

C. Power Backup: Online UPS of suitable rating should be supplied by the vendor to give minimum of 1 hour back-up to the entire system.

D. Warranty Period: 5 Years of comprehensive warranty on the entire system and Online UPS excluding consumables.

E. Periodic Preventive Maintenance: The service provider should perform quarterly Onsite Periodic Preventive Maintenance.

F. Reagents & Consumables: The following consumables required:

a) Aerobic Adult Bottle.
b) Anaerobic Bottle.
c) Aerobic Pediatric Bottle.
d) Other non-liquid based consumables**.**

22. ii. AUTOMATED MICROBIAL IDENTIFICATION/AST SYSTEM

A. Product Quality Standards:

1. The quoted model should be "USFDA approved (510k/CFG)" **AND** "EU-CE approved as per Annex-III of IVD 98/79/EC Directive or latest".
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" OR "IS/ ISO / IEC 80601 (Part 2)" OR "IS 13450 (Part 1)". Additionally, should also conform to IEC 61010-2-81 (Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes)
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification:

1. Analytical parameters: System must work on colorimetric/Flurometric and/or nephelometry/turbidometry and redox technology for identification and susceptibility testing.
2. Panel capacity: The system must have the capacity to accommodate minimum of 50 or more tests (either 50 ID and/or AST tests) or combo, at any time.
3. Type of panels: It should have different panels. (ID & AST separately depending on the user to save cost) it should be based on advanced colorimetric/Flurometric principle.
4. Panels: Identification and susceptibility panel of Gram Positive, Gram Negative and Yeast.
5. Testing base: Should be on disposable sealed bar coded card (ready to use) and automatic/ manual transfer of inoculums.
6. Data base: The System should have database more than 2000 or more reference phenotypes/ profile number.
7. Sample dispensing: System should not require any manual dispensing of Inoculum to avoid human error, it should be done automatically.
8. Bar Code: Positive sample identification with the bar code on the card. (ID or AST card)
9. Printer: External printer for direct report print outs.
10. Software: Should be Windows based, user friendly with touch screen key pad. Should facilitate monitoring of all the functions of a Microbiology lab and infection

control procedure (HAI). Software should be compatible with Blood culture system. Comprehensive antibiotic scope including the latest drugs, compliments formulary needs. During the warranty period whenever any software up-gradation is available, it should be intimated to the end user within 1 month of its availability and it should be given by the company free of cost.

11. Should have facility to design user defined alerts and option for designing drug suppression rules as per hospital internal infection control policy (Antibiotic policy). Customized reports, nosocomial and epidemiology reports should also be obtained. Software should be compatible with blood culture system to get report on blood volume monitoring as requirement of different accreditation bodies**.**

C. Online UPS: Online UPS of suitable rating should be supplied by the vendor to give minimum of 1 hour back-up to the entire system.

D. Warranty Period: 5 Years of comprehensive warranty on the entire system and Online UPS excluding consumables.

E. Periodic Preventive Maintenance: The service provider should perform quarterly Onsite Periodic Preventive Maintenance.

F. Reagents & Consumables: The following consumables required:

a) Gram Negative ID.
b) Gram Positive ID.
c) Yeast ID.
d) Anaerobic ID.
e) Streptococcus AST.
f) Yeast AST.
g) Gram Positive AST.
h) Gram Negative AST.

23. FULLY AUTOMATED COAGULATION ANALYZER

A) QUALITY STANDARD CERTIFICATION (Supporting document shall have to be submitted for below mentioned standards)

1. **Product:** The quoted model should have USFDA (510K/CFG) approved and EU-CE certified as per Annexure-III of IVD Directives 98/79 EC or latest.

2. **Manufacturer:** The manufacturer should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.

3. **Electrical Safety:** The quoted model should conform to "IEC 60601" **OR**" IEC 61010" **OR** " IS/ ISO / IEC 80601 (Part 2)" **OR** "IS 13450 (Part 1)".

4. **CDSCO Registration:** The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B) TECHNICAL SPECIFICATION:

1. Configuration Model: It should be bench top model.
2. System Type: Should be a closed type system.
3. Throughput (PT tests/hr): Should be able to perform at least 130 tests per hour or higher.
4. Throughput (APTT tests/hr): Should be able to perform at least 90 tests per hour or higher.
5. Throughput (Simultaneous PT&APTT tests/hr): Should be able to perform at least 110 tests per hour or higher.
6. Method Used for clotting assay: Should be photo-optical/Transmittance/Light scatter/ Mechanical clot detection.
7. Immunologic Assay: Instrument should have immunologic assay
8. Chromogenic Assay: Instrument should have Chromogenic assay
9. Should require Centrifuge for sample
10. Sample type: Should be plasma
11. Should have minimum 40 or more onboard sample capacity at a time.
12. Should have continuous loading capability of samples and reagents.

13. System should have at least 2 dedicated stat sample positions.
14. System able to perform platelet aggregometry test is optional(YES/NO)
15. Should have a STAT Facility for emergency samples
16. System should have at least 4 or more measurement channels.
17. It should have at least 50 or more user defined settings
18. System should be capable of performing PT INR,APTT,TT Test,D-Dimer Test, , Factor Assays, Inhibitor assay, LA1, LA2, Protein S and C, Plasminogen, Plasmin inhibitor,

    AT-III.
19. Should have Flagging of PT value when results exceed 120 seconds.
20. Should have APTT value provided when results exceed 180 second.
21. System have Multi wave length testing is optional (YES/NO).
22. System have wave form analysis is optional (YES/NO).
23. It should have dispensing feature.
24. System should be able to perform direct sampling.
25. Close- tube sampling in the system is optional (YES/NO).
26. Direct track sampling feature in the system is optional (YES/NO).
27. Auto sampler in the system is optional.
28. It should have LIS Interface feature.
29. It can read the bar code of reagents.
30. It should be supplied with a Laser Printer.
31. It should have an Automatic Calibration feature.
32. Inbuilt Quality Control feature should be available.
33. It should have onboard consumable loading option.
34. Inventory management can be controlled by software.
35. It should have liquid level detection feature.
36. Dead Volume for vial size 1-2 ml should be less than or equal to 200 microlitres .
37. Dead Volume for vial size 4-6 ml should be less than or equal to 200 microlitres .

38. Data management type should be PC Based or Inbuilt system with latest windows (Windows 7 or advanced) along with LCD monitor having monitor size 15 inch or more with hard disk of more than 500GB and at least with 2 USB port.

39. It should be supplied with a UPS backup system of 60 minutes.

Note: The bidder shall have to quote the cost of all type of reagents required to be procured of same OEM of the equipment as Close System in the separate price bid format (i.e Format-A) of the price bid in pdf format which shall be taken into account of price evaluation along with the cost of the equipment and same shall be approved for 5yrs from the date of signing and acceptance of the contract.Non-submission of format A as well as not specifying the cost of all reagents required for performing the tests as described, shall lead to rejection of bid during financial evaluation

24. DEFIBRILLATOR

Product Quality and Safety Standards Certification:

1. The quoted model should be USFDA (510k/CFG) or EU-CE certified. The EU-CE certificate should be issued from notified body having notified body Number.
2. The quoted model must be IEC 60601-2-4 certified Particular requirements for the basic safety and essential performance of cardiac defibrillators or equivalent BIS standard certification.

Manufacturing Quality Standards Certification:

3. The manufacturer of the quoted product should have ISO 13485 Certificate issued from notified body or ICMED 13485 (with or without) certificate issued from Certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered ,the acknowledgement copy of the online application for the said registration must be uploaded in the bid.

Technical Specification:

1. Capability parameter of defibrillator: ECG monitoring, external defibrillation,
2.Technology of defibrillator: Biphasic technology
3. Modes in defibrillator: Automated External Defibrillation and manual
4. Maximum energy selection: 200 joules **or more**
5. Capability of ECG Monitoring through : ECG leads , multi function electrodes , paddles.
6. Number of wave-forms: 2 or more
7. Patient compatibility to defibrillate: Adult and pediatric patients
8. Type of display: TFT or LCD
9. Size of display screen: 6 inch or more
10. Provision to display ECG waveform on bright high resolution display: Yes
11. Facility to have synchronized cardio version: Yes
12. Ability to CPR Feedback and display CPR index on screen: Yes
13. Provision of within built rechargeable battery: Yes
14. Battery backup to deliver number of shocks at maximum energy: 50 or more.
15. Weight of defibrillator with battery and paddles in Kg: 7 kg or less
16. Provision of in built thermal recorder: Yes
17: Provision of printing ECG trace & stored information: Yes
18: Facility of External non-invasive Pacing: Yes
19: Type of external transcutaneous pacing modes: Demand mode, fixed mode (asynchronous) ,Both Demand mode and fixed mode.
20. Pulse width of external non-invasive pacing in milli seconds: 40
21. ECG monitoring: using 3 lead or more
22. Provision of user selectable alarm settings: Yes
23: The machine should work on mains as well as on rechargeable battery: Yes
24: Ability to select energy from paddles or main unit : yes
25. Ability to charge and discharge through paddles as well as from main unit: Yes
26. Charging time for maximum energy: 7 seconds or less
27. Mechanism of self test of unit: Automatic and manual
28. Unit should do self test with facility to give printout of defibrillator testing report and also have code ready indicator on unit : Yes
29. Suitability of defibrillator for intra hospital transport : Yes
30. Defibrillator should display selected energy: Yes

31. Defibrillator should display delivered energy: Yes

32. Availability of suitable protection for dust and water: Yes

33. Accessories to be supply with each Machine:

i. Li-ion rechargeable Battery – 1 no.
ii. ECG Patient cable- 1 no.
iii. External defibrillator paddles (paediatric in built in adult) -1 set.
iv. Recorder paper roll -10 nos.
v. Multi function Defibrillator & Monitoring pads/gel sheets: 10 no.
vi. Gel bottle – 5 no.

Warranty: Comprehensive warranty should be 3 years for the Defibrillator and 1 year for reusable accessories from the date of installation excluding consumables.

25. DIRECT DIGITAL FLAT PANEL FLUOROSCOPY & RADIOGRAPHY SYSTEM

A. Product & Manufacturer Quality Standards:

1. The quoted model should have "USFDA (510K/CFG/PMA)" **AND** "EU-CE certified where the EU-CE certificate should be issued from a notified body having notified body number".
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted product must comply with or certified as per "IEC 60601" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601".
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.
5. The model should have AERB type approval certificate.

B. Technical Specification:

1. High powered X-Ray unit with direct digital flat panel equipped with completely integrated high-frequency generator, digital detector and Digital Image processing system. It should be capable of performing all plain and contrast enhanced radiography and fluoroscopy procedures.
2. The system should have the following essential configuration:

a) Table:

1. Floor mounted adjustable height table with floating table top of carbon fiber or equivalent suitable, scratch resistant surface.
2. Compact Bucky table with digital flat panel detector.
3. Continuously motorized remotely controlled longitudinal and transverse and vertical movements.
4. Motor-assisted digital detector movements synchronized with tube movements.
5. Motor driven + 90/-20 degree or more table tilt along with Digital angle display.
6. Removable grid for SID of 100cms for horizontal table applications.
7. Remotely controllable compression and controllable collimator.
8. Patient load 160kg or more.
9. System should have well designed foot switch for releasing fluoroscopy & acquisition.
10. System should have provision for collision protection.
11. Pressure injector should be provided with the system.

b) Digital Detector for Fluoroscopy & Direct Radiography:

1. Single Digital flat panel Detector of size 35 x 43cm or more, made of amorphous silicon with CSI scintillator.
2. Image Matrix 2688 x 2208 or better.
3. DQE > 65% at 0.05lp/mm.
4. Specify details of Image resolution.
5. Digitization depth 14 bits or more.
6. Pixel size should be 150 micron or less.
7. Three zoom levels.

8. Should allow centered/de-centered collimation.
9. Specify refresh cycle (time for second exposure).

c) Monitors:

Four number ultra-high resolution, high-definition monochrome monitors, medical grade 19" LCD or more for high-contrast (minimum 2.0 mega pixel), distortion free image display – separately for the live and reference images. Two monitors to be ceiling suspended in exam room and two in control console. Post-acquisition image processing, viewing, reprocessing, hard copy documentation and onward transmission should be possible while doing fluoroscopy or radiography.

d) X-Ray Generator:

1. Microprocessor controlled high-frequency generator with power output of 80kW at 1000 mA or 100 kW at 800mA.
2. Radiography:
   i. KV range: 40-150KV.
   ii. mA Range: up to 1000mA in radiography.
   iii. Minimal exposure time 1ms or less.
   iv. Anatomical programmed Radiography.
3. Fluoroscopy:
   i. Kv range: 40-110 kv or better.
   ii. mA range: 0.5 to 5mA or better.
   iii. Pulsed fluoroscopy should be available.
4. Protection required from overload and main supply automatic compensation.
5. Automatic exposure control. It should be possible to override AEC if required.

e) X-Ray Tube:

1. One number ceiling suspended/ Floor Mounted/Couch Mounted Dual focus X ray tube with rotating anode with 9000 rpm or more.
2. Anode heating capacity 300 kHU or more. Mention the heat dissipation rate.
3. Dual Focus Tube with small focal spot size size 0.6 or less and large focal spot 1.2mm or less. X-Ray tube rating should be compatible with X-ray generator output.
4. Small focal spot power rating should be in the range 30 to 50 kW.
5. Large focal spot power rating should be in the range 70 to 90 kW.
6. Longitudinal movement of tube across the patient must be 90 cm or more.
7. Rotation of X-ray tube assembly +/ -90 degree or more.
8. Variable SID 150cm or more motorized adjustments.
9. Should have provision of electromagnetic locks with collision protection sensors.
10. Multi-leaf collimator having halogen lamp/bright light source and auto shut provision of the light.
11. Collimator must be mounted on x-ray tube and Collimator must have an integrated Dose.
12. Area Product (DAP) meter. Output of DAP meter should be visible in software console.

f) Direct Digital imaging System for fluoroscopy:

1. Field of view of at least 40cms or more.
2. Collimator may be rectangular or iris type.

3. System should have real-time optimization techniques to maintain constant brightness at the lowest allowable dose to the patient.
4. Should have Cine loop facility and last image hold facility during fluoroscopy.
5. Acquisition matrix at least 1024X1024 at 10 bit rate.
6. Digital fluoro system in standard continuous fluoroscopic operating mode from single image display to serial exposures with varying frame rates. Please specify frame rate in continuous fluoroscopic operating mode and pulsed fluoroscopy mode.

g) Control Console, Image Processing, Image display, Image storage system and Transmission

1. Latest image acquisition system.
2. All system movements of table shall be controlled by the operator at the table in the examination room and also at the console.
3. The system should have fast and direct access to all series, single images, in both examination (Remote controlled and console room).
4. System should have angle/distance measurement, image labeling and patient positioning facilities.
5. System should have on line dosimeter on the console to display actual radiation dose or display on small console.
6. Fully loaded Digital Subtraction Angiography with all features (optional).
7. Spatial resolution should be 3 lp/cm or more.
8. Contrast should be high.
9. Multiple image display of 9 inch or more in one format.
10. Alphanumeric patient data input and Patient directory.
11. Image processing functions: The system should have facility for edge enhancement, positive/negative image display, windowing, contrast/brightness, electronic shuttering, image/pixel shifting, vertical and horizontal image reversal, text input, roaming and zoom functions.
12. Image storage with last image hold.
13. Storage of fluoroscopic images (optional).
14. Post-acquisition image processing, viewing, reprocessing, hard copy documentation and onward transmission should be possible while doing fluoroscopy or radiography.
15. Image stitching software.
16. Footswitch for fluoroscopy and release should be available.
17. Hard disk having capacity of at least 30,000 images in 1024 x 1024 matrix on the main system disk. or more including fluro loop sequence. The systems should be capable of storage of images on compact discs/DVD .DICOM Software with fast speed DVD Combo (Reader and Writer separately). Should be provided with 2 TB External hard disk to save the images as backup purpose .
18. The system should be DICOM 3.0 (or higher version) ready (like send, receive, print, record on CD/DVD, acknowledge etc.) for connectivity to any network, computer/PC etc. In DICOM format. A DICOM Print facility should be available to connect to a network Laser/Dry Printer.
19. The vendor should supply a compatible Laser/Dry camera with the DR system having a minimum resolution of 500dpi or more.

