9th Sepetember ,2025

Minutes of the Pre-bid meeting for Hybrid Cath Lab (Biplane DSA with Modular OT and Associated Equipment)

This is with reference to the specifications approved by the committee, including the external expert from AIIMS, New Delhi, for the Biplane DSA and Modular OT.

The tender was floated on GeM vide tender no. GEM/2025/B/6518481 dated 31/07/2025 for Hybrid Cath Lab (Biplane DSA with Modular OT and Associated Equipment) with the approval of the Competent authority.

Two pre-bid meetings were conducted with respect to the said tender, with a gap of seven days, on 8th Aug 2025(1st pre-bid meeting) & 20th August 2025(2nd Pre-bid meeting), both offline and in hybrid mode, to discuss the representations and seek clarifications regarding the installation site.

Both meetings were attended by the Head of the Department of Cardiology, other faculty members, and the following prospective bidders.

i) M/S Philips
ii) Erbis Engineering (on Behalf of Canon)
iii) M/S Siemnes
iv) M/S BPL
Iv) M/S Transforma
Vi) M/S Vikas Medical Devices
Vii) and other representatives from Prospective bidders

After due deliberation and review of the representations received via GeM and the amendment requests received through email, the following amendments to the tendered technical specifications were considered. These changes were made to ensure that all prospective bidders are able to participate with their latest state of the art products, while still complying with the tender requirements.

It is also noted that all prospective bidders requested the deletion of the following associated equipment from the current tender for the Hybrid Cath Lab, suggesting that these items may kindly be processed separately being these items are not manufactured by the same OEM as the main Cath lab unit :

- Impella
- IVUS
- FFR
- Non-invasive CO Monitor
- Syringe Pump
- Dual chamber temporary Pacemakers
- ACT machine
- Radiation Protection Equipment

The HoD,Department of Cardiology, after due diligence, has also recommended that these associated equipment—being essential for advanced procedures—may kindly be processed separately and simultaneously, subject to the approval of the competent authority. This will help ensure that the procurement of these essential systems is finalised before the commissioning of the Hybrid Cath Lab, thereby enabling a fully equipped, state-of-the-art facility capable of delivering comprehensive patient care. However, it was informed that the Impella device was already tendered separately in GeM with the approval of the competent authority.

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Cont...

Final Amended Technical Specification for Biplane DSA & Modular OT

Department of Cardiology NEIGRIHMS aims to establish a hybrid operating theatre with a Biplane Cathlab to provide cutting-edge care for complex coronary interventions, structural heart disease treatments, and electrophysiological procedures and to carryout hybrid procedures like transcatheter aortic valve replacement (TAVR), left atrial appendage closure (LAAC), or percutaneous mitral valve repair etc. with the onsite real-time, on-the-spot transition between diagnostic, interventional, and surgical procedures for treating high-risk patients with multi-organ or severe cardiovascular conditions, who may need a combination of catheter-based and surgical interventions. This facility will integrate interventional cardiac services alongside neurosurgery and cardiothoracic surgery. This system would promote efficient workflow, as it reduces the need for patient transfer between different areas of the hospital, thereby maintaining the highest standards of care and patient safety, including reduced procedural time. The Department of Cardiology has adequate space and manpower to run the above services regularly. The specifications for Biplane Cathlab with Hybrid OT are provided as below:

Sl no	Item Details	Qty
A.	DIGITAL SUBTRACTION ANGIOGRAPHY UNIT (BIPLANE) with hemodynamic Monitor & accessories	1
B.	Anaesthesia workstation with monitor & e-charting system	1
C	Cardiac Monitor with Defibrillator - 01 Unit	1
D	~~IABP machine~~	~~1~~
E	~~Radiation Protection Equipment~~	~~1~~
G	~~Dual Chamber Temporary Pacemaker~~	~~2~~
H	~~Syringe Infusion Pump~~	~~4~~
I	~~Handheld Non-Invasive Cardiac Output Monitor~~	~~1~~
K	~~FFR console~~	~~1~~
L	~~ACT machine~~	~~1~~
M	Modular Ot & its components	1

A.SPECIFICATIONS FOR DIGITAL SUBTRACTION ANGIOGRAPHY UNIT (BIPLANE)

The manufacturer/bidder must quote the latest 'state of the art' Bi-Plane Digital Subtraction Anglography with flat panel detector technology for vascular diagnostic and interventional procedures as per the specifications below.

- ~~The quoted model must be launched in or after the year 2019 onwards.~~
- The offered model should be BIS / European CE with 4 digit notified body number/ USFDA certified. USDA approved (authentic and legible certificate for the same to be annexed).
- Also, the vendor will guarantee that the system supplied is not refurbished and the DSA system quoted is the latest best available model in the segment quoted, at the time of delivery and should submit an undertaking in this regard.

Certifications:

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1. The system should be AERB type-approved, and a copy of E-LORA Listing should be submitted along with the bid. If the quoted model has not yet been installed in India, the vendor should submit an NOC from AERB. Regular QA according to AERB norms will be the responsibility of the bidder during warranty and CMC period.
2. Should have an import/manufacturing license from the Central licensing Authority or State licensing authority of CDSCO for Medical Devices, and a copy of a valid license should be submitted for the quoted model.
3. In case the vendor has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced at the time of supply/ NOC for the quoted model.

A. Gantry

1. The system should have two gantries: one floor-mounted and one ceiling suspended, providing full body coverage. The lateral plane should have motorised longitudinal C-arm movement.
2. It should be possible to pre-program the gantries for multiple examination positions.
3. All movements of the gantries should be controlled from the controller on the table side ~~as well as from the control desk.~~
4. The system should have adequate collision protection for the safety of the patient.
Both gantry movements should be rapid, motorised & collision-proof. Manual override by the operator should be possible.
5. Both gantries should have a fast speed for angulations and positioning. The frontal system should have a speed of at least 15 degrees/sec for all positions, and the lateral plane should have a speed of at least 8 degrees/sec.
6. Gantry angulations in both planes, frontal aria lateral, should be freely user selectable to satisfy clinical imaging needs.
7. Both the gantries should have an automatic positioning capability dependent on the reference image being selected.
8. C arm should be capable of scanning finger to finger and head to toe by operating the joystick on the table side with out repositioning the patient

B. Patient Table

1. The table should have motorised Vertical & longitudinal and free floating with electromagnetic locking facility.
2. It should have the motorised stepping facility for automatic bolus chase for peripheral angiography.
3. It should be possible to swivel the table or should have multiple floating success in case of emergencies.
4. Table should have a Trendelenburg tilt and cradle facility.
5. It should have patient load capacity of 200Kg or more
6. Table side touch control panel for 3D reconstruction and C-arm positioning with respect to 3D image & selection of 3D image positioning should be provided
7

C. X-ray Generator

1. System should have Microprocessor-controlled high-frequency (100 kHz) X-ray generator with automatic dose rate control for fluoroscopy and acquisition.
2. Generator should be multi-pulse/high frequency for constant output.
3. Max generator power output should be 1000 mA at 100 KV, equivalent to 100 kW.
4. Radiography KVP range should be ~~40 kV~~ 50 kv-125 kV ~~in 0.1 kV steps.~~
5. It should have an automatic exposure control device for radiographic fluoroscopy and angio mode. The Manual Override facility is preferable.
6. It should have a digital display of kVp & mAs.

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7. Tube current should be freely selectable in 0.01 10 mA steps for continuous fluoroscopy, pulsed fluoroscopy and angiomode
8. Anatomical programming radiography should be possible.
9. It should have overload protection.
10. It should have the facility for pulsed fluoroscopy at variable rates for reducing the radiation dose to the patient during the intervention procedure.

D. X-ray Tubes

1. Both planes should be provided with rotating anode high speed tubes with increased contrast during fluoroscopy, especially for examinations on obese patients
2. The focal spot should have the following sizes:

1.0 mm or less with load 80 KW or more in minimum one plane.
0.6 mm or less with load 38 KW or more in minimum one plane.

3. Anode heat storage capacity should be 3 MHU or more (true value) having liquid bearing technology or metal lubricant
4. The system should have adequate cooling facility for the x-ray tubes for uninterrupted performance during procedure.
5. Fluoroscopy power (maximum continuous power)-~~tubes~~—both X ray tube & X-ray generator, should provide at least ~~2.4kW continuous output for over 30 minutes.~~2.2 kW continuous output for long time.

6. Mention the Heat dissipation rate, higher heat dissipation rate is preferable
7. Leakage radiation should conform to international standards. Filtration & leakage radiation dose should be indicated in the offer.
8. ~~The lateral plane tube should be mounted on the far side (left of the patient) of the ceiling suspended C-arm to reduce scatter radiation to the operator.~~
9. System should be quoted with the latest dose reduction technique for better image quality with less dose.

E. Collimator

1. One collimator for each plane is to be provided.
2. The collimator should have facility for automatic /pre-program / suitable alternative technology copper pre-filtration for reducing the X-ray dose.
3. The collimator leaf should have IRIS/rectangular/ wedge shaped type arrangement with independent rotation and shift of filter blades
4. The collimator should have the facility for the dose measurement chamber in order to display the skin dose on the monitors in the lab.
5. The collimator should have facility for automatic copper pre-filtration for reducing x-ray dose as per patient thickness. Additional filters with multiple leaf's should be provided & it should be possible to position these filters & collimator leaf's without live fluoroscopy & independent of each other (clearly mention in the offer).
6. Automated exposure control with at least 3-level motorized Cu-filters
7. Independent rotation and shift of filter blades
8. Automatic synchronous rotation of the detector and collimator unit to compensate for image rotation at different examination positions.

F. Biplane Digital System

1. Dynamic flat detector system with high spatial and ~~14 bit~~ 16 bit contrast resolution with 1.5k matrix resolution with Integrated collision sensor, Removable grid and active detector cooling facility

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2. Size of the detector
- Size of frontal plane should be at least 43 cm diagonal
- Size of lateral plane should be at least 39 cm diagonal

3. Detector rotation in portrait to landscape made and Vice versa, should be possible at detector level, examination console and control console at least in frontal plane

4. Standard AAPM phantoms for resolution measurement to be provided.

5. It should have multiple input format / field with minimum of 4 field zoom sizes.

6. Spatial resolution should be at least 2.5 LP/mm in the frontal plane and 2.5 LP/mm in the lateral plane.

7. ~~Mention the Pixel pitch and detective quantum efficiency (DQE)~~ Pixel pitch should be 160 micron or less at full and all FOV's and Detector quantum efficiency(DQE) should be 75% or more

G. Imaging Display System

1. Examination Room Monitor

I. Medical grade large high definition display (minimum 55 inches) to display live. reference, 3D CT /MRI images of any patient, Hemodynamic and EP waveforms with layout selection from integrated tableside control in the exam room.