20. Easy integration and networking should be possible with future up-gradations (HIS and RIS and PACS).

H. Essential accessories:

21. Light weight lead aprons – 6 Nos. with Wall mounted Hangers(6) for radiation protection aprons- 1no
22. Thyroid shields - 6 Nos. (3 pediatric and 3 adult).
23. Lead Gloves -2 pairs
24. Lead Goggles -4 nos.
25. Gonad shield Male and female - 2 nos
26. The vendor should supply the lead sheet for the X-Ray room doors.
27. Voltage Stabilizer Servo Controlled 150 KVA – 1 No.
28. Lead Glass viewing window (2mm lead Equivalence) 100 cm x 150 cm - 1 No.

C. Warranty: The quoted model should have 5 years comprehensive warranty on the entire system.

26. ETO Sterilizer

Product Quality standard certification:

9) The quoted model should be either "USFDA approved (510K/CFG)" or "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
10) The quoted model should have IEC 60601 certified or Certificate issued from BIS conforming to IS 13450 or IS /ISO 80601. Sterilizer should be compliant with EN-1422 guideline and ROHS Directive 2011/65/EU.

Manufacturer Quality standard certification:

1) The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
2) The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specification:

1. The ETO gas sterilizer should be fully automatic type for sterilization of heat sensitive goods such as cardiac catheter with lumen 1mm and more and length of 30 cm till 200 cm., anaesthetic tubing and other plastic disposable materials etc.
2. The sterilization chamber should be double walled, corrosion and gas resistant of suitable alloy.
3. The inner surface should be smoothly finished to minimize gas deposits.
4. The chamber shall be insulated against heat emission and jacket shall be connected to warm water circulation arrangement.
5. The sterilizer door shall have a quick release locking arrangement, with door opening to the sides.
6. Suitable safety interlocking arrangement shall be provided for the door so that the sterilization process does not start unless the door is properly locked in position and during the programme run it should not open.
7. The sterilizer shall be provided with suitable vacuum pump and gas trap to separate and evacuate the gas.
8. The ETO sterilizer should be able to operate for the minimum essential following cycles programmes:
   a) Sterilization cycle for heat sensitive objects that ensure temperature from 33-55degree C with subsequent aeration for protection of the operating personnel.
   b) Aeration cycle/programme to extract residual gas out of the sterilized objects after each sterilization cycle.
   c) Automatic chamber evacuation cycle with subsequent venting before releasing the door lock for opening, thereby prohibiting exposure of the operating personnel by gas dissolving from the chamber walls during shutdown period.
   d) Gas disposal arrangement/catalytic converter.
9. Should have Sterilisation Chamber capacity 200 litres or more.

10. Each ETO sterilizer should supply with following accessories:
   a) Sterilization basket of suitable size: 1 No.
   b) EO Gas cartridge: 50 No.
   c) Packaging material with chemical indicator of all sizes, 5 roll.
   d) Sealing machine: 1 No.
11. Gas cartridges should be EPA certified.
12. Sterilization method: Cold sterilization of heat sensitive material.
13. Operating temp. Range: 33 to 55 C
14. No. of doors in the machine should be One.
15. All regulatory requirements for installation, including safe disposal of exhaust gas via copper pipe as per existing regulatory norms to be done by supplier.
16. The supplier shall obtain all necessary clearances for commissioning of ETO in liaison with the consignee. The supplier should visit the installation site & liaison with project team to meet all pre installation requirements.
17. Comprehensive warranty of 5 years on the complete system.

27. HIGH FREQUENCY GENERATOR X-RAY MACHINE (500/600mA)

A. Product & Manufacturer Quality Standards:

1. The quoted model should have "USFDA (510K/CFG)" certified **OR** "EU-CE certified and the EU-CE certificate should be issued from notified body having notified body number **OR** IS 7620 or latest certified".
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted product must comply with or certified as per "IEC 60601-2-54" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601" for electrical safety standard.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.
5. The quoted model should have AERB type approval certificate.

B. Technical Specification:

The X ray machine should be microprocessor controlled High Frequency Radiography machine using latest technology to optimize patient dose emission while providing excellent reproducibility and superior contrast.

Performance parameter: -

1. X-Ray Generator:

a) It should have Microprocessor controlled High Frequency X-Ray Solid State Generator.
b) Generator output should be 50KW or more.
c) Should have Generator frequency of 50KHz or more
d) Should have KV range of 40 to 125KV or more
e) Should have mA range of up to 600mA or more
f) Should have mAs range of 1mAs to 200mAs or more
g) Should have exposure timer range of 1ms to 10 sec or more.

2. X-Ray Tube & Collimator:

a) Should have dual Focus, Rotating Anode X-Ray Tube, Thermally protected. Small Focus: 0.6 mm^2 or better, Large Focus: 1.2 mm^2 or better. Anode heat storage capacity of 300KHU or more.
b) Should have Double slot collimator for full field illumination (LED) and adjustment of exposure area with Auto cut-off provision.

3. Control Panel:

a) It should have micro controller based Large touch / Soft Feather touch LCD display control Panel with user friendly User Interface.
b) Control panel should be floor mount type.
c) Should have 6" or more LCD display for KV, mA, ms, mAs, APR Program, error display .

d) Should have provision of 2 Point Technique and 3 Point Technique for exposure and should have radiography control for kV, mA, ms and mAs.

e) Should have Touch Screen/ soft feather touch LCD display of APR parameter and selection of 200 or more APR of Anatomy, which helps the user to select exposure parameters based on body part, examination view and size of the subject.

f) Should have dual action hand switch with retractable cord.

4. Stand:

a) Should have ceiling free Tube stand, Floor rail mounted with manual movements & counter balanced tube head.

b) Column rotatable ± 90º (180º) and tube head rotatable ± 90º and should have convenient movements. Should have Electromagnetic locks.

c) Material used in tube column stand should be made of corrosion free material like Aluminium, Titanium, super alloy etc.

5. Table:

a) Should have 4-Way Floating Table Top with waterproof, stain free & low radiation absorption paper phenolic white laminated radiolucent material such as carbon fibre/Bakelite/Melamine.

b) Should have Electromagnetic Locks controlled through foot switch for table top movement.

c) Should have Table Top dimension of 220cm x 80cm or more

d) Should have Longitudinal movement of +300mm or more

e) Should have Transverse movement of +125mm or more

f) Should have motorized reciprocating oscillating bucky with integrated high density Anti Scatter Grid* with grid ratio of 10:1, grid density of 103Lines/inch, grid size 17 ¼" X 18 7/8", accommodate cassette size 8"x10" to 14"x17".

g) Bucky should Travels entire length of the table and locked at desired position by Electromagnetic lock.

h) The table should have Anti-collision system for safety.

i) Should have accessories like Stainless Steel cassette tray and Compression band with the table.

j) Should have Patient Weight carrying capacity of 200Kg or more.

6. Vertical Bucky Stand:

a) Should be Floor Mounted Vertical bucky stand with vertical travel upto 1000mm or more equipped with stainless steel cassette tray.

b) Should have Electromagnetic locking system operated through cassette tray Hand Grips.

c) Should have Oscillating Bucky with integrated high density Anti Scatter Grid* with grid ratio of 10:1, grid density of 103 Lines/inch focus at 115cm

d) Bucky should accommodate cassette size 8"x10" to 14"x17"

e) It should be counterweight balanced.

f) Material used in vertical Bucky column stand should be made of corrosion free material like Aluminium, Titanium, super alloy etc.

g) Should have provision of doing chest radiography without grid.

7. Power Supply:

Should operate on Three phase 400 V.AC, ± 10%, Frequency 50 Hz.

C. Accessories:

1. The quoted model should have Patient fixing belts and compression device (for performing excretory urography).
2. The equipment should be supplied with 50KVA servo controlled voltage stabilizer.
3. The vendor should supply the lead sheet for the X-Ray room doors and lead glass for X-Ray console room viewing window having size: 100cm×150cm (2mm lead Equivalence).
4. Lead Apron full body skirt type (0.5pb)- 2 nos.
5. Light weight zero lead radiation protection aprons- 2 nos.
6. Male and female gonad shield- 2 nos. each.
7. Thyroid shield- 2 nos.
8. Wall mounted stand for radiation protection aprons- 1no.
9. Footstep (2 step) for the table- 1no.
10. Lateral cassette holder- 1no.

D. Warranty: The quoted model should have 5 years comprehensive warranty on the entire system and stabilizer.

28. CRYO MACHINE

(a) Product and Manufacturer Quality standard:

i. The quoted model should have "USFDA (510K/CFG/PMA)" AND "EU-CE certified where the EU-CE certificate should be issued from a notified body having notified body number".

ii. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" OR "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" OR "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".

iii. The quoted product must comply with or certified as per "IEC 60601" OR certificate issued from BIS conforming to "IS 13450" OR "IS/ISO 80601".

(b) Technical Specification:

1) The Cryo System should be Programmable based.
2) The system should have Cryo system with flexible Cryo Probes from the same OEM to perform Biopsies, Recanalization, ablation/devitalization & any Cardio Vascular Application.
3) LCD/LED/TFT/Monochrome Display.
4) Can be activate through footswitch.
5) The minimum freezing temperature should reach within 5 seconds or less.
6) Mounted on good quality mobile cart with wire basket.
7) CO2 Cylinder compatible with cooling gas - CO2 gas as coolant.
8) Provided with connection pipe for gas exhaust.
9) Flow controlled for operating gas pressure between 45 – 65 bar.
10) Feature to count the reprocessing cycle of the instrument.
11) Effect Settings should available up to 2 depending on the type of instruments used.
12) Programmable memory of up to 10 settings with activation from Foot Switch.
13) Machine can use in Frequency of 50/60Hz with an in line current of 0.4-0.8 Amp.
14) The System should compact and the weight should be less than 7 kg.
15) The offered Cryo system should be able to get synchronized with other compatible Energy Units (Diathermy, Argon plasma).
16) Of same make so that it can be used in Advanced Pulmonology & any cardiovascular procedures.
17) The Cryo System should be supplied with autoclavable probes as below:

a) Reusable flexible probes, size of 2.4mm diameter x length 900 mm -5 No.
b) Reusable flexible probes, size of 1.9mm diameter x length 1150 mm -5 No.
c) Disposable cryo probes of diameter – 1.1mm, 1.7mm & 2.4mm. – 5 No. from each.
d) Compatible CO2 gas cylinder (filled) -2 no.
e) Along with the standard accessories to make the machine functional.

(c) Standard Accessories & Consumables: All necessary accessories and consumables required to operate the machine shall be supplied.

29.ENDOSCOPE WASHING STATION

(a) Product and Manufacturer Quality standard:

i. The quoted model should have "USFDA (510K/CFG/PMA)" **OR** "EU-CE certified where the EU-CE certificate should be issued from a notified body having notified body number".

ii. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".

iii. The quoted product must comply with or certified as per "IEC 60601" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601".

(b) Technical Specification:

1) The Endoscopic washing station should be able to reprocess two scopes simultaneously.
2) The Endoscopic washing Machine should be able to perform ultrasonic cleaning and high pressure cleaning to remove debris from the endoscope.
3) The Endoscopic Washing Machine should have different sensors that include:
a) Pressure Sensor.
b) Disinfectant Level Sensor.
c) Leak Detect Sensor.
4) It should be compatible with all kinds of flexible endoscopes.
5) It should have different time settings for various steps during disinfection such as cleaning, disinfection, drying etc.
6) It should be compatible with most types of disinfectants like Gluteraldehyde, Paracetic acid etc.
7) Supply water flow – 17L/min. or more.
8) Should have built in heater in cleaning tube.
9) Cleaning tube capacity – Approx 14 L.
10) Disinfectant solution tank capacity – Approx 17 L.
11) Alcohol flushing for drain purpose, preferably automatic.
12) Machine should be compact and movable.
13) Operating voltage 220- 240 V AC & Frequency 50Hz.

30. LAPAROSCOPE SYSTEM

- **PRODUCT QUALITY STANDARD CERTIFICATION**:
  1. The quoted model should be both "USFDA approved (510K/CFG)" and "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
  2. The quoted model should have IEC 60601-1-2 standard or better for Electromagnetic Compatibility (EMC) and for radiated and conducted emissions.
- **MANUFACTURER QUALITY STANDARD CERTIFICATION**:
  1. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
  2. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.
- **TECHNICAL SPECIFICATION**:
  1. The system should Supply with 4k endoscopic camera with video processor system, LED light source with fiber optic light cable, HD documentation system,4K medical grade monitor, CO2 insufflators, High flow irrigation device and Laparoscopic telescope along with surgical hand instrument.
  2. The components like 4k endoscopic camera with video processor system, LED light source with fiber optic light cable, HD documentation system, CO2 insufflators, High flow irrigation device, Laparoscopic telescope, surgical hand instrumentmust be from the same OEM.

i. **4K ENDOSCOPIC CAMERA WITH VIDEO PROCESSOR SYSTEM**:

1. The 4K Camerashould have the resolution of 3840*2160 or more.
2. The video processor should be capable of Near Infrared fluorescence for ICG application.
3. Camera should have 3 or more programmable switch and white balance can bedone by the camera headorconsole.
4. The system should have Digital Zoom to enhance the quality of Image size & cross specialty standardization.
5. The camera head should be able to capture images and record video sequences using HD documentation system from same OEM only.
6. System should have facility to offer various visualization modes for surgery and diagnosis by shifting the color spectrum light for recognition of finest tissue structures and their differentiation.
7. Camera head should sterilize through Soakable or autoclavable by ETO/Plasma.
8. The video processor should have the 4K SDI or Display port 1.2 or 12G SDI along with DVI, HDMI, 3G SDI videooutputports.
9. The camera head should be able to perform both White light and near Infrared application.
10. The video processor has the facility of connection of video flexible endoscopes for the use of GI surgery/General Surgery.

ii. **LED LIGHT SOURCE WITH FIBER OPTIC LIGHT CABLE**:

1. Should be compatible for fluorescence imaging for ICG application.
2. LED light source with life span 30000 Hour or more with color temperature range is 6000K to 6500K.
3. Should have continuous adjustment facility of light intensity from 0 to 100% manually or automatically.
4. Thickness of the Fiber optic cable should be 3.5 mm or more and Length of the Fiber optic cable should be 230 CM or more.

iii. **HD DOCUMENTATION SYSTEM**:

1. System has the provision for storage of still images, video sequences and audio files in full HD format and should operate via touch screen, camera head buttons or foot switch.
2. Should have full HD 1920*1080 video recording having internal memory capacity 500 GB or more.

iv. **4K MEDICAL GRADE MONITOR:**

1. Should be a 32inch or more LED Flat-panel Medical grade Color Monitor having 3840 x 2160 or more resolution with aspect Ratio:16:09.
2. Monitor should have 4K video input& Output. Should have Picture in picture mode.Monitor should supply with Stand, and video cables.

v. **40 LITRES or HIGH INSUFFLATOR**:

1. Digital Touch Screen Electronic CO2 Insufflator with Gas heating & highest degree of patient safety.
2. High flow mode with flow performance up to 40 l/min. Gas flow: 0-40 l/min or MORE., Pressure: 0-30 mmHg (4000Pa).
3. High flow mode (0 to 40 l/min. or MORE), Sensitive mode pressure 15 mmhg & flow 15 l/min for sensitive application.
4. Electronic control and color touch screen.
5. Following data are displayed on touch screen:
   A. Insufflations mode.
   B. Set value pressure (0-30 mmHg) & Current patient pressure.
   C. Set value gas flow (0-40 l/min or MORE) & Current gas flow.
   D. Gas consumption (0-999 l).

vi. **HIGH FLOW IRRIGATION DEVICE with TOUCH PANEL CONTROL**:

1. Controlled high pressure irrigation unit for Laparoscopic, Operating Cystoscope and TCRE procedure to maintain intrauterine cavity pressure as desirable by surgeon. Pressure of irrigation to be maintained between: (pressure 0-500mmhg) or more with Flow to be maintained between 0-1000ml/L or More.
2. Main unit with Touch Panel digital display, pump head, indicator and preset and actual value for pressure, flow, with sensor attachment for reusable dome.
3. Should be supplied along with DISPOSABLE IRRIGATION Tubing Set-5 no's.

vii. **LAPAROSCOPIC TELESCOPE AND SURGICAL HAND INSTRUMENT**:

Wide Angled Telescopes with the 4K-ICG systems should be quoted with Dimensions as below: -

1. 10mm, 0-degree UHD 4K-ICG TELESCOPE with 30cm or more has working Length – 01 Nos.
2. 10mm, 30-degree UHD 4K-ICG TELESCOPE with 30cm or more has working Length – 02 Nos.
3. Safety trocar, 11 mm -02 Nos.
4. 5mm, 0 Degree UHD 4K-ICG TELESCOPE with 30cm or more works Length – 01 Nos.
5. 5mm, 30 Degree UHD 4K-ICG TELESCOPE with 30cm or more working Length – 01 Nos
6. 6mm safety trocar -02 Nos.
7. Reusable Veress Pneumoperitoneum Needle Spring loaded blunt stylet luer lock length 13 cm– 4 NOS.
8. Reusable Veress Pneumoperitoneum Needle Spring loaded blunt stylet luer lock length 15 cm – 2 NOS.
9. Reusable Trocar: - 6mm – Multifunctional, insufflation stopcock, pyramidal tip, length (10.5cm), multi-Functional valve - 06 no's
10. Reusable Trocar: - 11mm Multifunctional valve, insufflations stopcock, pyramidal tip, length (10.5cm), multi-Functional valve - 3 Nos.
11. Suction and Irrigation Cannula-Size 5mm length 36cm, used with suction & irrigation handle, size – 2 Nos.
12. Suction and Irrigation Cannula-Size 10mm length 36cm, used with suction & irrigation handle, size – 2 Nos.
13. Grasping forceps STRAIGHT toothed 2X4 teeth-Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33-36 mm, dismantling facility- 2 Nos.
14. Grasping forceps straight- LONG toothed 2X3 teeth-Single action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33-36 cm, dismantling facility-2 Nos.
15. Maryland forceps-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility– 2 Nos.
16. Grasping forceps-Atraumatic-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility - 2nos.
17. Grasping forceps-Allis-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility – 2 nos.
18. Grasping forceps, Right angle , length 33 cm, Diameter 5 mm –o2 No.
19. Grasping forceps BOWEL CURVED- Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33-36 cm, dismantling facility size 5 mm only-2 Nos.
20. Grasping forceps-plain dissection & Grasping-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility – 2 nos.
21. Grasping forceps- Babcock-Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33-36cm, dismantling facility, size 5mm - 2 Nos.
22. Hook Scissors-Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility- 2nos.
23. Rotating spoon shaped Scissors- Double action Sharp jaws, rotating with connector pin for unipolar coagulation size 5 mm, length 33-36 cm, Reusable -2 nos.
24. Rotational Bipolar coagulating with fine Atraumatic Serration- size 5 mm, length 33-36 cm fenestrated-2 nos.
25. ROTATIONAL Bipolar coagulating Maryland DISECTING & GRASPING forceps-Size 5 mm, length 36 cm, 3 mm width of jaws - 2 nos.
26. High Frequency MONOPOLAR Cord for 5mm hand instruments –5 nos.
27. High Frequency BIPOLAR Cord- 5 nos.
28. Knot pushers – Eye type, length 33-36 cm – 2nos. for intra and extra corpal knotting.
29. Needle holder coaxial type-5mm, tungsten tip, straight handle with ratchet, single moving jaw, length 33-36cm - 2nos. with carbide insert tips for straight and curved needles.
30. CAP REDUCER – 11/5 MM – 2 Nos.
31. REDUCTION SLEEVE – 11/5 MM – 2 Nos.
32. L-Hook-Size 5mm, length 33-36cm with pin for cautery- 2nos.
33. Spatula-Size 5mm, length 33-36cm with pin for cautery - 2nos
34. Washers-For 5& 10mm cannula and reducers - 40 each.
35. Assistant needle holder-5mm dia with a working length of 33-36 cms with carbide insert tips for straight and curved needles – 2 Nos.
36. Injection and puncture canula-5 mm diameter, 33-36cms length with luer lock - 2 nos.
37. Long Tooth Tissue Extractor 10mm Dia, 33-36Cms length with Luer Lock – 2 Nos.
38. Clip Applicator –LT 300 Qty 1 no., with compatible clip 50 No.
39. Clip Applicator- LT 400 Qty 1 no.,with compatible clip 50 No.
40. Hemolock clip applicator (all 3 sizes)qty 1 each ,with compatible clip 20 each.
41. Liver retractor, Fan shaped Diameter 5 mm, length 33 cm, qty– 1 no.
42. Double action jaw Stone extractor, Length 33 cm, dia 10 mm, qty -1 no.
43. Fascia closer ,2.8 mm diameter , 17 cm length -1 No.

44. LT 300 compatible Clip Applicator-Medium -Size -Rotatable, Provision for locking the shaft conveniently, 10mm, 1 nos with 50 No. of clip.
45. LT 400 compatible Clip Applicator - Large-Rotatable, Provision for locking the shaft conveniently, 10mm, 1 nos. with 50 No. of clip.
46. Hemolock applicator, diameter 5mm ,01 no
47. Hemolock applicator, diameter 10 mm ,2 No.
48. Hemolock Clips – 50 No.

viii. <u>ADDITIONAL ACESSORIES: -</u>

Each system should supply with following accessories:

1. Co2 cylinder ((9 Kg or higher) with compatible Regulator &High-pressure tubing- 2 sets.
2. Customized Lap Equipment Trolley -1 No.
3. 1KVA Online UPS-1 No.
4. FORMALIN CHAMBER of Minimum 26 inch- 2 Nos.
5. CIDEX TRAY - 2 Nos.

6. DISINFECTANT: - Aldehyde Free Medical Device Disinfectant contain 0.25% w/v at 16.2g/liter peracetic acid generated import in-situ from tetramethyl ethylene diamine (TAED) and Sodium Percarbonate, surfactants, corrosion inhibitor, excipients. (810g Bottle) Powder based effective against Bacterial spores in 10 minutes. Should be CE approved. – 2 Bottle

X. Warranty: **5 years** comprehensive warranty on complete system.

31. **General Operating Table**

Product Quality standard certification:

1. The quoted model should be USFDA (Listed with registration under valid FEI number/CFG) and "EU-CE approved and CE marked" or IS 7596: 2021 certified from BIS.
2. The quoted model should have Test Certificates / Reports conforming to IEC 60601-2-46 certified ,particular required for the basic safety and essential performance of operating table Certificate issued from BIS conforming to IS 13450(part 1) or IS/ISO 80601(Part 2).

Manufacturer Quality standard certification:

1. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
2. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

- The Table should provide an elevated surface for supporting the patient's body and include specific apparatus for supporting and/or providing traction for the patient's limbs during orthopedic procedures. These tables stabilize the patient's position and provide the operating surgeon with optimal exposure of the surgical field. Applications for these tables include both upper-extremity procedures (e.g., shoulder surgery, nonoperativemyelograms, spinal surgery) and lower-extremity/hip procedures (e.g., hip pinning, Ender nailing, intramedullary nailing of the femur, tibia, and fibula).
- Should have Electro-hydraulic actuator and all the movements should be through remote and backup panel.
- Table should have Trendelenburg / reverse Trendelenburg, lateral tilt, longitudinal shift, height adjustment, anti flex and flex position, back plate up / down movements and zero position by singleclick through remote/auxiliary switch through remote control. Also the table should have a emergency stop switch to stop the table during any electrohydrolic failure or incident.
- Operating Table along with all the attachments should be C-Arm Compatible and Radiolucent.
- The table top should have 6 or more positions.
- The table should have manual override system with auxiliary switch for all electro hydraulic function(height up/down, side tilt, trendelenburg, back up/down, and table top slide) and should be operated through foot pump after selection from selector mounted on table.
- The Table should have an anti collision system to prevent collision if any object or C-arm comes closer to the table top.
- The table should have Wheel mounted and Central locking mechanism.
- Table top length should be 1900 mm -2100 mm or more.
- Table top width should be 500 mm -580 mm or more.
- Minimum table top height should be 700 mm or less & maximum height should be 1000mm or more with ±5% tolerance.
- Material of the Body should be 304 grade SS.
- Should have latex free fully radiolucent, detachable, impermeable to fluid and easily washable mattress.
- The range of angle should be
    a. For Trendelenburg& Reverse Trendelenburgposition : 25 to 30 Degree
    b. For Lateral tilt left and right: 18 to 25 Degree
    c. For Head Section UP/Down: 45 to 90 degree
    d. For Back Section UP/Down: 90 to 30 degree
    e. For Horizontal Positioning left and right: 0 to 90 Degree
    f. For Leg Section UP/Down: 20 to 90 degree
    g. For Flex: Upto 230 degree

h. For Reflex upto 100 degree

- Table top longitudinal sliding, Range should be 5 inch to 12 inch or more.
- Should have patient weight bearing capacity 150 kg or more.
- Should have detachable head, leg and pelvic section.
- Should have battery backup of 3 Hr or more.
- Both arm board should have up and down and rotation function.
- Each table should supply with
    a. Anesthetic Screen with side clamp & lock - 1 set
    b. Arm rest with side clamp & lock -1 pair
    c. Shoulder support with side clamp & lock-1 pair
    d. Lithotomy with side clamp & lock-1pair
    e. Extension bar-1pair
    f. Horizontal Attachments-1no
    g. Number of Foot Support -2 No.
    h. Number of Bolster Pillow – 2 no.
    i. Supports bars – 2 no.
    j. Radial setting clamps – 4 No.
    k. Side rail extension – 2 No.
    l. Restraint body strap-1pair
- Should Operate in 220-240 Volt, 50 Hz , AC .
- 3 years comprehensive warranty on complete system.

32. Echocardiography Scanning System

Product Quality standard certification:

1. The quoted model should be USFDA (510k/CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.

2. The quoted model should have Test Certificates / Reports conforming to IEC 60601-2-37 : Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment or Certificate issued from BIS conforming to IS 13450 or IS / ISO.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.