II. Another Two medical grade (2kX2k) monitors (one for live, another for review) mounted on a movable trolley should be provided as a standard, for radiographer viewing while doing procedure.

2. Console room

I. Control room shall have at least 4 (QTY) of wide screen (19" or more each), Medical grade monitors for display of live, playback, reference images of each plane.

II. Gantry, collimator, table & injector operations should be possible from control room console without interrupting image review, hard copying and archiving or image transfer functions.

III. Separate/inbuilt Monitor for patient data registration.

IV. Integrated Two-Way communication system with integrated mic & speaker to allow duplex communication between Console & Exam room.

H. Digital Imaging System

1 Should be possible for Fast, direct access to all series, single images and reference images, store monitor images, in both the examination room and the control room

2. Should be Possible for display of USG/CT/MR images ~~as static reference image~~ on the examination room monitor

3. Post processing software facilities with Changing window values, real time edge enhancement, positive/negative image display, electronic shuttering, roaming. image reversal, zooming/panning. annotation, Distance, angle measurements image labelling, text functions, drawing lines, arrows and circles

4. It should have the capability to acquire images in 1024 x 1024 matrix with a maximum speed of 6 frames or more per second on-line subtraction. Specify the
maximum image acquisition rate without subtraction.

5. It should have a minimum image storage capacity of 50,000 or more images in the 1024 x 1024/12 bit.

6. Operating modes

A. Fluoroscopy mode should have following functions

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- Biplane Dual Fluoroscopy mode to allow side-by-side display of digitally processed non-subtracted fluoroscopy and trace-subtract fluoroscopy for visualization and catheter guidance during complex procedures
- Digital pulsed Fluoroscopy with 0.5-7.5,10,15,30 p/s
- Road Mapping with automatic pixel shift
- Overlay fade (online superimposing of active fluoro and reference image)

- Store monitor and store reference (even during fluoroscopy
- Store Fluoro: Last 1024; at least the last 900 images of the last performed fluoroscopy
- Last image hold (LIH)

B. DSA model should have the following functions

- Digital subtraction angiography with digital real-time filtering with frame rates from 0.5 f/s to 7.5 f/s in 1K/14-bit matrix or better
- Remask/move mask/Replace mask, peak pacification for Iodine contrast (Max Opac) and CO2 contrast (Min Opac) display of anatomical background (Landmark) from 0 to 100 %
- Pixel shift: Manual pixel shift, automatic pixel shift, flexible pixel shift

7. A separate workstation for 3D reconstruction of the rotational angiography images should be provided. The 3D image measurement and slicing should be possible.
Facility to display reconstructed images in the procedure room should be provided.
The same workstation should have the capability to query, retrieve images from existing PACS system and also should have 3D post processing capability and the same should be displayed on one of examination room monitor for viewing during interventional procedures

8. It should be possible to fuse the 3D CT data with 3D Angio to combine high resolution vessel information with soft tissue information.

9. The complete digital system along with the workstation should be networked and connected to a DICOM compatible laser camera. Entire networking and necessary switches should be borne by the vendor.

10. The digital system should have software for vascular analysis and quantification including stenosis %. All measurements should be possible from the patient table side

11. DVD reader and CD/DVD recorder should be provided with a workstation and main console Computer system.

12. The system should be able to Query, receive DICOM format CT/MRI/USG from PACS or other modality network nodes and display images on reference monitor,

13. DICOM print facility should be made available. Also compliant with HIS/RIS/PACS

14. It should have a facility to measure dose during the procedures.

15. The system should have latest radiation safety package like Clarity IQ/CARE & CLEAR MAX/Blueprint/ Auto right / equivalent

16. All software updates should be provided in warranty & CMC period.

I. Essential Applications and Software

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1. Dyna CT or equivalent for acquisition of 3D high contrast reconstruction based digital rotational angiography (2D/3D) at a speed of 40 degree/sec and acquis frame rate of atleast 50/sec. Automatic image data transfer to the advanced workstation while all parameters needed for the 3D reconstruction are already included in the exam set to generate cross sectional CT like images.
2. Road mapping facility (Real time 2D & 3D) should be available with possibility of superimposing fluoro image on reference image. 3D road mapping facility directly from CT/MR 3D image without rotational angio 3D image to save contrast and radiation.

3. Smart mask road mapping procedures by overlaying fluoroscopy with a selected reference image on the live monitor. The reference and fluoro images can be faded to taste on the monitors.

4. Peristepping/Bolus chase software (Stepping of the table with a single contrast-medium injection performed while observing the contrast medium bolus should be provided like Peri stepping or equivalent /Bolus chase software) should be provided.

5. Real time stent enhancement

6. Needle guidance to plan needle-based procedure in a 3D volume by specifying a target and multiple trajectories

7. Embolisation Guidance for planning and performing embolizations

8. Rotational angiography facility (2D & 3D) at a speed of at least 40 degree/sec. with acquisition frame rate of at least 25 frames/sec. in 1k matrix with facility for online display of subtracted images should be available. Rotational data acquisition with an output of cross sectional CT like images should be possible

9. System should have CT/MR/PET fusion application

10. Facility of CO2 angiography with supportive software should be provided

Optional Software:

1. 3D CT/DSA perfusion imaging. contrast-enhanced blood volume distribution of the whole brain in 3D cross-sectional images based on a steady-state contrast injection
2. Dyna 4D or equivalent software to see flow patterns in 3D
3. TAVR assist software or equivalent

J. Essential accessories:

The following essential accessories are to be provided with the unit
1. Broadband connection and LAN for the operation of the SRS System is the responsibility of the vendor
2. **Complete hemodynamic Multipara patient monitor- 01 units**

- Hemodynamic recording and documentation system with signal input /Amplifier (fanless design)unit at the table side in the Procedure room fulfils the hygienic requirements of a surgical environment
- The signal Input Module must have following inputs
  - 12 Lead ECG Amplifier with floating input with signal input unit at the table side
  - At least 4 IBP pressures with floating inputs with Zeroing options from Aplifier box / Signal input unit , Range from – 50 to 360 mmHg or better
  - Respiration rate
  - $etCO_2$ concentration

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- Body temperature
- Time measurement
- SPO2, Pressure gradient facility with 0 % – 100 % for heart rates 40 – 200 beats/min, Accuracy:- ≤2
- NIBP measurement For heart rate 40 – 200 beats/min: Adult Systolic: 40 – 260 mmHg Adult MAP: 26 – 220 mmHg Adult Diastolic: 20 – 200 mmHg Neonatal Systolic: 40 – 130 mmHg Neonatal MAP: 26 – 110 mmHg Neonatal Diastolic: 20 – 100 mmHg
- Cardiac Output

- Must have a flexible Mount option on cath table.
- Must be connected through a single cable to the control unit with proper cable management
- Storage of patient-specific data, procedure details, event log, and haemodynamic calculations on hard disk and retrieval can be done from the Console room as and when required.
- The entered data can be exported for statistical purposes from the Console room as and when required.
- ECG cable and pressure transducers with a facility for superimposition of pressure tracings with printing supports inside the operating room. 10 Nos (each to be supplied free of cost one one-time consumables).
- Must be HL7 and DICOM compatible
- Must be from the same Make /OEM from the cathlab equipment
- Must be Integrated with the Big Cath lab display
- Must supply with Control room monitors of size 19 Inch or more :-
- One for real-time waveforms, one for operator
- Computer for Hemodynamic monitor:- CPU Intel Core i5 or equivalent RAM 8 GB Disk drive Main drive: 256 GB SSD Service drive& 500GB or more HDD Disk drive Network Ethernet ports Wifi ,Operating System Microsoft Windows /Linux/Mac

~~Should be modular, portable and user friendly with 17" Touch screen LED large font display and be able to monitor adult, paediatric and neonatal paOents. Should be able to display up to 12 waveforms:~~

~~• Should have following vital sign monitoring for Adult, Paediatric and neonatal paOents such as 3/5 lead ECG;~~
~~Spo2, NIBP, Dual Temperature, RespiraOon & dual IBP, AGM, BIS and CO as standard parameters.~~
~~• Should have facility for transport monitor measuring ECG, Spo2, NIBP, Temperature & Resp. parameters.~~
~~• Should be able to monitor ECG: 3/5 lead, Cascade ECG waveform with HR measurement, arrhythmia detecOon;~~
~~ST segment analysis. 12 Lead ECG Analysis (OpOonal).~~
~~• Non-Invasive Blood Pressure (NIBP). Measurement and display of systolic, Diastolic and mean pressure values~~
~~on NIBP measurement through Oscillometric method for adult, child and neonate. Modes: Manual, STAT (ConOnuous 5 min. operaOon) and automaOc selectable interval 2- 480 minutes.~~
~~• RespiraOon: Display of respiraOon waveform with respiraOon rate using impedance principle.~~
~~• Temperature: Should be able to monitor two temperatures simultaneously. The unit selecOon should be possible.~~
~~• Pulse oximetry measurement should be suitable for Adult, Paediatric & Neonate.~~
~~• The main monitor must have a portable mulO-parameter module (built-in parameter displays of approx. 4 inch) that can be connected and disconnected easily with the monitor switched ON.~~
~~• The mulO-parameter module should be compaOble with paOent monitors in the OperaOng rooms or other~~
~~departments to support transfer of paOent data between monitors and departments (seamless data~~
~~conOnuum).~~
~~• Should have facility for Invasive Blood pressure (up to 2 channel) with pulse pressure variaOon.~~
~~• Should have facility for EtCo2, using side stream/mainstream technique.~~
~~• Should have facility for Anaesthesia gas Monitoring. - should be able to measure Co2, N2O~~

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and agent detecBon with MAC, using side stream technique.