4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

1. Echocardiography System have scanning facility of Cardiac (adult and paediatric),small organs, TEE(adult and paediatric),, vascular scan.
2. Should supply with
    i. Adult TTE probe of Frequency range 3-5 MHz (±2) : 1 number
    ii. Pediatric TTE probe of Frequency range 5-7.5 MHZ (±2) : 1 number
    iii. Adult TEE Probe of frequency range 2-7.5 MHz (±2) : 1 number
    iv. Pediatric TEE Probe of frequency range 3-8 MHz (±2) : 1 number
    v. Adult/Pediatric Linear probe-1 No
    vi. Matrix linear probe.
3. Should have Dedicated 3D/4D volume imaging for cadiology adult TTE ad adult TEE probes
4. Should have Live 3 D imaging in color doppler system
5. The Colour Doppler system should have application packages like ,Quad loop for serial studies with high frame rate revies, harmonic imaging capability in all modes and integrated stress echo package, digital storage and retrieval .
6. Should have 256 db or more grey shades for sharp contrast resolutions.
7. Should have High-definition acoustic zoom provision for enlarging sections of 2D and Colour flow images with more acoustic information for greater clarity and detail while maintaining an optimal frame rate.
8. Should have Colour Flow Imaging, Tissue Colorization (B-Colour) for improved contrast resolution .
9. Should have both Vascular and Transesophagal applications(inbuilt) for Adult and Paediatric
10. Should have features like
    i.Cine Loop having memory 2000 frames or more.
    ii. Frame grabber facility for post analysis
    iii. Various maps for pre and post processing
    iv. ECG trigger facility
11. Should have Dedicated integrated dynamic stress echo package for flexible user defined protocols with stacked sub loops facility and contrast stress protocol usable for stress echocardiography.
12. Should have Provision of Tissue movement colorization with quantification possibility for IHD/CAD/Heart Failure patients
13. Machine should have four or more transducer/probe ports.
14. Machine should have Scan modes like Cardiac 3D/4D automatic , B-Mode, M-Mode, Contrast Harmonic/Agent Imaging with angio mode, Tissue harmonic imaging mode, Provision of Harmonic imaging in TTE, TEE and Linear Probes , Color Doppler imaging (CDI), Power Doppler imaging (PDI), Continuous wave, Pulsed wave,Duplex wave, Triplex wave, Tissue Doppler imaging, Contrast-

enhanced ultrasound (CEUS) option, Tissue synchronization, tissue velocity , Gain control in two dimensions for additional level of flexibility for image quality control , Real time high frequency 2D,

15. Should provide probes of latest generation bandwidth with higher sensitivity for low frequency Doppler.
16. Should have 50000 or more channels in colour Doppler system.
17. System should be capable of generating real time live 3- D images
18. System should be capable of of Echocardiographic strain and strain-rate imaging with 2 D and 3D imaging.
19. **Image display and processing** : have the facility
    i.Display should be Dicom 3.0 Compliant
    ii.Adjustable transmit focus
    iii. Automated B-mode (2-D) image
    iv. Automated CDI image optimization
    v. Automated PW Doppler image optimization
    vi. Dynamic receive focus
    vii.256 or more Grayscale levels
    viii.Image magnification (zoom)
    ix.Real-time image
    x.Frozen image
20. Should have 21 inch or more HIGH RESOLUTION, TOUCH SCREEN monitor having provision of Tilt and Swivel to view in all angles and all light conditions, TWIN VIEW and Live Quad Screen . Depth of the monitor should be 30 cm or more.
21. Should have facility of PREPROCESSING, POST PROCESSING, SELECTABLE DYNAMIC RANGE, SPECTRUM ANALYZER, CINE LOOP PLAYBACK, Speckle-tracking strain and strain rate, Stress echo, EXAM PROTOCOL, 2-D wall motion tracking, 3-D wall motion tracking, cardiac, mitral valve analysis, user-programmable calculations,
22. The system should have DIGITAL IMAGE STORAGE capacity of 500 Gb or more hard drive.
23. System should have Digital callipers, EXAM PRESETS, Customizable presets , On-screen annotation, DVD/CD Writer, Flash Memory, USB connector.
24. System should facility for Connectivity to PC .
25. Should have Facility of Fusion/Superimpose application for CT/Fluro imaging . ii)Dynamic 4D LV ,RV & LA volume iii)Strain for LV RV LA iv) Multi slice up to 12 Slice.
26. Should supply one reporting PC with all software inclusive interfaced with echocardiograph machine with the system. The PC should have 1.7 or latest processor, Ram 4 GB or more, processor speed 3 GHz or more, Connectivity to Echocardiography system.
27. The Echo cardiography sytem should be DICOM Ready , Dicom Interfacability to HIS , Dicom Interfacability Dicom to PACS, Interfacability Dicom to RIS .
28. System should have supply with
    i. Color Laser printer for reporting -1 no.,
    ii.Thermal Printer(small & Compact) for printing of Ultrasound image -01 no. ,
    iii.Paper roll for Thermal Printer -05 no.,
    iv.TEE probe stand -1 no
    v. ECG cable 2 number
    vi. UPS with with back up 60 min or more.

33.ARTERIAL BLOOD GAS ANALYZER (ABG Machine Table Top)

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG) and EU-CE (IVD) certified.
   The EU-CE certificate should be issued from notified body having notified body number.
2. The quoted model should be certified to the electrical safety standard "IEC-61010-1" particular requirement for measurement, control, and laboratory.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

1. Fully automatic, upgradeable, fast electrolyte & Blood gas analyzer having liquid based reagent or Reusable cartridge.
2. Essential Measured parameters: a) pH, b) pCO2, c) pO2, d) Haematocrit/Hemoglobin, e) Lactate, f) Glucose, g) Na+, h) Chloride, i) K+, j) Ca++.All these parameters should be measured simultaneously .
3. Calculated parameters should include a) Haemoglobin – cHb/ Haematocrit b) Actual Bicarbonate - cHCO2 c) Total Carbon Dioxide - cTCO3 d) Base Excess of Extra Cellular Fluid - BE (ecf) e) Base Excess in Blood – BE (b), f) Oxygen Saturation -cSO2.etc.
4. Sample volume-less than 100 micro litre.
5. Fast analysis time – less than 60 sec.
6. Maintenance free electrodes with individual electrodes ON/OFF facility.
7. Fully automatic liquid calibration of all parameters at user-defined intervals without the use of Gas calibrated reagents, external gases, tanks or regulators.
8. Continuous reagent level monitoring with graphic display.
9. Data display should be well-illuminated Touch Screen/Soft Touch Keypad having adequate screen size .
10. Data print out on built in graphic printer.
11. Built in auto Quality control facility.
12. Suitable UPS with at least 30 min backup.
13. Capability to transfer patient data to LIS/HIS and should have USB/Lan/Ethernet port for connectivity.
14. The system should have patient bar code facility for ability to run a wide range of patient panels on one system.
15. The machine should have internal data storage capacity of 1000 patient data or more.
16. The complete system including Electrode and membrane etc. as applicable for the analyzer offered should have 3 years of comprehensive warranty.
17. Cost of reagents to be quoted for comparative evaluation.

34.ADVANCE ANAESTHESIA WORKSTATION

Product Quality standard certification:

- The quoted model of the Anaesthesia workstation along with integrated Multipara Monitor and Vaporizers should have USFDA (510K /CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from a notified body having notified number.
- The quoted model should be certified to the electrical safety standard "IEC-60601-2-13" for the basic safety and essential performance of Anaesthesia system.

Manufacturer Quality standard certification:

- The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
- The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification:

1) Operational and General Requirements-

a) Compact and modular, three gas Anaesthesia workstation with an inbuilt ventilator for Adult, Pediatric & Neonatal patient, integrated airway monitor for airway pressures and volume, integrated Multipara Monitor and vaporizers.
b) The machine should have 2 or more drawers to keep accessories,good mobility,antistatic caster wheels with locking facility in all the 4 caster wheel.
c) The anesthesia machine, inbuilt ventilator, integrated multipara Monitor and vaporizer should be from the same Manufacturer to maintain uniformity of part and efficient after sale service.
d) The system should have battery backup upto 1-2 Hrs.
e) Should be a Trolley mounted, Epoxy powder painted or rust proof ABS plastic workstation. The trolley should have provision for mounting portable equipment like Portable USG, Neuro muscular monitoring system with integrated power supply etc.

2. Gas Delivery system:

a) Should have pin index yokes for Oxygen & Nitrous Oxide besides separate connection for Central gas supply for Oxygen, Nitrous Oxide and Air.
b) The machine should have pressure gauges for cylinders & central supply lines mounted on front of Anaesthesia machine for better visibility.
c) Cascade type flow meter tubes for Oxygen & N2O and Single tube for air with rotameter control guards.
d) Mode of gas mixing should be Electronic technology.
e) Automatic cutoff of N2O by Oxygen pressure failure and should have Air/N2O interlock.
f) Should have Hypoxic guard to provide a minimum 25% concentration of Oxygen in O2/N2O mixture.
g) Should have a auxiliary oxygen port with flow meter.
h) Audible visual oxygen failure alarm.
i) Emergency Oxygen flush at 30 – 70 L/min bypassing the vaporizer.
j) It should have minimum of 200ml oxygen flow facility.

k) In the event of complete power loss and battery failure it shall be possible to manually ventilate and deliver anaesthetic agent.

3. Vaporizer:

a) Machine should have possibility to mount two quick mount type vaporizer with two nos.of selectable back bar for easy interchangeability, and safety with interlock facility.
b) Should be provided with a Temperature / pressure compensated and flow independent Vaporizer.for Isoflourane , Sevoflourane and Desflurane.
c) Minimum 225 ml capacity for free volatile anesthetic agent.
d) Vaporizer should have extended delivery range from 0 to 10 Vol. %
e) The vaporizer should have internal sensor to prevent disconnection and should be calibrated for 5 years or more.

4. Breathing System:

a) Should have fresh gas de-coupled/compensation, closed circle absorber system.
b) Should have adjustable pressure relief valve from 5 to 75 mbar or better.
c) Should have change over from Spontaneous to Bag ventilation with single step.
d) The system should have electronically monitored leak and compliance test.
e) Should have compact breathing system with 1.5 Ltr.or more Volume capacity.
f) Should have an external fresh gas outlet for connecting Magill or Bain's circuit
g) The device should have active anaesthesia gas scavenging system.
h) Should be supplied with 2 no.of reusable autoclavable closed silicone circuit each for Adult, pediatric and neonatal patient.
i) Should be supplied with 10 no. of adult bains circuit and 10 no.of Jackson Rees circuit for pediatric and neonates patient.

5. Anaesthesia Ventilator(Inbuilt)

a) The system should have inbuilt ventilator with electronically controlled and electrically/pneumatically driven technology.
b) The ventilator should be capable of delivering low flow and minimal flow anaesthesia. Should have Low flow software tool or End tidal control software tool for driving the efficiency in low and minimal flow anaesthesia techniques thereby reducing the agent consumption.
c) Should not require changing of bellows for adult ,infants & neonates.
d) Modes: Manual/Spont, Volume controlled, Pressure controlled, SIMV/PS,
e) The same ventilator should have pressure support mode.
f) Tidal Volume delivery range in volume or pressure mode of ventilation should be 5 ml or less to 1400 ml or higher for use in the patient age group from Neonatal to Adult.

g) PEEP : 0 ~ 20 mbar
h) Breathing Frequency : 4 to 60 BPM
i) I:E Ratio : 4:1 to 1:4
j) Inspiratory pause : 0 – 50% of Ti
k) SIGH should be available.
l) Screen size of the Monitor of the ventilator should be 12 inch or more.
m) Should be able to ventilate with atmospheric air, in case of total gas supply failure.

6. Integrated Airway monitoring and display of following parameters:

a) Expiratory Tidal Volume
b) Expiratory Minute volume
c) PEEP, Fio2 ,Peak & Mean and Plateau airway pressure
d) Frequency
e) Waveform display for Airway pressure.

7. **Adjustable high/low alarm limits with audio and visual alarms for the following:**

a) Minute volume,
b) Airway pressure (including stenosis and disconnect),
c) Insp oxygen concentration,
d) Audio power supply fail alarm,
e) Fail to cycle warning.

8. Machine should have 3 nos. of RS 232 connectivity port for interface with Patient Monitor, Central monitor and HIS/HL7 connectivity.

9. Specifications for Advanced Multipara monitor :

1. Should be suitable for adult, paediatric and neonatal patients monitoring.
2. Should monitor ECG, Respiration, NIBP, SpO2 (Nellcor Oxymax or Masimo set measurement technology), Dual Temperature, Dual IBP,Cardiac output ,BIS and AGM(Include ETCO2).
3. Should be ready to upgradable for Neuromuscular transmission (NMT).
4. Should have ST analysis, Arrhythmia detection, pacer spike detection, Drug Dose Calculation and Oxygen monitor .
5. Should have integrated 15'' TFT/LCD colour touch screen display with minimum 8 channels of waveforms.
6. Defib and ESU protection should be present in system along with accessories.
7. Should have monitoring, surgery and diagnostic mode of monitoring
8. Should have Advance Arrhythmia monitoring .
9. Monitor access should be with Touch screen, rotary knob for quick function.
10. Should have 72 hrs or more of graphical and numerical trend with waveform as standard in the monitors.
11. Monitor should have USB port for software upgrade
12. Should have min of 120mins of battery backup .
13. Upgradeable to export the Vitals as HL7 messages to the HIS.
14. Monitor should be ready for interface with select model of equipment like Anaesthesia ventilator for displaying ventilation parameters, waveforms & loops.
15. Anaesthesia gas monitoring-AGM (N2O, CO2, O2, MAC) with autogas identification.
16. Should have Connectivity to the central station both via wired and wireless network.

17. The Multipara Monitor Should have following parameters:

ECG:

- Monitor should have capability for display upto 7 Lead.
- ST Analysis
- Waveform Freeze option with review of 120 sec
- Range: 15 to 350bpm

RESPIRATION:

- Through impedance pneumography method or EtCO2

SpO2:

- Should provide value for oxygen saturation as well as plethysmographic pulse waveform for Adult, Paediatric and Neonatal with perfusion index.
- Must have Nellcor Oxymax or Masimo set SPO2 measurement technology.

NIBP:

- By oscillometric principle of measurement.
- Should display Systolic, diastolic, mean pressure in large easy to read display
- Range: 10 to 270mmHg or higher.

Dual Temperature : Skin and Rectal. Range: 0 to 50 Deg C or higher

Dual IBP : Should simultaneous monitoring of two temp and two IBP.Range :-50 to 300mmHg

Cardiac Output: Should have Thermodilution Cardiac Output Monitoring facility.

BIS: Should have BIS monitoring facility.

AGM including ETCO2 : Measurement should be side stream/Main stream having very fast response time.

10. i)Scope of supply for Anaesthesia Machine with standard accessories:

a) 3 gas Anaesthesia machine
b) Trolley with 2 or more drawers
c) Writing surface
d) Pin Index yokes with cylinder for O2 & N2O
e) Pipeline connections for all three gases
f) Anaesthesia ventilator(Inbuilt)
g) Integrated Patient monitor.
h) Closed breathing system
i) Adult, Paediatric and neonatal autoclavable patient tubings
j) Reusable silicon Face-mask size 0,1,2,3,4&5 for Adult,pediatric and Neonate-5 nos each.
k) Vaporisers for Isoflourane,Sevoflourane.
l) Central gas supply hoses (with Color coded with coupler)
m) Monitor basic unit ECG, Respiration, SpO2, Dual Temp, NIBP, Dual IBP, AGM with ETCO2 and inbuilt battery.
n) Reusable 5 lead ECG Cable for Adult, Paediatric and neonatal – 1 no each per monitor
o) ECG disposable electrodes for Adult, Paediatric and neonatal – 30 nos per monitor
p) Reusable SpO2 finger sensor for Adult, Paediatric and neonatal – 1 no each per monitor
q) Reusable Skin and Rectal temperature probe – 1 no each per monitor
r) NIBP Hose - 1no per monitor
s) Reusable BP cuff for Adult ,Paediatric and Disposable cuff for Neonatal – 2nos each per monitor
t) Should be supplied with intermediate IBP cable– 2 nos per monitor
u) Disposable transducers for IBP – 10nos. per monitor
v) ETCO2 sample line -10 nos.
w) Silicon Breathing Bag 2 ltr and 500 Ml -3 nos.each
x) Ventilating Bougie with curved tip for adult and pediatric- 2 nos each
y) Light wand stylet for adult and pediatric- 2 nos each
z) Endo tracheal tube exchanger for adult and pediatric- 2 nos each.