- Should have facility for Cardiac output monitoring.
- Should have facility for BIS (Depth of Anaesthesia).
- Should be upgradable to NMT.
- Should have facility to connect 4 USB & SD Card.
- The Graphical and tabular trends of 168 hours should be available.
- The monitor should have baBery backup of 2 hours.
- Should have automaBc pacemaker detecBon facility.
- Should be CompaBble with central monitoring system both wired and wireless.
- Should be CompaBble with HL7 and Central monitoring system.
- The Weight of monitor should not be more than 11 kgs.
- Should have three priorBes of alarm of all the parameters.
- Should have facility of reviewing waveforms for 24 hrs.
- Should have minimum 7 Screen Interface SelecBon.
- Should have Early Warning Score facility to quickly assess the severity of illness in a paBent.
- Should have opBon of recording up to 3 waveforms on paper roll. And also, should have Facility to choose printed parameter by the user.
- Should be able to export data through USB in excel format for future review of the same.
- Should have Bed to Bed view Feature through monitor not from CMS.
- Should be upgradable to Wireless BidirecBonal Central Monitoring System.
- Manufacturer firms should have the same make upgradable charBng system/ soluBon to

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upgrade the integraBon of these monitors with other ICU devices such as syringe pumps, venBlators, ABG machines, Heart & Lung machines, dialysis machines etc.

- Monitor Should have Hemodynamic, ReapiraBon, OxygenaBon, Renal FuncBon & Drug dose

Calculations as standard features.

Should be accompanied by the following accessories.

1. 3/5 ECG lead – 1 no.
2. Reusable Spo2 probe for adult -1 no.
3. Nasopharyngeal/rectal/skin temperature probe-1 No.
4. NIBP cuff for adult – 1no.
5. Reusable IBP cable-2 Nos.
6. Disposable IBP transducer -2 Nos.
7. AGM sampling lines-2 Nos.
8. BIS sensor-2 Nos.

Quality Standards

- Monitor should be European CE with a four-digit notified body number certificate and CDSCO certified and certificates to be submitted.
- The Manufacturer should be ISO9001 and ISO13485 certified.
- Electrical Safety conforms to standards for electrical safety EN 60601-1-2:2015, EN 80601-2-30:2019 General Requirements.

3. Suitable UPS of at least ~~120 kVA~~ 160 kVA with complete backup for the entire Biplane DSA and Hybrid OT, including other equipment and accessories.

4. Lead glass 100x150 cm for the console room

5. Single Head Pressure injector of reputed make should be coupled with DSA system.
100 Nos. disposable syringes sets and 500 Nos. of tubing should be supplied along with the system. Unit price for syringes and tubing should be quoted separately and the same should be valid during warranty and CMC period.

Cath Lab / DSA Pressure Injector Specification

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i. Reputed make 1200 PSI single head pressure injector compatible with front loading 150ml syringe size.
ii. For patient safety from under and over infusion, injector should have Automatic mechanical stop function.
iii. System should have in built heat maintainer 37C +-2C for easy operation.
iv. Console should be a touch screen with option to save minimum 80 protocols with different names.
v. Variable flow rate software with hand controller. (optional item at extra cost)
vi. Interfacing Cable subject to scanner compatibility.

6. Ceiling suspended radiation protection system OF 0.5 Lead equivalence and table side protection system.

7. Focused ceiling mounted high luminous light with a handle for positioning the light.
8. ~~Activated Clotting Time (ACT) machine and 30 no's cartridges / tubes. Unit price for cartridges and tubes should be quoted separately and the same should be valid during warranty and CMC period.~~

9. Ultra-light weight double sided Lead Gown with lead equivalent of 0.5 mm: 10 Nos

10. Thyroid Guards - 10 Nos

11. Lead spectacles - 10 Nos.

12. Fully ergonomic foot switch for fluoro/acquisition control with both cordless ~~and with~~ / cord should be provided.

13. Wooden/Metal household staircase

14. Lead Apron Hanger - 4 No's
15. Lead Apron Stand - 1 No
16. Accessories for the table should include: (Supply of 2 nos. each)
a. Head fixing aids
b. Chin support:
C. Carbon fibre radiolucent arm support for brachial approach
d. Body straps
e. Shoulder harness
f. Easy to clean suitable soft mattress
g. Drip stands
h. Arm support
Sand bags for thickness compensation for the head - adult & paediatric

B. State of the art Anaesthesia workstation equipment- 01 unit

Sl	Specification
1	Should be advanced, reliable, compact and mobile with an integrated ventilator
2	Should be based on a microprocessor and suitable for low-flow as well as minimal-flow anaesthesia for adults, paediatrics and neonatal use.
3	The machine should be suitable for premature babies, neonates, paediatric and adults.

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4 Should have a facility to connect to the central supply (oxygen, nitrous oxide and air) pin index cylinder one each of oxygen and nitrous oxide with on-screen digital display of pressure gauges for central supply and cylinder.

5 The machine should have a working surface and illumination with storage space for keeping accessories. Should have a central brake to lock the machine.

6 Should have electronic gas mixing with FiO2 & total flow setting along with virtual flow meter displays.

7 Should have integrated safety features like an electronic hypoxic guard, N2O cut-off in case of O2 low pressure/failure, alarm and O2 flush etc.

8 Should have an onscreen virtual flow meter display of O2, N2O and air.

9 Should have a compact autoclavable breathing system and a soda lime chamber maximum capacity of 1.5L. The soda lime canister should be compatible with the devices in all the operating rooms.

10 Should have an electronically controlled and electrically/Pneumatically driven anaesthesia ventilator, ~~should not require driving gas.~~

11 The machine should be suitable for low & minimal-flow Anaesthesia application

12 Should be able to log all alarms, self-tests, messages and other events.

13 Should have integrated touch screen colour display with minimum 15" screen size.

14 The machine should have automatic calculations and presetting of patient-specific ventilation settings via ideal body weight, Age and height.

15 The machine should calculate agent consumption and agent uptake by the patient on a case-by-case basis and display fresh gas consumption in the unit logbook

16 The Anaesthesia ventilator should have the following settings:

a Automatic breathing circuit Compliance correction

b Spot. Breathing

c Manual Ventilation

d Volume controlled mode

e Pressure controlled ventilation

f SIMV in VCV & PCV

g Pressure Support, PS with CPAP, PS with SIMV in VCV/PCV

h Should be upgradeable to Autoflow or PCV-VG or similar mode – delivering set tidal volume at minimum airway pressure. and in combination with SIMV

i High peak inspiratory flow upto 120 LPM

j Tidal volume adjustment range 10 ml (in VCV) to 1500 ml and upgradeable to 5 ml in VCV

k Adjustable PEEP: Off, 2 to 35 hPa (or cmH2O); and CPAP: 0, 2 to 35 mbar

l Resp frequency from 3 to 100 per min.

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m I:E : ~~max 1:50 to 50:1~~ 1:4 to 1 :8 or better

n ~~Should be able to ventilate with atmospheric air, in case of total fresh gas failure including Oxygen.~~

17 Should have tidal volume compensation or fresh gas decoupling valve

18 Should have an external fresh gas outlet for connecting the open circuits.

19 Integrated breathing system warmer for breathing gas conditioning and avoidance of condensation.

20 Should have flow sensors at the inspiratory and expiratory side.

21 Should have a simultaneous display of 3 or 4 real-time wave forms for the concentration of CO2, O2, and anaesthetic agents, airway pressure, inspiratory and expiratory flows and loops for P-V and F-V loops.

22 An anaesthesia machine should monitor and display the measured value of minute volume, tidal volume, peak airway pressure, mean pressure, plateau, PEEP, dynamic compliance and resistance.

23 Should have pause mode for short-term interruptions of ventilation.

24 Should have alarms for high/low volume for expired tidal volume, minute volume frequency and airway pressure.

25 Should be supplied with Sevoflurane and Sevoflurane and Isoflurane vaporizer

- Fast and instant agent delivery with no warming time.
- Vaporizer must be isolated from the gas flow in the off position.
- Agent specific, maintenance free.
- No warm-up time
- Built-in Overfill protection with a locking mechanism.
- Prismatic liquid level indicator
- Low agent level" Alarm for all Anaesthetic agents.
- Total Agent consumption in ml, used during surgery to be measured and displayed on the display screen of the anaesthesia system.
- Vaporizers for Isoflurane, Sevoflurane and Desflurane, one each

26 Should have dual detection of anaesthetic agent in case of change of anaesthetic agent.

27 Should have RS232 port /USB /LAN to interface monitor to transfer the expired parameters on the monitor and in-built data output port / USB for data retrieval.

28 Should have battery back up to at least 60-90minute including that for a ventilator.

29 The system should have backup oxygen control in case of complete power failure and an auxiliary oxygen supply source.

30 Should have an auxiliary Oxygen supply system.

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31 Should have any time facility for manual ventilation possible at least with fresh gas O2 delivery and dosage of volatile agents with airway pressure monitoring in case of system failure/system "off".

32 Should have the indicator or decision support to show the efficiency of fresh gas setting while used in Low flow and minimal flow

33 The machine should be with integrated anaesthesia gas monitoring with automatic identification of anaesthetic agent (MAC and end-tidal concentration) as well as O2, N2O, FiO2 and ET CO2;

34 Should have sample gas return into the breathing system for better gas efficiency in low flow and minimal flow usage.

35 Should have heated breathing system for optimized minimal flow anaesthesia usage and ventilation quality.

36 Should be possible to deliver oxygen and anaesthetic agents in Manual/spontaneous mode even when the machine is in switched-off mode as an emergency backup

37 The machine should have adjustable alarm limits for all the parameters with a set alarm function

a The machine should have an automatic display of MAC values

b Should have automatic activation of low agent alarm

c Should have alarm logbook for displaying and saving alarm history

d System leak and fresh-gas deficiency alarm

e Should have a cardiac bypass mode

38 Should have fully automated self-test including calibration of all sensors without any user action necessary after start to test.

39 Should have a backup manual mode to allow the direct change to manual ventilation while maintaining gas and ventilation monitoring; O2 and anaesthetic agents from the vaporizers can be continuously delivered

40 Should have facility for data storage on USB storage device like self-test results, alarm history, screenshots, trends and machine configurations

41 Should have integrated active AGS system and necessary accessories with adoptor (PB type//Compatible to pendant/Outlet supplied) Must be supplied

B Specification for Patient Monitor

1 Should be suitable for adult, paediatric, and neonatal patients monitoring in a fixed environment.

2 Should have a 17" and above touchscreen display with large fonts and provide access to a minimum 12 or more waveforms with ergonomic representation of multi-functionality

3 Monitor should be IT enabled for single point access to web-based applications (like HIS, PACS, PDMS, LIS and more) without requiring extra server, hardware and software.

4 Should have minimum ECG, NIBP, SpO2, 2 -temperature and 2- Invasive pressures as standard and all other parameters should be through upgrades as pods/modules and software.

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5 Should have basic arrhythmia detection for life-threatening alarms that include asystole, ventricular fibrillation, ventricular tachycardia, and bradycardia and more.

6 Should have non-volatile graphic and tabular trending of all monitored parameters as standard for minimum 96 hrs.

7 Should have manual as well as automatic setting of screen format.

8 Should have integrated transport monitor with battery backup of 180 min and one-button disconnect and without additional modules or batteries and shall allow transport with all currently monitored parameters remaining active.

9 The transport display shall automatically adjust its orientation using a gravitational sensor when it is rotated to a different view.

10 The transport monitor should have minimum 6 inches of touch screen and 3 or more waveforms

11 Should have Defibrillator and ESU protection, ECG Sync, IABP interface (ECG and Arterial for triggering and deflation with a device delay of <20 millisec)

12 Ready for wired/wireless networking.

13 Automatic electronic charting and data management solution with data archival facility for patient monitor and ventilator data. It should be a single centralized server based for multiple bed's upgrade. Charts should be seen on the patient monitor screen itself.

14 Monitoring solution shall support at least sixteen (16) different display layouts, and at least five (5) for the transport component.

15 While using another application, the monitor configuration will always allow for continuous viewing of the real-time parameter data using Touchscreen, Rotary knob & keyboard

16 Monitor when interfaced with Anaesthesia Machine, the monitor shall provide capabilities for display of multiparameter sets to be used in lung recruitment procedures through an analysis tool.

17 Monitor shall provide the option to connect a secondary display that can be configured independent display without the need for additional hardware and users the ability to configure the location, speed and color of the parameters and their associated waveforms separately to the monitoring workstation

18 Monitor should able to connect to anaesthesia machine and should be able to display ventilator waveforms, parameters and loops.

19 Should have following parameters

a ECG

- 5 lead ECG monitoring with three leads of ECG waveform simultaneously monitoring

- Should display 12 leads of ECG monitoring

- Range 15 to 300bpm

- Should display 12 leads of ECG by connecting 6/5 ECG lead wires (Reduced lead set algorithm) as standard feature with max. lead positions as per standard lead placement.

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b RESPIRATION

- Through Impedance pneumography/ Capnography method

c SpO2

- Should be supplied with Masimo SET/Nellcor technology with respective sensors

- Should display digital value and Plethysmograph

c NIBP

- By the Oscillo metric principle of measurement with step wise - deflation

- Suitable for adult, paediatric, neonatal patients

- Should display Systolic, diastolic, mean pressure in large easy to read display

- Should have manual/ stat mode or automatic mode with adjustable time intervals from 2 – 240 minutes and adjustable alarm limits

- Monitor should have capability for continuous arterial pressure monitoring through non-invasive technique – preferred

d IBPs - Simultaneous monitoring of 2 Invasive Pressures should be standard

e Temperature - two temperatures one core and second skin simultaneous monitoring

f Depth of Anaesthesia Monitoring either BIS or Entropy module with 50 sensors with each monitor. Machine.

C Specifications for Charting System / Documentation System

1 The Software should be able to integrate Patient monitors, Anaesthesia machines and Syringe pumps and other third-party devices.

2 Should display all OR Patient information like Name, Room Number, Patient ID, Ventilator status and attending physician names in a single screen.

3 Should enable OR workflows such as ADT (Admission Discharge and Transfer), flowsheet, Anaesthesia documentation, Infusion Management, Medication, notes, scoring and other workflows.

4 Should have electronic patient charts (flowsheets) which are populated with data acquired electronically via medical interface to other devices/information systems. Flowsheet data can be edited, validated, and annotated.

5 Should have automatic/manual fluid input/output sheets which allow the tracking of a patient's total fluid intake and output.

6 Should have medication scheduling to create care-unit-based medication schedules which alert the staff to upcoming/past-due medication needs

7 Should have special data screens for OR care units, such as customized data forms, outcomes documentation, staffing documentation and OR scheduling and Data annotation (notes/event, notes/OR event capture).

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8 Should have data protection Data and System Protection and Security like all users should be given an individual password that only they or the admin can change. Personal data (name, DOB, etc. of patients and staff) should protected in the database under special password protection.

9 Should have staff documentation during the case and should provide a configurable list of staff members like Name (first, middle, and last), Role, Group, Supervisor/Supervisor level, Time In/Time Out

10 Should have data protection Data and System Protection and Security like all users should be given an individual password that only they or admin can change. Personal data (name, DOB, etc. of patients and staff) should protected in the database under special password protection.

11 Should have post-op prescription and should be able to generate final anaesthesia report in pdf format

12 Must Customisable Software as per need of the User .

13 Detail documentation /datasheet of charting system must be provided in the technical bid

D Scope of Supply:

1 Anaesthesia workstation with integrated ventilator, integrated anaesthesia gas analyzer and monitor with End tidal control / Target control anaesthesia

2 Electronic Gas mixing with Pneumatic back up of 100% O2.

3 Auxiliary Oxygen Flowmeter.

4 Integrated, fully autoclavable Advanced Breathing System with absorber. Additional reusable canister to be included

5 Colour coded Pipeline Hoses and Inlets for Oxygen, N2O and Air.

6 Oxygen Cylinder Yoke.

7 N2O Cylinder Yoke.

8 Auxiliary Common Gas Outlet (ACGO) to connect open/semi circuits.

9 Integrated Anaesthesia Gas Scavenging System (AGSS) and its accessories with adoptor ..

10 AC Power inlet with additional outlets.

11 Integrated High End Electronic Ventilator.

12 CO2 Bypass mechanism with condenser to take care of moisture.

14 Pead. Reusable Patient circuit – 1 No.

15 Reusable Face mask of all sizes 0,1,2,3,4,5. Additional reusable masks of size 3, 4 and 5 each.

16 Extra flow sensors – 10 Nos.

17 Anaesthesia Monitor, 17-inch color touch-screen with 8 waveforms

18 5 lead wire ECG with electro-cautery filter and trunk cable – 2 Sets.

19 SPO2 probe adult – 2 Nos.

20 NIBP hose – 2 Nos.

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21 Adult cuffs size – XL, L, M, and child and infant and cuffs – 2 Sets.

22 Sample lines (pack of 10).

23 Water traps- (pack of 10 Nos.).

24 BIS / Entropy cable – 2 Sets.

25 BIS / Entropy sensors (pack of 50).

26 NMT cable and NMT adult mechanic sensor.

27 Skin Temperature Probe and central probe.

28 2X IBP cable and Disposable IBP transducer (Pack of 5 Nos.).

29 Recorder paper – 20 Rolls.

30 Isoflurane electronic vaporizer.as per specification

31 Sevoflurane electronic vaporizer.as per specification

32 Desflurane electronic vaporizer.as per specification

33 Main stream ETCO2 module-1no with sensor cable and adopter-2nos..

34 Flow sensor :-5 nos.

35 Oxygen sensor must be cover under warranty & CMC

36 PM kit :-2 nos

37 HARDWARE & software for REQUIREMENTS (for e-charting System) :

b Client Inside OT (2 Sets)

- Touch PC can be deployed :

Description & Requirement

- RAM-> 6 GB (minimum)

- Display Properties ->

- Resolution : 1280 x 1024 (1920 x 1080 recommended).

- 24–Bit or higher Color Depth Graphics Adapter.

- Display size a minimum of 22" or more.

- Hard Disk Capacity : The client system shall have 100 GB of free space on the hard disk

- Network Interface Cards : Client systems shall have a wired network interface card (NIC) at 100 Mbit/s (recommended 1 Gbit/s)

- Keyboard : Multifunctional Keyboard country-dependent

- Mouse : Microsoft Mouse or compatible

- Display Properties :

- Resolution: 1280 x 1024 (1920 x 1080 recommended)

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- Color depth (graphics adaptor): 24-bit or higher

- Display size a minimum of 22" or more

- MS-OS License : With latest OS (Windows/Mac)

- Touch Screen (Medical Grade) : Technology: Medical grade Capacitive Touch (or Projected Capacitive Touch if latex gloves are routinely used).

- Touch PC Mounting Arms with Anaesthesia Machines.

c Device Connection Units :

- 2 or 4 Port per OT for device integration.

- 4 (3 mtr. standard CAT 6 cable) per OT.

d Network Printer (One Number)

- All software should have a license of not less than 10 years.

38 **All updates should to be done free of cost throughout the warranty & CMC period**

The Anaesthesia Workstation, Patient Monitor, Charting system and its server (All in one Medical grade PC -fanless)and other accessories must be Integrated and necessary accessories /Mounts needed for stand-alone installation and commissioning must be included in the offer

E Standards, Safety and Training

1 Should be FDA/CE/UL /BIS /CDSCO/ISO13485 approved product

2 Comprehensive training for lab staff and support services till familiarity with the system. Electrical safety conforms to standards for electrical safety IEC 60601- 1 (Or equivalent International National standard) general requirement for Electrical safety of Medical equipment

C. Cardiac Monitor with Defibrillator - 01 Unit
Specification:-

The defibrillator should be latest, lightweight, with color TFT display

1. The defibrillator should have latest advanced Biphasic waveform Technology with impedance adjustment and minimum 4 wave form color display with screen size of more than 8 inches diagonal and should have adult & Pediatric modes of Operation
2. It should display of both selected and delivered energy on the screen,
3. In manual mode the unit should provide energy selection from 1 to 200 (1-10, 15, 20,30, 40,50,75, 100,125, 150,175,200,) joules. The option to increase upto 360J should be available.
4. It should have AED as a standard feature with latest AHA guidelines with CPR Metronome and graphical Step Icon for ease of use.
5. Should display respiration by impedance method with a range up to 150 bpm
6. The unit should have an option of adding transcutaneous external pacing with pacing rate up to 180 ppm and should have both demand and non-demand modes. It should have a pulse width of 40ms for the pacing.
7. System should have both Adult and Pediatric external paddle. The paddle should have all control of Energy selection, charging, and discharging.
8. Charging time should not be more than 6 sec for 200J.
9. The defibrillator should have a built in 3 channel thermal printer of minimum 80mm paper width.
10. Unit should have option of adding SPO2 Monitoring and NIBP, 2X Temp as optional with pediatric & adult reusable sensors. SPO2 should be Masimo/ or Nellcor technology.