10.ii) Additional accessories under the special scope of supply to be provided as or when or where it is required :

a) Vaporizer unit for Desfluorane.
b) Modules for Multipara Monitor such as “Cardiac Output” and “BIS”
c) Module for Neuromuscular transmission (NMT) for up-gradation.
d) Side Arm with integrated power supply in the trolley for mounting portable equipment.

(NB:The accessories mentioned above shall NOT be supplied to all institutions but the same shall be supplied to only Medical Colleges. Price of these above items at (10.ii) should quote separately in the Price BOQ of Format-B)

11. **Warranty Period:** The Complete Anesthesia Work station including Multipara Monitor and Vaporizers along with their Accessories Should 3 years of Comprehensive warranty from the date of installation excluding consumables.

35. CR SCANNER WITH 2 TRAY PRINTER

A. Product & Manufacturer Quality Standards:

1. The quoted model should have "USFDA (510K/CFG)" certified **OR** "EU-CE certified and the EU-CE certificate should be issued from notified body having notified body number.
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted product must comply with or certified as per "IEC 60601" **OR** certificate issued from BIS conforming to "IS 13450" **OR** "IS/ISO 80601" for electrical safety standard.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification:

Computed Radiology must be a state of the art system manufactured by a reputed brand or manufacturer adhering to following specifications. CR system should broadly comprise of following modules/ components:

1. **Image recording system (cassettes & reading plates)**:

   The following sizes of radiography cassettes along with image plates should be supported by the unit:

   a) 35 cm X 43 cm or 14" X 17": 4 nos.
   b) 24 cm X 30 cm or 10" X 12": 4 nos.
   c) 18 cm X 24 cm or 8" X 10": 4 nos.

2. **Image Reader (CR Reader/ Digitizer):**

   a) The CR reader / digitizer should be able to process 30±5 image plates/hr or more for 14" X 17" cassette size.
   b) CR reader / digitizer must be able to handle phosphor image plates. CR reader capable of handling latest Dual side /needle/structured/flexible/columnar image plates will be preferred.
   c) The Digitizer must have a resolution of 5 pixels/mm (minimum) for standard resolution cassettes & 10 pixel/mm (minimum) for high resolution cassette reading.
   d) Gray scale resolution: CR reader/digitizer should have a minimum resolution of 12bits/ pixel for images sent to CR processing station.

e) Minimum image preview time should be less than 60 sec.

f) Unit offered should have resolution of 100 microns or less should have provision for highest resolution scanning for any size.

3. Identification Station & processing server:

a) The processing station must have at least 1TB HDD and 21 inch LCD/ LED monitor. The PC hardware and monitors must be from reputed brands like DELL, HP, etc.

b) Processing server capable of identification of patient demographics to the acquired images will be preferred, else a separate identification station must be provided.

c) The system should have software & hardware to perform full leg/Full spine/ Long Body imaging/imaging stitching.

d) The server and /or ID station must be DMWL (DICOM modality worklist) compliant to access patient and study data from Hospital Information System (HIS) or Radiology Information System (RIS).

e) It should provide display of acquired images with greater details of demographics viz. patient/ study listing for easy access.

f) The server must 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, automatic cassette identification etc.

g) It should facilitate fully fledged DICOM printing and should be able to print multiple formats of patient study.

h) Should be able to send DICOM images to DICOM workstation or PACS without loss of information.

i) Should be equipped with DICOM CD writer for transferring image.

j) Should be able to store image on external device viz. CD or pen drive etc.

k) The system should have a facility to indicate over /under exposure in the preview screen. Kindly specify the image preview time.

l) The software must have dedicated pediatric and mammography image processing.

4. Dry imager:

a) The system must have a dry imager without need of any wet chemistry.

b) It must be DICOM 3.0 compatible allowing multiple modalities to be connected at a time.

c) The system must be able to print at least 70 films/hour for 14” X 17” cassette size.

d) The system must deliver its first film within 80 seconds from the request sent.
e) The imager must have a minimum spatial resolution of 500 dpi.
f) The system must have contrast resolution of 14 bits/ pixel or more. The system must have at least two online film sizes and should be capable of printing any of the 8" X 10", 10" X 12", 12" X 14" or 14" X 17" films**.**
g) 100 numbers of films to be provide of 14" X 17", 10" x12", 8" x 10" sizes.
h) The imager should support daylight loading of films.
i) Interconnectivity between various CR modules should be Ethernet / TCP IP Based i.e. RJ 45 Connection (10 / 100 Base T / LAN).

5. Online UPS of suitable rating for back up must be provided for 30 minutes power backup for the whole system.

C. Warranty: 5 years of Onsite Comprehensive Manufacturer warranty on the entire system along with Online UPS excluding consumables**.**

Note: Bidders must quote cost per film (of Same Equipment OEM) as of each sizes (14" X 17", 10" x12", 8" x 10") separately pdf file (Format-B) of financial bid which shall be taken into account for price evaluation under the financial bid.

36. ULTRASOUND MACHINE WITH 4 PROBES

A. Product & Manufacturer Quality Standards:

1. The quoted model should be USFDA (510k/CFG) **AND** EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number".
2. The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" **OR** "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" **OR** "ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA".
3. The quoted model should comply with IEC 60601-2-37 or equivalent: Basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification:

1. **Clinical use**: General purpose ultrasonic scanning systems provide two-dimensional (2-D) B-mode images of soft tissues without subjecting patients to ionizing radiation. It intends to primarily for abdominal, obstetric/gynecologic (OB/GYN), small-parts, and vascular imaging.
2. **Applications:** Abdomen, abdominal vascular, urology, OB/GYN, neonatal brain, small parts (breast, thyroid, scrotal, prostate, MSK).

a) Types of Probes with features:

1. The quoted model should have **Flat Linear Probe** with purewave/single crystal/matrix 1500 elements for Abdomen, Vascular etc with Strain & Shear wave elastography. The frequency range should be 2-22MHz with operating frequency of 4-18MHz (±1MHz) and 14cm depth.
2. The quoted model should have **Convex Array Probe** with Strain & Shear wave elastography. Working frequency 1-5 MHz (±1MHz).
3. The quoted model should have **Volume Convex Probe**, working frequency 1-8 MHz (±1MHz).
4. The quoted model should have **Linear Probe** for small parts such as Thyroid, Breast, MSK applications. Working frequency 5-15 MHz (±1MHz).
5. The quoted model should have **TV/TR Probe** for Gyaenac Studies with strain elastography for prostate. Working frequency 4-9 MHz(±1MHz).
6. The quoted model should have E- Breast elastography, E- Thyroid elastography, Liver elastography.
7. The quote model should be upgradeable to Volume linear probe & volume TV probe.

b) Scan modes with features:

1. The quoted model should have the following scan modes:
    i. B-mode.
    ii. M-mode.
    iii. Contrast harmonic imaging with angio mode.
    iv. Tissue harmonic imaging mode.
    v. Provision of Harmonic imaging in Linear Probes.
    vi. Color Doppler imaging (CDI).

vii. Color Doppler 3-D/4-D option.
viii. Power Doppler imaging (PDI).
ix. Continuous wave.
x. Pulsed wave.
xi. Duplex mode.
xii. Triplex mode.
xiii. Tissue Doppler imaging.
xiv. Contrast-enhanced ultrasound (CESU).

2. The quoted model should have Tissue synchronization, tissue velocity feature.
3. It should have Gain control in two dimensions for additional level of flexibility for image quality control.
4. It should have "Provision for higher resolution" i.e Real time high frequency 2D.
5. All the probes should be supplied with latest generation bandwidth.
6. It should have provision for higher sensitivity for low frequency doppler in all probes.
7. If channels are being designated as digital channels, then the Number of Channels in color doppler system should be 450000 or more.
8. It should have real time Live 3D imaging feature in color doppler system.
9. It should have Colour Doppler system with all application packages, Quad loop for serial studies with high frame rate revives, harmonic imaging capability in all modes and integrated stress echo package digital storage and retrieval.
10. The Number of grey shades for sharp contrast resolutions should be 280db or more.
11. It should have High-definition acoustic zoom provision for enlarging sections of 2D and Color flow images with more acoustic information for greater clarity and detail while maintaining an optimal frame rate.
12. It should have Color flow imaging option and provision for tissue colorization (B-color) for improved contrast resolution.
13. All application packages should be inbuilt into the system.
14. It should have Cine Loop Features with loop memory of 1000MB or 2000 frames storage or more.
15. It should have various maps for pre & post processing (frame grabber facility for post analysis).
16. It should have total 4 nos. of live transducer/probe ports.
17. It should have User defined system and application presets for multi-user department.
18. System shall support the ability to store digital data in, that allows to optimize imaging parameters such as B Gain, TGC, Color Gain, Dynamic Range, Speckle Reduction levels, Doppler Gain, Doppler Base Line on old Images & old loops recalled from the image archive.
19. Real-Time 2D Shear Wave elastography should be available in convex & Linear Probe.
20. System should be Fusion/ Navigation ready for future upgrades & System should be upgradable to volume navigation feature which fuses live ultrasound imaging with different multimodality imaging such as CT/MR/PET-CT and System should have a facility to register CT/MR modality volume automatically on an ultrasound image.
21. System should have the capability to measure the area of lesions/Cyst automatically.
22. Equipment should have fat quantification software.

c) Image display and processing:

1. The quoted model should be DICOM 3 complaint or higher.
2. It should have the features: Adjustable transmit focus, Automated B-mode (2-D) image, Automated CDI image optimization, Automated PW Doppler image optimization, Dynamic receive focus, Image magnification (zoom), Real-time image, Frozen image.
3. The quoted model should have monitor with high resolution with "Provision of Tilt and Swivel monitor should be able to view in all angles and all light conditions".
4. The quoted model should have dual display (image display and touch panel) with split screen twin view.
5. The monitor should be LCD type with screen size 21inchs or more.
6. Imaging depth ≥40cm.
7. The quoted model should have pre processing and post processing feature, selectable dynamic range, spectrum analyzer, DIGITAL IMAGE STORAGE and cine loop playback.
8. It should have Maximum number frames of 2000.
9. The model should have Digital storage hard drive of 500GB or more.
10. The model should have features: Speckle-tracking strain and strain rate, Exam protocols, Digital calipers, Exam presets, Customizable presets, On-screen annotation.
11. The model should have DVD/CD Writer, Flash Memory and USB connector.
12. The model should have Facility for high definition digital acquisition, review and editing of complete patient studies.
13. The model should have processor I7 or latest, 4GB or more RAM, 3GHz or more processor speed.
14. It should have PC with all software inclusive interfaced with USG machine with option of CD/DVD drive.
15. PC should be supplied with color laser printer (1no.) for reporting, thermal printer(1no.) (Small & compact) in USG for printing ultrasound image.
16. The model should have Dicom 3.0 Interfacability to PACS and RIS.
17. The supplied USG system should be upgradable to next generation system on site.

C. Accessories:

1. Glossy color paper print for color laser printer- 1000 sheets.
2. Thermal printer paper roll- 10 nos.
3. The machine should supply with ultrasound transmission gel for approximately 500 patient's exam,

D. Power requirements:

1. Power input for the quoted equipment should be 220-240VAC, 50Hz fitted with Indian plug.
2. It should have Resettable over current breaker shall be fitted for protection.
3. The equipment should be supplied with Online UPS (3KVA) with battery backup for 30 minutes to the Ultrasound system.

Warranty: The quoted model should have 5 years comprehensive warranty on the entire system along with Online UPS**.**

37. ADVANCED MULTIPARA MONITOR (7 Para) With CENTRAL MONITORING STATION

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.

2. The quoted model should be certified to the electrical safety standard IEC 60601-2-49, Particular requirements for the basic safety and essential performance of multifunction patient monitoring Equipment.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specifications:

A. ADVANCED MULTIPARA MONITOR (7 Para):

1. Advanced high end modular patient monitor having integrated non-invasive, invasive measurement & features suitable for neonate, paediatrics & adult patients.
2. Monitor must have bright, highly visible at all ambient light levels of minimum 12 inch or more color TFT/LCD display with full touch screen facility.
3. Monitor must have the facility to display minimum 8 waveform or more along with related numerical parameters on single screen.
4. Should be able to monitor ECG, SpO2, Respiration, NIBP, dual Temperature, dual IBP, and ETCo2 for Adult, Paediatric and Neonatal application.
5. The patient monitor also must be ready to be upgraded to connect the module for Minimal invasive Cardiac Output "CO" monitoring (Thermo dilution). Integration of external measuring device for any parameters shall not be accepted. All the additional modules for measurement of parameters such as EtCO2, Cardiac Output etc. can be detachable and Interchangeable.
6. Monitor must have facility to display 12 lead ECG through 5 lead ECG cable. Must have advanced arrhythmia detection and ST Analysis through four lead or more as standard feature. Accuracy of the ECG measurement should be ±2 bpm or better.
7. Measurement range for Respiration Rate (RR) should be 0-150 bpm or more.
8. The measurement technique for NIBP should be Step-deflation oscillometric having automatic and manual option, Systolic blood pressure monitoring range 40-250 mm/Hg or more ,Diastolic BP range 10-200 mm/Hg or more, Accuracy should be ±5mm/Hg or better.

9. For measurement of pulse oximetry, the monitor should have measurement technology of Nellcor Oximax or Masimo Set **.**which should capable to measure Spo2 during motion and low perfusion conditions. SPO2 measurement range should be 40-100% and accuracy should be ±3% or better.**Pulse Oximetry Technology**: The model having MASIMO-SET technology or Nellcor Oximax technology,must have to submit the authorization letter from the technology

provider i.e. MASIMO/NELLCOR for offering their technology in the quoted make and model of Multipara monitor.

10. The ETCO2 sensor should be mainstream/sidestream/microstream. It can be use for both intubated and nonintubated patient and CO2 measuring range should be 0-99 mm.Hg or better.
11. The monitor should have measure and display the perfusion Index .
12. System must have minimum 72 hours review data including graphical and tabular trends, arrhythmia event recalls.
13. Monitor must have the time linked review function. Monitor must show the waveforms for the time when the arrhythmia occurred in case of arrhythmia recall.
14. Must have facility to connect with network printer, at any point of time and able to take print any review data (Trends, Graphs, waveform full disclosure, arrhythmia recall etc.) and also should have direct connectivity to HL 7.
15. Monitor must be able to connect to central monitoring station and should use single network for all kind of networking with the central station or other hospital information system (HIS) through LAN port/RJ45 port/wireless.
16. The Monitor should have inbuilt Rechargeable battery with minimum 90 minutes of power backup.
17. The system should have Alarm facility as below :
    i.Should have Escalation of Alarm based on priority as high ,medium and low and facility to activating silence of alarms having duration of 120 sec or better with provision for suspension of all alarms and latching. ii. Should have audio visual alarms such as Cuff leakage&disconnect ,inflation/deflation error, Battery low,EtCo2 low&high, Sensor/Wire/Probe disconnection alarm etc.

18. The monitor should supply with good quality Wall mounting bracket to mount the Monitor on bed site wall of the ICU.

19. Modules requirement in each monitor:

All parameter modules should be compatible with the quoted model of monitor with required Accessories having same quality standard as mentioned above.

1. ECG, SpO2, NIBP, Respiration, Dual temp , Dual IBP (All independent / dual/ combined/Inbuilt): 1No.each
2. EtCO2 (mainstream/sidestream/microstream): 1No.each
3. Cardiac Output (CO): 1No.

[Price for the individual modules along with accessories should be quoted separately in the price bid (Format-B) which will be taken into price evaluation.]

20. Accessories to be supplied in each Monitor:

i. Reusable 5 lead ECG electrode cable for Adult-Paediatric and Neonates (complete set): 1 No. Each.
ii. Reusable SPO2 Probe (Adult, Paediatric & Neonates) - 01 No. each (Clip or Silicon type for adult & Paediatric, Y or Rap type for Neonates).
iii. Reusable NIBP Cuff (Neonates, Paediatric, Adult) with hose -2 no. each of different sizes.

iv. Reusable Temp Probe: 2 Nos. (skin & Rectal/oesophageal one each)
v. IBP connection cable: 02 Nos.
vi. IBP Disposable Pressure Transducers: 5 Nos.
vii. EtCO2 Accessories for adult, Paediatric & Infants: 1No. Each
viii. Packs of 100 disposable ECG connection electrodes.
ix. Wall mounting bracket: 1 nos.
x. Power cable for Power supply: 220 to 240V AC, 50Hz fitted with Indian plug of appropriate

Warranty: Comprehensive warranty should be 3 years for the Patient monitor with Modules and 1 year for reusable accessories from the date of installation excluding consumables.

B. CENTRAL MONITORING STATION (CMS):

1. Central Station Monitor of minimum 21" screen to be provided with one laser printer. The cabling has to be done by supplier in the ICU. One CNS should be able to connect up to 16 monitors.
2. CMS should have the facility to communicate and command any patient bed connected with wired network.
3. Should able to monitor all the waveforms of connected patient monitors.
4. Should have single screen display of minimum 08 patient monitors.
5. Should have data storage & management of patient information of minimum of minimum 72 hours with trend data.
6. Should provide the capability to enter patient demographic information at the bedside or central monitor. On – screen keyboard shall be present for entering this data.
7. Waveform zone display colour must be user-configurable at any time to allow differentiation on patient waveforms.
8. CNS monitor shall support use of mouse, keyboard and barcode scanner when using remotely-accessed applications.
9. Central monitor should have the full bed review of the beds selected.
10. Should provide the required server based computer system of latest generation with suitable software & laser printer for printing patient information.
11. Should provide online UPS for minimum 2hrs power back up for server based system & CMS monitor.

Power supply:

Power input to be 220 – 240V AC, 50Hz fitted with Indian plug of appropriate rating.

Warranty: Comprehensive warranty should be 3 years for complete CMS system from the date of installation.

(NB: Central Monitoring station shall NOT be Ordered with each monitor and it shall not be supplied to all institutions but the same shall be Ordered and supplied to only the institutions where it is required now and as or when required by other institutions. Price for the "Central Monitoring station" should be quoted separately in the price bid (BOQ Format-B) which will be taken into price evaluation.)

38. ENT Treatment unit

Product Quality standard certification:

1. The quoted model should be either "USFDA (510K/CFG)" or "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
2. The quoted model should have IEC 60601 certified or Certificate issued from BIS conforming to IS 13450 orIS /ISO 80601.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.

4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specification:

The components of the system should have Mainunit with storage, Suction system,
Light source with head lamp, cautery system, Microscope system, Ent patient examination chair , Doctors examination chair,Endoscopy system with camera and endoscopes, Stroboscope with software, Otoscope.
All the components should be from Same OEM or having product quality standard USFDA (510K/CFG)" or "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.

A.MAIN UNIT :

1. The main unit should be coating of anti-fungal and antibacterial and easy to clean and disinfect, Durable steel casing, non-rusting.
2. Large instrument surface made of stainless steel with dividers and heating system to heat the instruments, laryngeal mirrors and endoscopes
3. Compressed air system continuously adjustable from 0.1 to 2.5 bars or more for spray and politzering, spray liquid with autoclavable nozzle for cleaning
4. Handle for compressed air should be having a regulation valve
5. Medication reservoir be made of stainless steel/Glass, should be detachable and suitable for all type of medications
6. Stainless steel tank for compressed air of capacity of 1.5 or more
7. Compressor unit should be completely separate from suction unit
8. Inbuilt motor suction unit with capacity of 60 liters per minute with maximum 92% vacuum
9. Should have a vacuum gauge, bacterial filters, 1.5 liters liquid container and effective device to prevent overflow
10. Suction tube should have automatic on off switch and small ear rinse funnel
11. Warm water rinsing Device with autoclavable stainless steel handle with snap closure system and fine spray regulation valve .
12. Separate stainless steel tank to prevent mineral build up and heat up to 38 degree temperature
13. Cold water irrigation through existing water connection
14. Automatic liquid container discharge system should be provided
15. Kidney shaped air rinsing funnel on a swivel support including ear wax separator with additional suction tube connected to liquid jar
16..Suction tube cleaner with exchangeable re-usable adapter.
17. Should have X-ray viewer integrated in a writing draw, Dispenser for cotton and paper , with waste container & melamine drawer for used instruments
18.Should have cold light source with two outlets with 150 watt or better LED light having 30000 hr LED life.
19. Head light with fibro-optic cable to be used with above light source for examination.
20. Two warming quivers for rigid endoscope - should be removable for autoclaving and cleaning
21. Automatic on/off switch for single light outlet with light barrier.
22. Should supply 80 watt or more manopolar and bipolar cautery system with set of reusable cables/Probes/Forceps for ENT procedure.

23.**The ENT examination microscope** with integrated, fanless high transmission, high performance LED illumination in the microscope head.

a. Integrated, fanless high performance white-light-LED Luminescence: min. 120 klux (200 mm), 30 klux (400 mm)

b. Color temperature: 5.500 K or better

c. Optimized stereo effect by 24 mm stereo basis

d. In built LED light source with CCD camera with a facility to take images, video & transfer the same to any smart phone via the wi fi card

e. Mechanical support arm for the microscope

f. Expandable with scale projection at the image plane with an option of green filter Objective: 200 mm, (fine focusing)

g. Objectives with manual fine focusing Visualization

h. Wide-field eyepiece 10x to 16x magnification

i. Colour filter green, with pivot mechanism

j. The ENT microscope should be integrated & mounted on the main treatment unit

k. Monitor holder, HD monitor, lateral double hand grip

24.**ENT PATIENT EXAMINATION CHAIR**

a. Should be motorized and ergonomically designed examination and treatment chair facilitating the posture of both doctor and patient.

b. Heavy base casing

c. All elements of chair should be anatomically shaped

d. Seat should have motorized lifting device

e. Seat should have height adjustment for children

f. Integrated foot switch for easy adjustment of height

g. Should have complete rotation 360 degree with locking device

h. Should be comfortably padded and folded back for enabling easy sitting of overweight and handicapped patient

i. Head rest - 15cm with adjustable height

j. Backrest adjustable and can be made to incline 10 degree forward to vertical position and backward completely to a horizontal position and can be rolled back

k. Movement of armrest and footrest should be synchronized with backrest movement .

25.DOCTORS EXAMINATION CHAIR

a. Wide base, should have rolling casters for easy movement

b. Should have back rest

c. Easy height adjustment of hydraulic nature

d. Comfortably cushioned seat

26**.STROBOSCOPY (INTEGRATED)**

a. The LED stroboscope should be noiseless with flash light & pilot light for vocal cord diagnostics based on LED technology.

b. The LED stroboscope should have the variable phasing & slow motion mode, adjustable with the footswitch

c. Should display voice frequency, sound pressure level, audio output for archiving the voice signal including attachable laryngoscope microphone, also should have a body sound adapter for voice asthenic patient, stethoscope adapter for clip microphone for a better connection of the microphone signal to the stroboscope control.

d. The flash frequency should be 70-1000 Hz, without reduction, sound level metering range 70-125 dB +/-1 dB, operating modes, continuous light, slow motion 0.5–2 Hz, frozen image 0 degree– 400 degree, hunting over the footswitch adjustable, light durable approx. 50,000 hrs

e. The system should have an integrated LED light source, light durable approx. 50,000 hrs, brightness 220 kLux / 175 Lumen, length of the cable 1.9m

f. The system should indicate the status of light - pilot light, flicker & slow motion

g. The LED stroboscope should have the variable phasing & slow motion mode, adjustable with the footswitch. A foot switch for recording purpose.

27.**Endoscopy Camera System and Monitor:**

a.System should provide single chip CCD/CMOS having 24 inch or more HD medical grade monitor.

b. Compatible System for easy recording of images and videos in HD digital formats. Easily transferable to External hard drives and USB pendrives/storage cards without losing resolution.

28.**ENDOSCOPES**

The system should provide following endoscopes

a. 4mm/0 & 30 degree rigid nasal endoscopes – 1 each in number

b. 2.7mm/0 & 30 degree rigid nasal endoscopes – 1 each in number

c. Magnifying 90 degree rigid Laryngoscope with facility to focus manually - 1 in number

(All above endoscopes should be wide angle &autoclavable)

d. Flexible Laryngoscope (1 in number) - 3.4-3.8 mm OD, 300-340 mm length, Bend up and down 130 o -150o , Depth of field up to 50 mm h. Co-axial fibro-optic light cable/2.5mm diameter - 1 in number

e. Otoendoscope , o degree ,diameter 2.7 mm ,length – 8.5 cm to 10 cm -1 No.

29.System should provide FibreopticOtoscope with all size speculums including Seigel's pneumatic Speculum .

a.Should provide 3.5, volts Halogen bulb with 5 spare bulbs.

b. Pneumatic bag for Sieglisation of tympanic membrane

c. Reusable and autoclavable speculum sets of 4 or 5 — 2 sets for each Otoscope

d. Heavy duty handles with charger and chargeable long life battery with spare battery.

26.**SOFTWARE**

a. 1 no. Acoustic analysis/Recording of the voice signal (Multi Dimensional Voice Profile (MDVP) software, archiving and recording the voice, and taking report. Should have editing facility, annotations like arrow, text marker ,lines, circle can be done on images, Should have audio as well as video capture facility.

b. 1 no. P.C. (Personal Computer) should consist of a CPU, Keyboard and Mouse for installation for software.

31. Should Supply Online UPS of 1 KV or better back up of 30 min battery or more.

32. System should function on 220 to 240 V /50 HZ single phase AC.

33.5 years comprehensive warranty on complete system.

39.Nasal Endoscopy System

Product Quality standard certification:

1. The quoted model should be "USFDA approved (510K/CFG)" and "European CE certified". The EUROPEAN-CE certificate should be issued from notified body having notified body number.
2. The quoted model should have "IEC 60601" OR "IEC 80601" OR Equivalent IS standards, i.e. "IS 13450" or "IS / ISO 80601".

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.

4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical specification :

1. The Nasal Endoscopy system should have Video processor, Endoscopic video Camera Head, LED light source, Fiber optic cable, Medical grade monitor, Documentation system, telescope and surgical hand instrument.
2. **Video Processor :**
   i. The Video processor should have facility to connect the ulta high definition endoscopic camera head . The output resolution of the system should be 3840 x2160.
   ii. Should have video output port: Display port 1.2 : 1 Number or DVI-D port – 1 Number or 12G SDI port 1 number along with DVI ,HD SDI, HDMI, Composite ports.
   iii. The unit must have the facility for Connection of VideoFlexible Scopes (Digital Scopes/Chip on tip) like Video Flexible BRONCHOSCOPY & LARYNGOSCOPE.
   iv. Should have facility of inbuilt capturing 4k UHD still image and UHD videos or or should supply external documentation system having facility to capture HD still image and HD videos.
3. **Endoscopic video Camera Head :**
   Should be 4k Digital camera having resolution 3840 x 2160 or more, aspiration ratio 16:09 , 3 or more programmable buttons ,universal digital zoom coupler with integrated zoom lens 18 mm or more.
4. **LED light source and Fiber optic cable :**
   Should be LED of 30000 hour or more life having Colour temperature range 5500-6500K. Light source should have universal adapter for fiber optic cable and efficient cooling technologies.

5. **Medical grade monitor**
   Should supply atleast31 inch 4k LED monitor having resolution 3840x2160, aspiration ratio 16:09,anti glare panels, 16 milion or more display colour, picture in picture facility, colling facility.
   Should have input portsDisplay port 1.2 :- 1 Number or DVI-D port – 1 Number or 12G SDI port 1 number and output port DVI , 3G SDI or 12 G SDI .
6. **Telescopes(Should be from same OEM of Nasal Endoscopy System)**
   1. Telescope 0°, 4mm: Straight forward telescope,0-degree UHD Wide Angled enlarged view, size: 4mm rod lenses system, Length:18-19 cm, Autoclavable, Fiber optic light transmission incorporated – 1 No.
   2. Telescope 30°, 4mm: Forward oblique 30-degree UHD Wide Angled enlarged view, size: 4mm rod lenses system Length:18- 19 cm, Autoclavable, Fiber optic light transmission incorporated – 1 No.
   3. Telescope 70°, 4mm: Straight Forward Telescope 70-degree UHD Wide Angled enlarged view, size: 4mm rod lenses system, Length: 15.5-19 cm, Autoclavable, Fiber Optic Light Transmission Incorporated – 1 No.
   4. Telescope 0°, 2.7mm-3.1 mm: Straight forward telescope,0-degree UHD Wide Angled enlarged view, size:2.7mm rod lenses system, Length:16-19 cm, Autoclavable, Fiber optic light transmission incorporated – 1 No.
   5. Telescope 30°, 2.7mm-3.1 mm: Forward oblique 30-degree UHD Wide Angled enlarged view, size: 2.7mm rod lenses system Length:16- 19 cm, Autoclavable, Fiber optic light transmission incorporated – 1 No.
   6.Compatible Telescope Handle, round, standard model, length 11 cm, for use with Telescope 30°- 120° with diameter 4 mm and length 18 cm – 2 No.