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11. Defibrillator should have option of adding EtCO2, 2X IBP parameter and 12 lead ECG measurement and interpretation should be available.
12. Built in battery should be capable of delivering 5 hrs of operation and capability of delivering up to 200 shocks of 200 joules once fully charged. System should work on mains even when battery is depleted or removed. There should be an option of attaching Two batteries with an ability to give 10 hrs of Monitoring.
13. System should be easy to operate with facility to give charge and energy selection on both external paddles and the main unit.
14. Should have the capability of an integrated CPR feedback system to provide information of depth and speed on the screen while performing CPR.
15. Integrated CPR sensor should be quoted as an option
17. Should have facility to record at least 250 events with event review facility when printing event all the monitored parameters including ECG.
    Further data recording should be available on data card for additional information.
18. System should be light weight and not more than 7 kgs
19. Defibrillator should have an option to add Internal paddle when needed.
20. Defibrillator must supplied with an ergonomically designed trolley with lockable castors & accessories tray.
21. Should be supplied with adult and pediatric external paddles, 2 Nos of Adult /Pediatric AED/DEFIBRILLATION/ PACING electrodes, 3 lead or 5 lead ECG cable and printer papers 2 packs.
22. The Unit should be F.D.A / European CE 4 digit notified body/BIS approved certificate.

Company must have similar products working in leading institutes in India for past 2 years with good performance result.

~~D. IABP machine :1 unit~~

~~Specification –Intra Aortic Balloon Pump Machine.~~

~~1. Third Generation Autopilot, Touch screen IABP System, with Wave form touch access control.~~
~~2. Transportable, Compact IABP System with minimum 90 Min of battery Backup.~~
~~3. Fast Pneumatics to provide accurate & reliable ventricular support enhancing augmentation& improved After-load reduction. Preferably a stepper motor Driven Bellows system for faster drive –gas shuttle speed.~~
~~4. System should provide start-up checklist, when the pump is ready to start.~~
~~5. System should be capable of using fibre optic Balloon and conventional balloons.~~
~~6. Should have 1).Automatic. 2.) Operator Modes of operation.~~
~~7. System should be able to Trigger on Pulse Pressure as low as 3mm Hg.~~
~~8. System should be free from scheduled Maintenance and replacing the Spares on basis of usage.~~
~~9. System should stop shuttling of gas in case of balloon rupture and avoid chances of blood leak – to machine (with Alarm).~~
~~10. Should be capable of removing Condensation automatically without interrupting the therapy.~~
~~11. System should be capable of automatically selecting appropriate trigger that is A).ECG, or – B).Pressure and also accurately select the inflation and deflation point in automatic mode. C). Trigger on pacer (V pace, Apace), D). Automatic internal trigger rate. F). A fib Mode.~~
~~12. In automatic and operator mode single ECG trigger should be able to track various ventricular and atrial arrhythmia including VE's bigeminy ,Trigeminy, Couplets etc and atrial fibrillation, without any user intervention and still give optimal performance.~~
~~13. Machine should provide print of Therapy report &100 Alarm History report.~~
~~14.360° Visible priority colour intensified Alarm status required.~~
~~15. In automatic mode, advanced software should automatically adapt the Timings for various rhythms and rate variations, without any user intervention.~~

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16. In automatic mode it should automatically identify atrial fibrillation and adopt r-wave deflation mode for better patient support without any user intervention.
17. Single key start up to make it fast, user friendly and easy to use.
18. Should be able to display at least 3 wave form as ECG, Invasive Pressure and balloon pressure Wave form.
19. Large detachable display for brighter and very good visibility from a distance in any lighting conditions.
20. on screen indication for helium level in the cylinder and battery level for timely intervention and correction.
21. ECG Inflation marker to indicate inflation period on ECG which can be usefully when atrial pressure wave form is not available.
22. on screen indication of stand by time and should give alarm after 20 mts to draw user's attention on the system being on standby.
23. Should give extensive help message to correct the alarm conditions that are specific to the alarm conditions, this should help the user to overcome the alarm problem immediately and with ease.
24. In-built comprehensive service diagnostics to help the technician to locate the faults immediately.
25. The system should be supplied with the followings.

- ECG cable with lead wires 01 Nos.
- Compatible pressure transducer cable -01 Nos.
- Refillable helium cylinder compatible with the iabp system helium (or other) gas cylinders 1 Nos. certificate from the explosives dept.

26. The entire unit should be mounted on the wider wheel with max 50 kg weight, for Easy trans
27. 15 IABP Catheters along with other disposables required

E. Radiation Protection Equipment-1 set

Broad Based QR of Radiation Reduction equipment with Carbon on platform & Quad foam layer set up with head, shoulder & Radial shields. System must also have Radial set up & clear spot shield

1. It should be fully integrated and comprehensive system.
2. It should provide protection for the entire medical team.
3. It should have Carbon Fiber Platform with internal shielding replaces patient mattress on X-Ray table.
4. It should have built-in railing system to support Radiation Protection components
5. It should have Quad Layer Memory Form with Support for chest Compressions
6. It should have Head Flex Shield to secure both left and right side.
7. It should have Side Flex Shield on both left and right to rail on base platform
8. It should have Corner Head and Pillow Flip Shields
9. It should have Workbench with flip shield.
10. It should have Clear Spot shield with hanging drape attached with flexible arm.
11. It should have reputed regulatory body certificates.

F. Deleted
G.Dual Chamber Temporary Pacemaker-2 nos

Specification

1. Pacing Modes - Primary: DDD, VVI, AAI, VDD Supplementary: D00, V00, A00, DVI
   a. DAI, VAT, AAT, DDD+AT, DAT
2. Auto Functions - AV-Delay, PVARP, MTR, and Sensitivity
3. Sensitivity Atrium: 0.2 - 20 mV , Ventricular: 1.0 - 20 mV
4. Stimulation amplitude 0.1 - 10 V
5. Refractory period PVARP 100 ... 500 ms

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6. Maximum tracking Rate (MTR) 80 ... 230 ppm
7. Basic Rate 30 – 220 ppm and high pacing rate 70 – 1000 ppm.
8. High rate function provides rapid atrial stimulation of up to 1,000 ppm (adjustable while applying rapid atrial stimulation)
9. Refractory period -atrial ——— 250 ... 400 ms
10. Refractory period -ventricular -250 ms
11. AV-Delay 5 .. 400 ms
12. Battery life : 240 hrs (9.0 V) Alkaline
13. Both visual and audible battery life indicators should be available
14. Weight : 490 Grams (Including the battery)
15. On pressing pause button it automatically measure P and R Wave amplitudes AV interval
16. Unit should have real time impedance display to check electrode position , quality of pacing and should give error messages.
17. Should give statistical value of number of events paced and sensed within a given time to evaluate patient dependency.
18. Should have an emergency pacing button
19. Unit should be supplied with 6 extension cables.
20. Should have an electronic locking mechanism to prevent the accidental change of setting
21. Should have approved by US FDA/CE/BIS or equivalent standards.
22. **Service life : 10 years .**
23. Dual chamber Pacemaker should be compatible to connect to a heart simulator for the skill development on external pacing.

H. Syringe Infusion Pump-4 units

Should accept all internationally produced/marketed syringes and should be able to detect it automatically and should be able to pre-set different range of Bolus supply.
Preferably the unit should be of front-loading technique.
Technical characteristics

1. Flow rate programmable range at least from 0.1 to 1500 ml/h.
2. Flow Rate Range: 0.10-1500 ml/h
3. Bolus rate: Manual (Std.) & Automatic Range: 0.10-1500 ml/h
4. Should have Selectable levels of occlusion pressure: high, medium, and low. 10-135 Kpa (10-1022 mmHg).
5. 3.5" TFT colour and touch screen for easy view and convenient operation.
6. Must work on commonly available Auto size detection of 5/6ml, 10ml, 20ml, 30ml, 50/60ml Syringes.
7. Tamper-resistant case made of impact resistant material Securely mountable on tabletop, IV stand or bed fitting.
8. Automatic detection of syringe size and proper fixing.
9. Anti-bolus system to reduce pressure on sudden release of occlusion.
10. Daytime mode and night-time mode interchange automatically.
11. Should have Drug library of up to 100 from specified drug category.
12. Multiple infusion modes: Rate Mode, V-T Mode, Dosage Mode, R-T Mode Loading Dose, Sequence Mode, Ramping Mode, Intermittent Mode.
13. Should have audio & Visual Alarm AC Power Interruption, DC Power Interruption, Low Battery, Depleted Battery, Forget Reminder, Infusion Near End, Infusion Complete, Injector Empty, Flow Rate, Syringe Unlocked, System Exception.
14. Should include KVO (Keep vein open) enabling feature, KVO should be 0.1 to 5ml/hr at 0.1ml increment.
15. Volume Limit should be 0-9999.99 ml.
16. Time limit from 1min to 99hrs .
17. Flow rate deviation should be ± 2%.

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18. Should have dual CPU design if one CPU fails off then other can take over automatically.
19. Should have Customise time for day/ night mode setting.
20. Should have Customisable time for screen lock facility
21. Both audible and visible alarm, and alarms sound adjustable.
22. It should be compact & Light weighted, weight not exceeding 2 kg.
23. Should have facility for approx. 2000 event log with automatic recording of the last infusion.
24. Single loadable with one syringe of minimum 5/6 ml.
25. Should have LAN interface and Wi-Fi connectivity (Optional)
26. Should have the facility to connect with HL7 compatible Docking Station and 1 docking station must be supplied along with 4 pumps
27. Energy Source: Power: AC: 100V–240V, 50Hz/60Hz, 35VA
28. Battery - Rechargeable lithium-ion battery 10-15V/2.5A, Battery Life: ≥8 hours at 5ml/h Charging Time: ≤4 hours
29. Environmental & Operating condition:

Capable of being stored continuously in ambient temperature of 0 to 50° C and relative humidity of 15 to 90% in ideal circumstances.