7. **Surgical Hand instruments**

Should be from same OEM of Nasal EndoscopySystem or having product quality standard-USFDA Approved & EU-CE (Issued from notified body having notified number)

1. Bipolar Suction Forceps, 45° upturned, with Suction channel, for bipolar coagulation in para nasal areas, working length 12.5 cm, for use with Bipolar High Frequency Cords – 2 Nos.
2. Sickle Knife, pointed, length 19 cm – 2 Nos.
3. FREER Elevator, double-ended, semi sharp and blunt, length 20 cm – 2 Nos.
4. Antrum Curette, oblong, small size, length 19 cm – 2 Nos.
5. Frontal Sinus Curette, 55° curved, oval, forward cutting, length 19 cm – 2 Nos.
6. Frontal Sinus Curette, 90° curved, oval, forward cutting, length 19 cm – 2 Nos.
7. Probe, double-ended, maxillary sinus ostium seeker, ball-shaped ends diameter 1.2 and 2 mm, length 19 cm – 2 Nos.
8. Elevator, double-ended, semi sharp and blunt, graduated, length 20 cm – 2 Nos.
9. Suction Tube, conical, malleable, with finger grip plate, LUER-Lock, outer diameter 2mm,3 mm,4mm , working length 13 cm – 2 set
10. FRAZIER Suction Tube, with mandrel and cut-off hole, with distance marking at 5 – 9 cm, 9 Fr., working length 10 cm – 2 Nos.
11. Antrum Grasping Forceps, jaws curved downwards, fixed jaw curved 90°, movable jaw backward opening 120°, with cleaning connector, working length 10 cm – 2 Nos.

12. Double Spoon Forceps, vertical opening, 65° upturned, spoon diameter 3 mm, with cleaning connector, working length 12 cm – 1 Nos.
13. Double Spoon Forceps, horizontal opening, 65° upturned, spoon diameter 3 mm, with cleaning connector, working length 12 cm – 1 Nos.
14. Biopsy and Grasping Forceps, extra fine, with oval cupped jaws 3 x 5 mm, sheath diameter 1.5 mm, with cleaning connector, working length 14 cm – 2 Nos.
15. Antrum Punch, left side downward and forward cutting, with cleaning connector, working length 10 cm – 1 Nos.
16. Antrum Punch, right side downward and forward cutting, with cleaning connector, working length 10 cm – 1 Nos.
17. Biopsy and Grasping Forceps, vertical opening, malleable sheath end, cupped jaws diameter 4 mm, with cleaning connector, working length 18 cm, to be used for sinoscopy through Trocar. – 2 Nos.
18.. Punch, circular cutting, for sphenoid, ethmoid and choanal atresia, diameter 4.5 mm, working length 18 cm, including Cleaning Tool – 2 Nos.
19. Punch, circular cutting, 65° upturned, for frontal sinus recess, diameter 3.5 mm, working length 17 cm, including Cleaning Tool – 2 Nos.
20.. Blakesley, Nasal forceps, upturned 45 Degree, size 0, length 13 cm – 2 Nos.
21. StammbergerAntrum punch, small pediatric size, left side back ward cutting 10 cm – 1 Nos.
22.. StammbergerAntrum punch, small pediatric size, right side back ward cutting 10 cm – 1 Nos.
23. StammbergerAntrum punch, small pediatric size, upside back ward cutting 10 cm – 1 Nos.
24. Blakesley, Nasal forceps, straight size 0, length 13 cm – 2 Nos.
25. Blakesley, Nasal forceps, straight size 90 degree, length 13 cm – 1 Nos.

8. Additional Accessories

i.Each system should supply with : Trolley -1No, Online UPS(1 KVA)-1 No., FORMALIN CHAMBER of Minimum 26 inch- 2 Nos, CIDEX TRAY - 2 Nos.

40.ADVANCED MULTIPARA MONITOR (7 Para)

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.

2. The quoted model should be certified to the electrical safety standard IEC 60601-2-49, Particular requirements for the basic safety and essential performance of multifunction patient monitoring Equipment.

Manufacturer Quality standard certification:

5. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
6. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specifications:

C. ADVANCED MULTIPARA MONITOR (7 Para):

18. Advanced high end modular patient monitor having integrated non-invasive, invasive measurement & features suitable for neonate, paediatrics & adult patients.
19. Monitor must have bright, highly visible at all ambient light levels of minimum 12 inch or more color TFT/LCD display with full touch screen facility.
20. Monitor must have the facility to display minimum 8 waveform or more along with related numerical parameters on single screen.
21. Should be able to monitor ECG, SpO2, Respiration, NIBP, dual Temperature, dual IBP, and ETCo2 for Adult, Paediatric and Neonatal application.
22. The patient monitor also must be ready to be upgraded to connect the module for Minimal invasive Cardiac Output "CO" monitoring (Thermo dilution). Integration of external measuring device for any parameters shall not be accepted. All the additional modules for measurement of parameters such as EtCO2, Cardiac Output etc. can be detachable and Interchangeable.
23. Monitor must have facility to display 12 lead ECG through 5 lead ECG cable. Must have advanced arrhythmia detection and ST Analysis through four lead or more as standard feature. Accuracy of the ECG measurement should be ±2 bpm or better.
24. Measurement range for Respiration Rate (RR) should be 0-150 bpm or more.
25. The measurement technique for NIBP should be Step-deflation oscillometric having automatic and manual option, Systolic blood pressure monitoring range 40-250 mm/Hg or more ,Diastolic BP range 10-200 mm/Hg or more, Accuracy should be ±5mm/Hg or better.

26. For measurement of pulse oximetry, the monitor should have measurement technology of Nellcor Oximax or Masimo Set **.**which should capable to measure Spo2 during motion and low perfusion conditions. SPO2 measurement range should be 40-100% and accuracy should be ±3% or better.**Pulse Oximetry Technology**: The model having MASIMO-SET technology or Nellcor Oximax technology,must have to submit the authorization letter from the technology

provider i.e. MASIMO/NELLCOR for offering their technology in the quoted make and model of Multipara monitor.

27. The ETCO2 sensor should be mainstream/sidestream/microstream. It can be use for both intubated and nonintubated patient and CO2 measuring range should be 0-99 mm.Hg or better.
28. The monitor should have measure and display the perfusion Index .
29. System must have minimum 72 hours review data including graphical and tabular trends, arrhythmia event recalls.
30. Monitor must have the time linked review function. Monitor must show the waveforms for the time when the arrhythmia occurred in case of arrhythmia recall.
31. Must have facility to connect with network printer, at any point of time and able to take print any review data (Trends, Graphs, waveform full disclosure, arrhythmia recall etc.) and also should have direct connectivity to HL 7.
32. Monitor must be able to connect to central monitoring station and should use single network for all kind of networking with the central station or other hospital information system (HIS) through LAN port/RJ45 port/wireless.
33. The Monitor should have inbuilt Rechargeable battery with minimum 90 minutes of power backup.
34. The system should have Alarm facility as below :
    i.Should have Escalation of Alarm based on priority as high ,medium and low and facility to activating silence of alarms having duration of 120 sec or better with provision for suspension of all alarms and latching. ii. Should have audio visual alarms such as Cuff leakage&disconnect ,inflation/deflation error, Battery low,EtCo2 low&high, Sensor/Wire/Probe disconnection alarm etc.

18. The monitor should supply with good quality Wall mounting bracket to mount the Monitor on bed site wall of the ICU.

19. Modules requirement in each monitor:

All parameter modules should be compatible with the quoted model of monitor with required Accessories having same quality standard as mentioned above.

4. ECG, SpO2, NIBP, Respiration, Dual temp , Dual IBP (All independent / dual/ combined/Inbuilt): 1No.each
5. EtCO2 (mainstream/sidestream/microstream): 1No.each
6. Cardiac Output (CO): 1No.

[Price for the individual modules along with accessories should be quoted separately in the price bid (Format-B) which will be taken into price evaluation.]

20. Accessories to be supplied in each Monitor:

xi. Reusable 5 lead ECG electrode cable for Adult-Paediatric and Neonates (complete set): 1 No. Each.
xii. Reusable SPO2 Probe (Adult, Paediatric & Neonates) - 01 No. each (Clip or Silicon type for adult & Paediatric, Y or Rap type for Neonates).
xiii. Reusable NIBP Cuff (Neonates, Paediatric, Adult) with hose -2 no. each of different sizes.
xiv. Reusable Temp Probe: 2 Nos. (skin & Rectal/oesophageal one each)

xv. IBP connection cable: 02 Nos.

xvi. IBP Disposable Pressure Transducers: 5 Nos.

xvii. $EtCO_2$ Accessories for adult, Paediatric & Infants: 1No. Each

xviii. Packs of 100 disposable ECG connection electrodes.

xix. Wall mounting bracket: 1 nos.

xx. Power cable for Power supply: 220 to 240V AC, 50Hz fitted with Indian plug of appropriate

Warranty: Comprehensive warranty should be 3 years for the Patient monitor with Modules and 1 year for reusable accessories from the date of installation excluding consumables.

41.ICU BED

Product & Manufacturer Quality Standard Certification:

1) All the certificates commonly asked in the "General Requirement for all items" under "Product & Manufacturer Quality Standards".
2) In addition to the commonly asked certificates, the bidder has to furnish the test report of PU foam complying to IS 7933 standard from any "ISO 17025 and NABL" accredited laboratory.
3) Should comply with IEC 60601-2-52: Particular requirement for basic safety& essential performance of medical beds. IEC Type testing Report should be submitted for the quoted model.

Purpose: ICU Bed are required to be used in Intensive Care Unit for comfort of Patient & facilitate comfortable transfer to & from Emergency/ OT/ Ward etc. & also to carry out point of care process including Radiological procedure at bed side.

Technical Specifications:

1. Type of ICU Bed Actuator should be Electro-Mechanical (Motorized).
2. Type of mechanism for functioning or controlling angular motion of bed part Actuator should be Electro-Mechanical (Motorized).
3. Type of mechanism for functioning or controlling Height of bed should be Electro-Mechanical (Motorized).
4. Should have Bed top perforated. Bed should have radio translucent top (X-Ray translucent).
5. The panel of ICU bed should have the followings;
    a) Swing up down type side panel.
    b) FOUR (4) Number of Side panel.
    c) B-type shape or D-type Head & Foot panel /Board.
    d) Detachable type or Swing up down type Head & foot Panel.
6. Number of hooks provided in IV rod should have minimum 2.
7. Should have Availability of rectangular telescopic tube box housing for tension spring.
8. X-Ray film holder used from one side.
9. Power of motor should be (0.5 hp or 0.7 hp.)
10. Number of caster to which braking system provided 2 or 4 numbers.
11. Safe working load capacity of ICU bed is 200 kg or more.
12. Therapeutic Weight limit for mattress 175 kg.
13. Facility of Resettable over current breaker shall be fitted for protection.
14. Should have Electric Shock Protection of class 1 (type-B) as per IEC.
15. Should have Ingress Protection (IP).
16. Bed height adjustment range should be 500-900mm.
17. Clearance between Bed Base frame and Floor surface should be 150mm.

MATERIALS:

1. Material for the frame of bed should be MS.
2. Material for side railing/ Side Safety guard should be ABS plastic.
3. Material for Head & Foot Panel/Board should be ABS plastic.
4. Material for Bed top Section should be ABS Plastic.
5. Material of wheels should be Polyester.
6. Material for IV rod with chromium plated should be SS.
7. Material for ICU Bed Mattress should be PU foam.

MAXIMUM DEGREE:

1. Maximum Adjustable Back Rest Angle in Degree should be 0 to 70.
2. Maximum Adjustable Knee Rest Angle in Degree should be 0 to 25.
3. Maximum Trendlenburg Angle in Degree with tolerance ±2 degree should be 12.
4. Maximum Reverse Trendlenburg Angle in Degree with tolerance ±2 degree should be 12.

DIAMETER OF ICU BED:

1. Length of bed with 2% tolerance should be 2100-2200mm.
2. Width of bed with 2% tolerance should be 1000-1050mm.
3. Bed height adjustability range should be 500-900mm.
4. Diameter of Castor Roller should be 125-150mm.

Number of position of the ICU Bed:

The model should have minimum 7 numbers of positions as below:

i. Back rest.
ii. Upper leg/Knee rest.
iii. Height Up & Down.
iv. Trendelenburg.
v. Reverse Trendelenburg.
vi. One key auto CPR.
vii. One key Cardiac chair positions.

Power Supply: Single phase 230 Volt, 50 Hz (AC Supply) fitted with Indian plug of suitable rating.

Warranty: Should have 3yrs. of comprehensive manufacturer warranty excluding consumable parts.

Accessories to be supplied:

1. MS Powder coated urine Bag Holder - 1no.
2. Plastic moulded File/ Chart Holder - 1 no.
3. Hand Sanitizer holder: 1No.
4. MS powder coated Oxygen cage cylinder cage - 1no.
5. Minimum Four section X-ray translucent mattress with cover and minimum 4" thick high quality foam.
6. MATTRESS: Having the following technical specification;
    a) Mattress should be provided with each ICU bed.
    b) Mattress shall be made of High resilient & bio-density foam.
    c) Mattress should be translucent to allow radiography using portable X-ray machines.
    d) Mattress should be made in cube cut design & independent cubes promote air flow to reduce moisture.

The ICU mattress should be 4 section quality X-ray radio translucent foam mattress (PU foam of high density greater than 30 Kg/m^3 with Water-proof, anti-microbial and flame resistant PVC rexine covering.

42.BEDSIDE LOCKER

Product & Manufacturer Quality Standard Certification:

All the certificates commonly asked in the "General Requirement for all items" under "Product & Manufacturer Quality Standards".

Operational Requirement:

- A stainless Steel of 20 Gauge tray top with raised borders on 3 sides forming the upper surface.
- The body should be made of 20 G MS CRCA sheet.
- All MS parts to be pre-treated and epoxy powder coated.

Technical Specifications:

1. Overall size (Approx):40 (W) X 40 (D) X 80 (H) cms.
2. Frame Tube Thickness should be 1.2 to 5.0mm or higher.
3. No. of castor wheels should be 4 numbers.
4. Diameter of castor should be 50 to 150mm.
5. Should have bumper at the back.
6. Painting should be powder coating.
7. Slide of drawer should be fitted with Telescopic Channel.
8. Material of Enclosure of bedside locker should be SS.
9. Material of cabinet and Drawer should be Mild steel.
10. Should have Locking system for cabinet and drawer.

FEATURES AND FRAME TUBE:

1. Number of Shutters should have 1.
2. Number of Open shelves should have1.
3. Number of Shelves should have 2.
4. Finish should have Power Coated.
5. Frame tube material should have mild steel.
6. Section of frame tube should have rectangular.

Warranty of the Product:

- 2 years.

43. **CT Scan (128 Slice)**

Point wise technical compliance report supported by the technical catalogue/specifications must be submitted.

 Any product quality standard or technical specification without supporting documents shall not be considered by the technical evaluation committee.

 Any information not available in the brochure/ datasheet should be verified by original equipment manufacturer on its letterhead and only then the same will be accepted by technical committee.