30. Certification:

- Should have European CE approved from the notified body/FDA/CDSCO/BIS or equivalent certification
- The product Should conforms IPX4 as per IEC-60529.
- Electrical Safety conforms to standards for electrical safety IEC 60601-1-2, IEC 60601-1, Reports Must be submitted

I. Handheld Non Invasive Cardiac Output Monitor- 01 unit

1. It should be a hand-held device, weighing less than 800grams to easily carry in different departments and in the ambulance during emergency.
2. It should display minimum following parameters:
   a. **Stroke volume/index**
   b. **Cardiac output/index**
   c. **Systemic vascular resistance/index**
   d. **Index of contractility**
   e. **SVV (Stroke Volume Variation)**
   f. **TFC (Thoracic Fluid Content)**
   g. **FTc (Flow Time Corrected)**
   h. **It should give index in both BSA and in Weight.**
3. Technology, clinical validations
   a. It should be a non- invasive cardiac output monitor
   b. It should be based on advanced electrical velocimetry or similar proven technology.
   c. It should have the facility to measure the beat-to-beat cardiac output :
   d. It should work in Pre- Term & Neonatal , Pediatric and adult patients
4. User-friendly and compatibility with other devices
   a. It should require only 4 externally applied sensors.
   b. Sensor placement should be on one side of the patient and can be applied fast.
   c. It should work with pacemaker and display the pacing signal.
   d. Sensor should work for minimum 72 hours .
5. Display
   a. Display parameters must show the bar diagnostic screen with normal range and measured value for each parameter, trends, charts, and waveform screens.
6. Storage and back-up
   a. It should record continuous data , have internal data storage of at least 72 hours, and transmission to PC through serial cable.
   b. It should have rechargeable battery backup of at least two hours.

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7:—Certifications and Warranty

a:— It should be approved by US FDA/CE/BIS for use in Neonatal, Pediatric and Adult.

8:—Others:

Price to be quoted for I sense Adult/Pediatric & I sense Neonatal/Pre-term separately

J. Deleted

K. FFR console

1. System should be latest generation, easy-to-use designed for peripheral vascular, structural heart and coronary procedures; operable directly from the sterile field with four modality 3FFR (including DFR/IFR/RFR)
2. mobile system. It should be easy to move. Full integration options should be available.
3. Should determine FFR/DFR/IFR/RFR value with Optical sensor-based wire to assess Arterial Pressure through Cath Lab transducer system.
4. It should have 15" color full HD display screen with in-built speaker and microphone. Tablet and Docking station: 13.3" LED Backlight Screen with Capacitive Touch.
5. FFR/DFR/IFR/RFR Pressure Guide wire should be one optical sensor pressure wire for entire procedure i.e. for FFR measurement and angioplasty procedure with better torque and push ability.
6. Operating system: minimum requirement window 10 and above. Archiving Options: internal hard disk with sufficient storage capacity and should have USB drive option for data export.
7. System should have option for external integration of FFR mobile cart with existing Cath labs.
8. Sterile Field control for both sterile & non-sterile operator.
9. Multiple Image Screen Format should be available
10. System should be USFDA/DGCI/CE approved.
11. 5 years CMC and 5 years warranty
12. Requirement of additional accessories in addition to IVUS System:

(2) FFR catheter - 30 quantities;

13. At the time of supply the intravascular ultrasound system should be of latest generation.
14. IMPORTANT NOTE:

The offer should indicate all parts with details specifications and the Brand clearly as required in our specifications.

Training must be given at sight, and the training schedules should be at least 6 days. The supplier should enclose the technical compliance statements against our technical specifications clearlymentioning for each point. The statement should be supported by relevant literature/date.

M. Modular OT

Complete plan, design, supply, construction, testing and commissioning of Cath Lab with Truly Modular Operating Theatre in accordance with the specifications, bill of quantities. The design and construction oftheatre shall be made using pre-engineered solution with objectives of Infection control, Promoting high standard of asepsis, Facilitating coordinated services, Ensuring maximum standard of safety, Optimizing utilization of OT with flexibility andstaff time, Optimizing working condition, Ensuring functional separation of spaces, Patient and staff comfort in terms of thermal, acoustic and lighting requirements, minimizing maintenance and regulating flow of traffic

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TECHNICAL SPECIFICATIONS OF MODULAR OT

Complete plan, design, supply construction, testing and commissioning of Cath Lab with Truly Modular Operating Theatre in accordance with the specifications, bill of quantities. The design and construction oftheatre shall be made using pre-engineered solution with objectives of Infection control, Promoting high standard of asepsis, Facilitating coordinated services, Ensuring maximum standard of safety, Optimizing utilization of OT with flexibility andstaff time, Optimizing working condition, Ensuring functional separation of spaces, Patient and staff comfort in terms of thermal, acoustic and lighting requirements, minimizing maintenance and regulating flow of traffic.

1. **Truly Modular Wall & Ceiling System (Factory Finsihed)-**

   i. Wall and Ceiling Panels, should be from standard Indian make with certification of quality of make as mentioned in table below.
   ii. All components: Panels, Steel Sub Structure, Aluminium profiles, Cover profiles, Angular supports should be from same make, same manufacturer and same standard.
   iii. The clean, dry installation method should enable optimum programming of the various work phases, allowing optimization of the installation of technical systems and any necessary alterations to be made right up to checking and final testing of the installed systemsbefore the modules are sealed.
   iv. System should assure the maximum independence from the surrounding environment because it should be composed of a sub frame made of section bars specifically manufactured for the loading structure and designed to create the necessary technical voids to house utility networks and pipe/cable drops. This entire system comprising of the sub frame, wall and sealing gasket should be of a single make.

The system should comprise of:

a) Substructure
b) Wall Panel System
c) Ceiling Panel System
d) Sealing Gaskets

a. Sub Structure for SS 304 Wall Panels:

- The hybrid OT shall be fully pre-fabricated and truly modular in design.
- These shall have self-supporting, freestanding substructure without the need for any brick walls except the bounding (outer) walls of the main building. The substructure shall be made of galvanised steel of minimum 2.0mm sheet thickness.
- The substructure shall be firmly fixed onto the floor, slab/ceiling RCC with high quality fasteners. The depth of the substructure shall vary at different locations to allow ample space to accommodate various components / equipment to be installed inside it. Substructure shall have additional horizontal support (mounting bracket) for medical gases outlets, x-ray viewer, monitors etc.
- The Framework should be made of upright profiles entirely made of a galvanized steel of suitable thickness. The structural steels shall have suitable section for rigidity and bearing the loads. The structure components should be joined together by means of

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coupling system in order to create a solid rectangular frame, able to support different infill panels with a load not less than 20kg/sqm. The suitable upright forms the vertical part of the frame and should be equipped with proper slot suitable for the panel coupling. The profile should be the elements that constitute the basic module of the structure.

- The "U" profiles shall be placed in a horizontal position on the upper and lower partof this structure. "U" shaped upper and lower track profile should be suitably sized to support the weight of the self-loading modules. The upright should be fitted in such a way as to accommodate the co-extruded upright gasket providing a vertical seal on the rear sides of the finishing panels.

- The front/side of the upright features a series of regularly spaced slots to allow the connection with the interlocking gravity system of the finishing panels, after vertical level adjustment/to be fixed with screws. The structure shall be provided with stiffening ledgers or profiles for sliding door fixing and other accessories according to needs.

- Suspended ceiling perimeter support profile should be made of extruded aluminium/Galvanised steel to be fitted, after installation of the finishing panels, the suspended ceiling perimeter profile or, optionally, the suspended ceiling perimeter profile with integral coving.

b. Truly Modular Wall Panel System (Factory Finished)

- The wall Panel system should be based on a technological modular unit designed to clad and divide interior space in bacteria-controlled environments in a flexible and functional manner.
- The substructure shall be covered with the wall cover panels made of Stainless steel (Material-Nr. 1.4301, SS 304 grade) of thickness not less than 1.0 mm. No other material other than Stainless steel 304 grade shall be used for this purpose.
- All the cover panels, components of the structural material shall be totally prefabricated from the factory itself . No welding , grinding , painting will be allowed at site .
- All the wall Panels shall be pre-powder coated and no painting job shall be carried out at site. The antimicrobial pre-powder coating shall be maintained at a minimum deposit thickness of 60 microns and should have JIS Z 2801 certification (or equivalent) from a third party.
- The SS wall panels shall be reinforced with a minimum 12mm non-flammable, high quality plaster/Gypsum board glued on the back of wall panels to make a total thickness of 13 mm (1mm+12mm). Wall Panelling Material like puff panels, High Pressure Laminate panels,Corian/Solid Mineral Surface etc. shall not be used for wall panelling.
- Wall and ceiling panels shall be easily openable /closable for quick resumption of operations after repair/maintenance and for future expansion and up-gradation. The wall panels on both sides of the substructure shall be openable except where there isan unavoidable brick / RCC structure.
- The wall panels shall be firmly fixed on the substructure with the help of screws. The vertical joints between two wall panels shall not be more than 8 mm wide. Full-height silicon rubber seal of Medical Grade with matched color shall be used to fill the gap between two wall panels to ensure a 100% hermetically sealed vertical, flush with wall panels mounted joint. In all the corners of the OTs, especially fabricated, one-piece, angular SS wall panels shall be used both inside & outside the OTs. Wall panels shall not have any horizontal joint, at any height from floor to false ceiling, except for installation modules i.e. control panel, X-ray, monitor, doors & cabinets etc.
- Finished Floor to False Ceiling Height inside OTs shall be 3000 mm (approx.) subject to site height availability).

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- The system should offer total ease of cleaning and sanitization of the partitions should have no live corners; adjacent surfaces should be moulded flush by means of connecting elements (surfaces should be completely co-planar without protrusions).

- The Wall Panels should be of standard Indian make with certification of quality of SS 304 of the make as mentioned.

- ~~The Wall Panels should be CE certified in accordance with class I of Medical device directives / GDSCO equivalent certification~~

Suspended Ceiling System (Factory Finished)

- The substructure of the ceiling panel shall have bracing of load bearing sections and cross bracings shall form a rigid grillage to take care the load of ceiling panels. There shall be vertical hangers with a vertical height adjustment according to the site requirements. The vertical hangers shall be fixed to the concrete ceiling by means of metal dowels. All components of the substructure to be made of galvanised steel.
- The Ceiling panels shall be made of Stainless steel (Material-Nr. 1.4301, SS 304 grade) of thickness not less than 1.0 mm. No other material shall be used for this purpose. The modular grid, which shall be 600 x 1200mm/600mm x 600mm, or variable, allowing the integration of sealed lighting fixtures, air anemostats and /or variousservice units. The variable module grid should make it possible to adapt the size of the ceiling module to match the equipment to be mounted. It should also allow the use of different module sizes within the same room.
- Coating of the Ceiling Panel shall be not less than 40 micron with 180°C stove enamelling and the colour RAL 9010, powder coated. The ceiling panels shall be secured by means of clip system and punched-in-knobs shall keep the panels in place and shall ensure an exact ceiling level. The panels are openable for future repair / maintenance & up-gradation.
- The Ceiling Panels should be from standard Indian make with certification of quality. The suspended ceiling should be hermetically sealed by means of silicon gasket application. The function of silicon sealing should be that of assuring an airtight environment in the room and eliminating crevices in which dust could accumulate. The gaskets to be made of nontoxic silicon in compliance with regulations applicable to clean rooms (to US FDA/CE standards), providing a durable and non-degradable seal that should be should be resistant to microorganism attack. Colour of inner surface wall of OT shall be as per the decision of Project team
- ~~The Ceiling Panels should be CE certified in accordance with class I of Medical device directives and GDSCO certified~~

c. Sealing gaskets/ Silicon sealants:

- Vertical and horizontal gaskets in non-toxic silicone rubber/ silicon sealants around all the contact perimeters between the various materials, and the hermetically sealed gapsbetween modules, should ensure optimum space segregation and ensure that sterileair pressure values are maintained in the protected environment, this be being a fundamental prerequisite for guaranteed sterility.
- Wall modules should be joined with a hermetic seal. The various sealing solutionsrange from the rubber non-toxic silicon rubber gasket, shaped in such a way as to assure a seamlessly connected surface, to the monolithic structural sealing, both materials should be immune to attack by microorganism. The wall modules should be individually dismountable independently from ceiling and floor.

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system to allow inspectability, maintenance of technical systems, and any variations that may become necessary for future alteration, modification and repair. Colour of silicone rubber must watch with wall panels of OT .

- The complete Wall and Ceiling System should be FDA/CE certified in accordance with class I of Medical device directives and CDSCO-certified.

2. Laminar Air Flow Ceiling System

- Unit for laminar flow diffuser should be made of a thick aluminium sheet. The complete unit should have factory prepared fine sealing system along with proper test certificates from the manufacturer. The laminar air flow should be supplied at site dulysealed in factory made packaging. The laminar air flow unit should be made of extruded aluminium sections which should support the fire retardant housings in such a manner that the air is passed only through the Minipleat Hepa/H14 filters (not Stype Hepa filter). A test certificate of this regard should be provided along with the unit.The Laminar flow system should have anodized aluminium perforated diffuser grill.
- The absolute filters installed in the system should be suitable for applications for Laminar flow and clean rooms, these absolute filters should be mini pleat HEPA filters having extruded anodized aluminium, 65 -70 mm deep frame, and filter should providefollowing specifications:
    - Protective grids White epoxy painted micro drawn grid
    - Separators Continuous thermo plastic chord
    - Sealant Polyurethane
    - Gasket One piece polyurethane
    - EN 1822 class H14
    - MPPS average efficiency > - 99.99%
    - 3 micron DOP efficiency > - 99.99%
    - Final pressure drop 600 Pa (maximum)
    - Maximum RH 90 percent
    - Efficiency Tests Filters individually tested and certified

- The laminar box size shall be minimum 2400mm x 2400mm for all the OTs unless specific size otherwise specified. Perfect tightness should be guaranteed by a seal between filters and holding structure enabling no bypass of Mini Pleat filters. It shall have double tight seat system to prevent leakages from sides of filter gaskets, filter frame and pressure frame.

- The laminar air flow ceiling shall have horizontally placed HEPA Filters of H14 grade,DIN EN 1822 standard or equivalent. The HEPA filters should have efficiency of 99.995%. The laminar air flow system shall comply with internationally accepted standards & meet with ISO Class 5 requirements & should strictly comply with DIN 1946-4-2008-12 standard or equivalent.
- The laminar air flow system shall have four exhausts in each OT and the exhaust of contaminated air shall be carried out both from the top as well as from the bottom.
- Laminar air flow system and mini–Pleat HEPA Filters should meet relevant standards or equivalent and should have appropriate certifications to prove the claim of compliance.In order to have perfect sealing both laminar air flow and filters must be installed fromthe same manufacturer.

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- Complete air management system should be supplied with complete test certificates from manufacturer and should be CE certified in accordance with class I of Medical device directives and CDSCO certified

3. Operation Theatre Flooring (Antistatic Conductive Pvc Roll)

- A cement concrete floor will be laid flat to within a tolerance of +/- 3 mm over the entire ot area. Onto this sub floor, a self – levelling compound will be laid prior to laying of the floor finish. Copper grounding strips (not less than 0.05mm thick ,50mm width) will be laid flat on the floor, spaced at 300mm c/c distance, both ways, in the conductive adhesive and connect to copper wire of grounding. The connection from copper grid should be brought out uniformly at places to form equi-potential grid.

- A self-levelling compound should be laid prior to lying of the floor finish. Underground earthing has to be done by the vendor.
- The floor finish in the operating room will be 2mm conductive PVC, laid on a semi – conductive adhesive base. The floor finish will terminate at the room perimeter passing over a concealed cove former (to be supplied and Fixed in position by the vendor) and continuing up the bottom of the wall panel in the form of rounded skirting, approx. 100 mm height. All joints will be thermally welded with filler wires ofthe same material to provide a continuous sealed surface.

- The Operation theatre floor finish should be laid with 2 mm antistatic seamless conductive PVC Roll on a semi-conductive adhesive base. The floor should be stain resistant, scratch resistant, fire resistant, chemical resistant, non-corrosive, slip resistant, smooth, anti fungi, antimicrobial impervious material conductive enough to dissipate static electricity but not conductive enough to endanger personnel from electric shock. The connection from copper grid should be brought out uniformly at places to form equi-potential grid. A self levelling compound should be laid prior to lying of the floor finish. One earthing lead should be brought out of from every 150 Sq.ft. area and attaching it to main earthing strip/ground.

- Continuous roll should be used and all the joints should be welded by heat fusion process to get seamless floor. The joints in the flooring should be sealed by using a PVC welding bar of matching colour and hot air gun for fusion of welding bar with flooring to provide a continuous sealed surface, confirming the European/US standards. The sheets should be highly durable with resistance to shock, scratch proof and indentation. Corners should be uniformly curved. The conductive material should be uniformly impregnated as grains. The floor should be inert to body fluids, chemicals, detergents and disinfectants and it should not be affected by temperature variation within the OT. The floor should be able to withstand the weight of all standard and special equipment in OT (OT tables, Carms, Portable CT scan machines and O arms) along with their movement without any damage. Colour should be uniform, pleasant and matching with ambience and after consultation with JPNATC, AIIMS. The floor should have electrical resistance (Point to ground) within 2.5×10^4 to 2.5×10^6 Ohms as per NFPA-99/ DIN 51953/ATMF-150 B1 class of fire resistance.

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4. Doors And Frames (Automatic Hermetically Sealed Sliding Doors)

- To maintain sterility and correct air pressure in the theatre, the door should be sliding and hermetically sealed type. Door should meet international quality and safety requirements.
- Controller should be Microprocessor based controller (CE marked) Imported from European Countries only
- Should be hand and foot sensor operated and no over-door sensor should be there
- Regulated electro-mechanical sliding door drive.
- Suitable capacity of Motor should be equipped.
- Noise level of movement should not be more than 60 decibels.
- Power efficiency should be 0.95 (in AC 100 V full load).
- The door track should be a minimum 300-400mm and its cover should be made up of single piece extruded aluminium only to protect from rusting.
- All door automation should be installed in the aluminium extruded door track.
- Environment temperature should be –20 °C to +55° C.
- Electrical safety codes for High & Low voltage system design should meet HTM2020/2021 standards.
- Hermetically sealed Sliding Automatic Door shall be with Vision Panels 600mm x 400mm with double glazed panels and hermetically sealed should be equipped for OT. The Door panels are to be of the same material as that of the wall panels i.e. stainless steel SS 304 of 1.00 mm thickness on both sides & shall be pre-powder coated and no painting job shall be carried out at site. The antimicrobial pre-powder coating shall be maintained at a minimum deposit thickness of 60 microns and should have JIS Z 2801 certification (or equivalent) from a third party
- All doors shall be made of stainless-steel Material-Nr. 1.4301, SS 304 grade only& door frames of aluminium. The door frame should be in aluminium and not be less than 1.5mm. thickness. There shall not be any visible screws or similar other uneven surfaces on the door panel. All Automatic & manual doors should have sturdy SS door handles on both sides.
- Automatic doors shall have potential equalization (earthing) as per VDE 0107 or equivalent guaranteed by a sliding contact. Its automation unit shall be short-circuit proof and shall have an integrated power supply unit 200-240V, 50-60 Hz, 24V~/2A and shall comply with ISO 9001 and CE requirements.
- The automatic doors shall have a vertically placed conductive push strip of minimum 1.0 mt height on both sides of the door for Auto operation by elbow, foot or knee for entry / exit. There shall be separate entry push buttons for OT staff, trolley. There should be a dedicated push button on one side of door for cleaning purpose i.e. during cleaning area near OT door, if required the said button is pressed which will open the door remain upon until pressed again. All the buttons & conductive push strip should be mounted on SS door frame and should come pre-wired internally from factory.
- Sealed airtight system should be provided to prevent further ingress of any microbial organism. Nylon runner guides should be fixed to the door in such a way that there shall be no obstruction to the Trolley movement.
- The door leaf should have high quality synthetic rubber gasket with long life to ensure hermetic sealing to maintain pressure differential. Air tightness 99.99% at a pressure75pa (Test certificate for hermetic sealing with door frame should be provided with predespatch documents. The finished door on either side of the door should beperfectly level (maximum permissible difference +1mm). The track of the door and its cover shouldbe made up of single piece extruded Aluminium and the running surface for the top rollers shall be suitably angled to reduce resistance to movement. The door leaf shouldbe hung by means of hard plastic rollers of high quality with double bearing at the top. Powder coated

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Roller should be provided under the stainless steel/extruded aluminium track to enable smooth and noiseless movement.

- The doorframe, track and the wheelshould be designed in such a way that during last 50 mm at travel on the closing cyclethe door should make a tight sealing with the frame. The door should be provided withhigh quality cylindrical lock. The lock should be activated or switched off by means ofthe key switch accessible from both sides of the door.
- For Hybrid OR – ALL the door attached to the X ray equipment should be lead protected in door panel.
- The door should be governed by two sensors for half and full closure. The controller should be capable of either operated by elbow switch; foot switch (Touch fewer sensors). The door should be operated easily manually in the event of failure of the power supply or the automatic mechanism. Door opening handle should be strong and sturdy and the handle material should be AISI-304 Stainless steel and glossy finish. High and Low voltage system of the door should meet electrical safety code.
- ~~The door should be FDA/CE certified in accordance with class I of Medical device directives and CDSCO-Certified~~

5. Pressure Relief Dampers

- The Pressure Relief Dampers are to be equipped with the theatre to prevent contamination of air from clean and dirty areas. The Dampers of suitable size should have AISI-304 Stainless Steel blades of thickness 1 mm each. The body should be epoxy powder coated as per standard BS colours.
- The statically and dynamically balanced Pressure Relief Damper should be properly placed. The Dampers enable to maintain differential room pressure to close tolerance inside the Operation theatre. Counter weight balancing system should be provided in the Pressure Relief Damper to maintain positive pressure inside the operation room. The PRD should remain closed at pressure below the set pressure and should open fully at a pressure only fractionally above the threshold pressure.