 Refurbish product or model shall not be supplied. The supplied machine should be of latest technology and not older than 4 yrs old introduced globally. The bidder should submit the declaration from Original Equipment Manufacturer (OEM) regarding the technology of the quoted model not older than 4 years. The service provider shall furnish the New Machine Manufacturing Certificate from the Original Equipment Manufacturer along with import data with machine serial number during the signing of agreement.
Product Quality Standards:
1) The quoted model should have "USFDA (510K/CFG)" AND "EU-CE certified. The EU-CE certificate should be issued from a notified body having notified body number.
2) The manufacturer of the quoted product should have "EN ISO 13485 certificate issued from a notified body" OR "ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB" OR "ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA".
3) The quoted model should be certified to the electrical safety standard "IEC-60601" OR certificate issued from BIS conforming to "IS 13450" OR "IS/ISO 80601".
4) Should furnish the clear model approval of the quoted model from AERB.

General Requirement: The system should be the latest generation multi-slice CT scanner capable of generating/ acquiring/ producing 128 or more slices per 360 degree rotation for all types of scans and applications. CT Procedures:
1. Contrast Media Tracking.
2. CT Angiography.
3. CT Pulmonary Angiography.
4. CT Fluoroscopy for Biopsy.
5. Advances 3D analysis.
6. Dynamic cerebral perfusion mapping & Lungs perfusion.
7. Head CT.
8. Thoracic CT.
9. Abdominal CT.
10. Pelvic CT.
11. Skeletal CT.
12. Interventional CT.
13. Cardiac CT.
14. Liver segmentation & Volume quantification.

The offered product should meet the following specifications: 1. Gantry:
a) Should incorporate low voltage slip rings technology.

b) Minimum scan time for a 360º rotation should be less than or equal to 0.35 sec. (350 mili sec.).

c) Should have minimum Physical/Digital tilt of -24 degree to +30 degree or more on either side.

d) Gantry aperture should be at least 70 cm in diameter.

e) Should have ceiling suspended online imaging system inside the gantry room for CT fluoroscopy for biopsy with 17 inch medical grade LCD monitor.
2. X-Ray Generator:
a) Should be compact and in-built in the gantry.

b) Should be high frequency having at least 72 kW output or more.

c) The mA range available should be between 20 to 600mA or more.

d) Tube Voltage: 80 to 140 kV. 3. X-Ray Tube:
a) The anode heat storage capacity should be of at least 7 MHU or more.

b) Peak heat dissipation rate of anode should be at least 1000 KHU/min

c) X-ray tube cooler unit should be inside the gantry. 4. Detectors:

a) These should be of solid state type.

b) The system should have at least 64 “physical rows‟ of the detectors. Number of elements in each row should be specified.

5. Patient Table:
a) Minimum weight bearing capacity of at least 200 kilograms

b) The minimum table top height should not be more than 53cms from floor level for easy transport of trauma patients.

c) Table top width to be at least 40 cms

d) The range of metal free scanable range should be at least 160 cm.

6. Spiral CT capabilities:
a) Minimum slice thickness should be 0.63 mm or less and maximum 10 mm or more.

b) Pitch factor (volume pitch): Variable between 0.5 to 1.5 or more and should be user selectable.

c) Spiral length: 150cm or more.

d) Single continuous 'spiral-on time' should be minimum 100 seconds or more.
7. Topogram:
a) Length and width: specify range.

b) Scan times: specify range
c) Should be possible to interrupt acquisition manually once the desired anatomy is obtained.

8. Data acquisition system:
a) System should have minimum 64 rows of detector capable of acquiring/generating 128 slices.

b) Mention minimum acquired slice thickness in Axial & Helical mode after reconstruction.

c) Acquisition of cardiac images with ECG gating (prospective & retrospective) should be possible.

d) Step and shoot technique during cardiac scanning for dose reduction, or a similar alternative technology should be available.
9. Image Evaluation Tools:
a) Parallel evaluation of multiple ROI in circle, irregular and polygonal forms.

b) Statistical evaluation for area/volume, S.D., Mean, Min/Max and histogram.

c) Distance and angle measurement, freely selectable positioning of co-ordinate system, grid and image annotation.
10. Latest Iterative Reconstruction Technique:
a) ASIR-V/ iDose4 Premium / SAFIRE or latest available with the manufacturer to be quoted as standard.

b) Low dose protocols for pediatric and infant scanning.

11. Image Reconstruction:
a) Real time reconstruction speed: 20 images per second or more at 1024 x 1024 matrix.

b) Display matrix: 1024 x 1024 or more.

c) Reconstructed slice thickness range should be less than 0.625 mm to 10 mm.

12. Image Quality:
a) The high contrast resolution be more than 16 lp/cm in all routine scans, including spiral and axial mode.

b) The low contrast resolution should not be more than 3 mm at 0.3%.
13. Patient Communication System: An integrated intercom and automated patient instruction system (API) should be provided.
14. Image Transformer/Networking:

The unit should have DICOM Interface for transmitting images and information in DICOM standard and also to permit communication between devices of various manufactures. The unit should have provision for connectivity of the Hospital Information System/Radiology Information System.
15. Software and Workstation:
a) The workstation software should be from original equipment manufacturer of the CT scan machine.

b) Should be provided with two independent workstations as a client server based solution with minimum 40,000 slices with minimum 64GB RAM, 3TB storage, 19 inch medical grade LCD dual monitor and fully DICOM compatibility and complete post processing software as follows,
i. Multi planar reconstruction (MPR).

ii. Minimum and Maximum intensity projection.

iii. 3D Volume rendering.

iv. 3D SSD (Shaded Surface Display).

v. Advance Vessel Analysis with plaque visualization.

vi. Auto Bone Removal.

vii. Volume measurement.

viii. Lung Nodule analysis & Quantitative analysis of Pulmonary emphysema.

ix. Liver lesion analysis (Complete Liver Segmentation & Semi automated Segmentation of arterial, portal venous & venous vascular & bile duct tree with analysis)

x. Colonography.

xi. Perfusion CT (Whole body including brain).

xii. Image Fusion of CT, MR & PET Data.

xiii. Neuro DSA.

xiv. Coronary tree analysis: automated 3D processing of coronary arteries,
calcium scoring, stent analysis, LV analysis.

xv. Multi-modality automatic tumor tracking & Automatic measurements in RECIST, WHO, Volume & Choi criteria calculation.

xvi. Virtual endoscopy.

xvii. AI based feature: Patient positioning with 3D camera/precise position & Precise planning and similar.

xviii. Dynamic CTA (4D scan): Dynamic CTA with minimum coverage of 8cm or more using bi-directional table movement technology or to cover large area greater than detector width(Helical Shuttle/Adaptive 4D Spiral/Jog Scan/Equivalent Technology)
c) Standard dual energy applications should be available in the system.

d) One workstation should be installed in the console room capable of simultaneous viewing with all post processing applications & operations independently without help of main console provided with Two 19 inch medical grade LCD color monitor.

e) Second workstation with two 19 inch medical grade LCD color monitor having all post processing applications need to be installed for examination and reporting purpose.

OTHER REQUIRED ITEMS:
1. Dual head Pressure Injector:

(i) Should be EU-CE certified from Notified body.

(ii) Flow rate: 0.1-10 ml/sec, Volume: 1 ml to syringe capacity, programmable pressure Limit of 325 psi with 200 ml disposable sterile syringes. Syringe heater range 35 deg C+/- 5 deg C.

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

(iv) 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.
2. DICOM Printer (dpi 500 or more) of a reputed make Integrated with main console and workstation and should support 5 Multiple Film Sizes.

3. Color Laser Printer (High Resolution) for color coded images.

4. UPS of suitable rating with 30 minutes, back-up‟ to run Console Workstations and DICOM Printer.

5. LED based view boxes with adjustable illumination to view 3 films of 14” x 17” in each view box.

6. Light weight Lead Aprons -5 Numbers,

7. Thyroid Collars: 2 Numbers,

8. Gonad Shields: 2 Numbers for male and 2 numbers for female,

9. Lead apron Hanger for hanging at least 5 Lead aprons)-1 Number,

10. Lead glass for console viewing window size 150X100cm (imported quality).

44. HPLC MACHINE FOR HAEMOGLOBIN ELECTROPHORESIS

A. Product Quality Standards:

1. The quoted model of the product should be "USFDA approved (having 510k/CFG)"**AND**"EU-CE approved as per Annex-III of IVD 98/79/EC Directive or latest".
2. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body **OR** ICMED 13485 (with or without plus) certificate issued from certification bodies accredited by NABCB **OR** ISO 13485 certificate issued from certification bodies accredited by NABCB / Nationally Recognized Accreditation Board under IAF MLA.
3. The quoted model should confirm to "IEC 61010" **OR** "IS/ ISO / IEC 80601 (Part 2)" **OR** "IS 13450 (Part 1)".Should mandatory conform to IEC 61010- 2-40 for the Safety requirements for electrical equipment for measurement, control, and laboratory use.
4. The quoted model of the medical device must be registered under CDSCO and submit the license to manufacture for sale or for distribution of the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

B. Technical Specification:

1. Automated, Integrated system, dedicated to Glycosylated Hb, Thalassaemia and hemoglobinopathy testing and screening based on HPLC technology.
2. The system should be able to screen and quantitate different variant haemoglobin and detect the most commonly occurring abnormal hemoglobin like Hgb S, Hgb F, Hgb D, Hgb E, Hgb C, Hgb Q-India and other rare abnormal hemoglobin.
3. Complete ready to use kit should be provided with Buffers in transparent plastic tanks to view the level of buffers; columns, primers, calibrators & sample vials.
4. Should be suitable for labs with greater than 200 samples/day.
5. The system should have optional features to load atleast 50 samples simultaneously with continuous loading facility.
6. The system should have in-kit external standards for instrument calibration ensuring accurate quantitation of results.
7. The system should have a bi-directional LIS.
8. The system should have a feature sample position identification to avoid error in case of faulty barcode reading.
9. The system should have a visible alarm system for low buffer reservoirs, low level value for cartridge injections and overflow for the waste tank, as well as in built alarms for calibration failure.
10. The system should be capable of positive sample identification using a Barcode reader.
11. The system should have the facility of primary tube sampling and direct dilution of the samples without manual intervention.

12. It should have an inbuilt system check facility which checks that all the system parameters (eg, cartridge, buffer, reagent, waste etc) are ready before the sample analysis.
13. It should be able to print a hard copy report giving identification and information on the subtype and quantity of haemoglobin detected. It should have the facility to view current and stored chromatograms & should enable storage of chromatograms.
14. The system should have software for real time viewing of the analysis of the sample.
15. The company should have offline library of chromatograms for result interpretation
16. The company should have optional feature of capillary collection kit for remote sample collection with sample stability at 2-8 degree C for 14 days.
17. Compatible Online UPS to be provided for 1 hour back up.
18. Computer and printer should be provided with the HPLC system.
19. Appropriate software for data analysis.
20. Equipment should be provided with reagents for atleast 100 tests for standardization.
21. Company should take the responsibility for doing IQC and EQAS for 5 years.
22. Company should take responsibility for corrective action as necessary for any errors, detected either internally or through EQAS for atleast 5 years.

C. Warranty- 5 years of Comprehensive warranty on the entire system along with the Online UPS excluding consumables.

<u>Note:</u> Refurbished machine shall not be allowed. Supplier must provide original documentary proof of the date and place of manufacturing of supplied equipment.

45.MULTIPARA PATIENT MONITOR (5-Para)

Product Quality and Safety standard certification:

1. The quoted model should be USFDA (510k/CFG/PMA) and EU-CE certified. The EU-CE certificate should be issued from notified body having notified body number.
2. The quoted model should be certified to the electrical safety standard IEC 60601-2-49, Particular requirements for the basic safety and essential performance of multifunction patient monitoring Equipment.

Manufacturer Quality standard certification:

3. The manufacturer of the quoted product should have EN ISO 13485 certificate issued from a notified body or ICMED 13485 (with or without plus)certificate issued from certification bodies accredited by NABCB or ISO 13485 certificate issued from certification bodies accredited by NABCB/Nationally Recognized Accreditation Board under IAF MLA.
4. The quoted medical device must be registered under CDSCO and submit the license for manufacture to sale or distribute the medical device. If not registered, the acknowledgment copy of the online application for the said registration must be uploaded in the bid.

Technical Specifications:

1. Patient monitor should be preconfigured or Non Modular having monitoring facility for ECG, RR, SpO2, NIBP ,Temperature and the features suitable for neonate, paediatrics & adult patients.
2. Monitor must have bright, highly visible at all ambient light levels of minimum 10 inch or more color LCD/LED/TFT display with full touch screen/Rotary Knob/Rotary knob and touch screen facility.
3. Monitor must have the facility to display minimum 4 wave form or more along with related numerical parameters on single screen.
4. Monitor must have facility to display 12 lead ECG through 5 lead ECG cable. Must have advanced arrhythmia detection and ST Analysis through four lead or more as standard feature.
5. The measurement technique for NIBP should be Step-deflation oscillometric having automatic and manual option.
6. For measurement of pulse oximetry, the monitor should have measurement technology of Nellcor Oximax or Masimo Set which should capable to measure Spo2 during motion and low perfusion conditions**. Pulse Oximetry Technology**: The model having MASIMO-SET technology or Nellcor Oximax technology,must have to submit the authorization letter from the technology provider i.e. MASIMO/NELLCOR for offering their technology in the quoted make and model of Multipara monitor.
7. The monitor should have measure and display the perfusion Index.
8. System must have minimum 48 hours review data including graphical and tabular trends, arrhythmia event recalls.
9. Must have facility to connect with network printer, at any point of time and able to take print any review data (Trends, Graphs, waveform full disclosure, arrhythmia recall etc.) and also should have direct connectivity to HL 7.

10. The Monitor should have inbuilt Rechargeable battery with minimum 120 minutes of power backup and recharging time of the battery should be less than 6 hrs.
11. The system should have Alarm facility as below :

    i.Should have Escalation of Alarm based on priority as high ,medium and low and facility to activating silence of alarms ii. Should have audio visual alarms such as Cuff leakage &disconnect , inflation/deflation error, Battery low, Sensor/Wire/Probe disconnection alarm etc.

    12. The monitor should supply with good quality Wall mounting bracket to mount the Monitor on wall of the patient bed site.

13. <u>Accessories to be supplied with each Monitor</u>:

i. Reusable NIBP Cuff (Adult, paediatric and neonate) with hose pipe -2 No. each
ii. Reusable 5 Lead ECG electrode Cable for Adult-Paediatric and neonate (Complete Set) – 01 No.each
iii. Packs of 100 disposable ECG connection electrodes.
iv. Reusable SPO2 finger Probe (Adult-Paediatric and Neonate) - 01 No. each (Clip or Silicon type for adult - paediatric and rap type for neonate)
v. Reusable Temp. Probe: 1No. Each for Skin & Rectal.

Warranty: Comprehensive warranty should be 3 years for the Patient monitor and 1 year for reusable accessories from the date of installation excluding consumables.