6. Internal Ducting Inside Ot With Insulation:

- The internal ducting till the existing AHU system of the Operating theatre should bedone as per ISI-655 duly fabricated out of 22 swg Aluminium sheet complete with flanges and accessories such as GI suspenders and GI supports completely sealed with Silicon sealant duly insulated with Aluminium foil and (XLPE) Polyethylene/ Nitrile Rubber self-adhesive type insulation. The type of insulation and its thicknessshould be such that there is no sweating.

7. Peripheral Light Cum Clean Room Luminaries

- It should be fitted outside the air ceiling system area and flush with the ceiling in the operation theatre suitable to required illumination (500 Lux) of OT. Peripheral lights should be LED based (Size-2ft x 2ft) and clean room luminaries fitted in the frame should be 8 in numbers for each OT.
- Luminaire body made of sheet steel, white, powder coated supplied ready for connection. The reflectors should be of high quality, cleanable and non-deteriorating. It should have flicker less design with color.
- The fitting should be flush with the ceiling and should be removable formtop or bottom. Lighting units should be properly sealed with the ceiling by means of fillers and beadings so that all lighting units are airtight with ceiling panels.
- The light fitting should be uniformly and aesthetically distributed on the ceiling to provide uniform illumination in the OR. Peripheral lighting should be done according to IP65 protocol.

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8. Surgeon Control Panel – Touchscreen

- The OT Control Panel should be designed to cope with changing technology and equipment in operating environments. Control panel should be user friendly and ease of operating and maintaining purpose.

- The touch screen Control panel should be 21" LED panel stationed in the sterile field. The Control Panel should be configured to incorporate all the services required by the staff in the Operation theatre. It should be mounted flush in the theatre wall.

- The Control Panel should comprise of following services in addition to Instruction board.:
  - Day Time Clock
  - Time Elapse Day Clock, On screen digital time elapsed controls;start/stop/pause count up &down
  - Full control of Operating Lights.
  - General Lighting System on/off and dimming and control should be of each individual General light
  - Hands free IP telephone set
  - Temperature and Humidity Indicator with Controller and set point and can be set from 16-30deg (to enablesetting the temperature and humidity from control panel) with datalogging facility
  - Ventilation On and Off option
  - HEPA Filter status
  - Medical Gas status/alarm and status indication and alarm
  - Digital Room Pressure Indicator
  - Music control
  - Dimming of PERIPHERAL LIGHT CUM CLEAN ROOM LUMINARIES should be possible from the control panel
  - UPS status
  - Door Window Controls

- Day Time clock/Time Elapsed day Clock should be digital type and bright.

- Temperature and Humidity Indicator should indicate temperature and humidity of the theatre and the display shall be digital and bright. The temperature and Humidity controller should be connected to the Air Conditioning system and to be integrated to the Surgon conytral panel

- General Lighting System should incorporate all the necessary controls of all the lighting system including Dimmer for peripheral/planar lights.

- Medical Gas Alarm should indicate high, normal and low of gas pressure for each gas service provided in the Operation room. Alarm should be equipped with audible buzzer.
- The pressure sensor of the Alarm should be connected to MGPS for monitoring the pressures.
- A differential Room pressure monitor with audio visual indicator must be placed outside the OT door and must integrate with the Surgon contral panel with datalogger
- UPS status /Alarm can be monitored form the surgeon control Panel.

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- The control panel should be user friendly and ease of operation and maintenance. All internal wires should be marked with plastic ferrule type cable markers, for ease of identification. The control panel should be able to be integrated with the commonly used OT software in future. The control panel should meet Electrical Safety Code for High and Low voltage system, wired to the current IEE regulations or equivalent.
- The Touch screen Surgeon control should be FDA/CE /CDSCO certified and in accordance with class I of Medicaldevice directives

9. Adjustable Movable Boom Arm Systems

I. Retractable Surgeon Pendant System:

- The Ceiling boom arm systems are designed to provide convenient positioning of medical equipment, medical gas terminal units, electrical and specialty services. The Ceiling Pendants should comply with international standard medical device directive. The arms should be easy to move, and each should come with electromagnetic brakes as a standard option to support a locked position. In case of pressure or power failure, the arm should remain locked in its previous position and should not automatically move. Pendant shouldbe European CE with 4 digit notified body/US FDA /BIS certified.

- The Equipment Boom should be custom designed to meet all the specific needs of the operating room such as concealed cables and tubes, unlimited equipment combinations. The arms should be easy to move, and each should come with electromagnetic brakes as a standard option to support a locked position.In case of pressure or power failure, the arm should remain locked in its previous position and should not automatically move.

- The Equipment Pendant with a service head column adjustable height and should be with Double-arm (1000 + 800 mm) with Horizontal Motion & Vertical motion. There should not be any sharp edges or grooves.
- Should have a motorized articulating vertical drop. Vertical articulation should be through a Heavy-Duty Electric motor.Should have at-least 2 shelves of minimum 400mm x 400 mm(LxB) size for various medical devices with a maximum thickness of 25 mm having a load bearing capacity of minimum 40 Kg for each shelf.
- The shelves should be scratch proof, smooth and should have antistatic surface. Should have one drawer for attachment to shelf described above with minimum load capacity of 5 kg with non-protruding handle with option for easy cleaning by option of easy removal capability of whole drawer.
- Top-armRotation & Lower arm Rotation should be at-least 330 degree & Service-head rotation should be at-least 330 degree and end point should be customizable at site as per requirements of user
- Must be motorised and height adjustable and can be control from the buttons provided at panel.
- The Equipment Pendant should have a service head column 600-800 mm length and should be modular type for further scope of increasing the column length.
- The arms should be fitted with electromagnetic brakes to prevent inadvertent movement.
- The arm should be wide enough so that all required cables, tubes can pass through same. The arm should be min 200-220 mm wide and 110-120mm in height.
- Service Points/Outlets:
  - It should have pre piped gas outlet points with NIST connection .

- Should have standard Medical Gas Service outlets (7 bar Surgical Air outlet x 2 Vacuum Outlet x 2,1 oxygen outlet) & at least 10 no. of standard duplex conditioned Electrical Service outlets.
- Outlets should be CE certified/UL listed.
- Each terminal unit should be identified by theappropriate recognized name or symbol, colour, coding and shape as per HTM 02-01/NFPA 99C.
- The Column should have at least 8 no. of Data (Audio/Video/Control) Ports for connections to various other medical devices desired to be integrated in future.
- Pendant should have RJ 45 /cat 5 for telephone communication and 2 x RJ 45/cat 6 for data communication.
- And must be configured with 2 HDMI port for routing Videos
- Should have ceiling-based interface for connection of supply unit for electricity and gases

ii. **Retractable Persfusion /Anesthesia Boom System**

➢ The Equipment Boom should be custom-designed to meet all the specific needs of the operating room such as concealed cables and tubes, and unlimited equipment combinations. The arms should be easy to move, and each should come with electromagnetic brakes as a standard option to support a locked position.In case of pressure or power failure, the arm should remain locked in its previous position and should not automatically move. The pendant shouldbe European CE with 4 digit notified body/US FDA marked.

➢ The boom system should be available as follows:

- 800-1000 mm column length.
- 1000mm with moveable arms with 330 deg. Horizontal movement.
- The arm should be wide enough so that all required cables, tubes can pass through same. The arm should be min 200-220 mm wide and 110-120mm in height.
- The weight carrying capacity of the arm should not be less than 180 Kg.
- Each arm should be capable of 330 degrees of rotation, which can be easily adjusted to suit the desired mode of operation.
- The arms may be fitted with electromagnetic brakes to prevent inadvertent movement.
- It should have pre piped gas outlet points with NIST connection.
- The Pendant Service Head should be supplied with medical gas terminal units and sockets as mentioned below. Each pendant should have:
- Oxygen Outlets– 4
- Medical Air(4 bar) Outlet– 2
- Vacuum Outlets– 2
- AGSS Outlets-1 no.s
- Electrical Sockets 5/15 amp –10 nos.
- Shelf with two rails one on each side – 2 no.
- Monitor Input & Output – 1no.
- Infusion pump pole – 2
- IV management – 2
- RJ 45 /cat 5 for telephone communication.
- RJ 45 /cat 6 for data communication.
-

➢ Outlets should be CE certified/UL listed.

➢ Each terminal unit should be identified bythe appropriate recognized name or symbol, colour, coding and shape as per HTM 02-01 /NFPA 99C.

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- The Gas Outlets are to be provided with adapters in OT Pendants and must be as per the standards/guidelines maintained in the Medical Gas Manifold System inthe hospital.
- Suitable adapters compatible with the hospital Medical Gas Manifold system and hospital equipment with numbers as per the requirement of the hospital will be provided by the bidder.

10. X-RAY FILM VIEWER

- The system should have electrical safety codes for high & low voltage system. The theatre is to be equipped with a 2-plate X-Ray viewing screen.
- It should be designedto provide flicker free luminance for the film viewing purpose. It should be installedflushed with the theatre wall for hygienic and ease of cleaning purpose.
- The X-Ray viewing screen should be designed for the purpose of front access.
- The X-Ray viewing screen should be illuminated by LED and the dimming is controlled by the usage of dimming ballast with the PCB that is mountedinside the box.
- Must be flush mounted in wall panel

11. WRITING BOARD (OPERATING LIST BOARD)

Writing Board as operating list Board of size-1000 x 700 x 60 deep should be made of ceramic having magnetic properties and should be flushed to the wall of the operating Room.

12. Built-In Storage Unit

- Storage Unit should be made out of not less than 1.00 mm thick AISI-304 Stainless steel. The storage unit should be divided 2 or more parts and each part should have individual glass doors with high quality locking system.
- These doors should beinstalled on the storage units with the help of imported fittings allowing an openingallowance of 90-100 degree. Each part should be provided with Stainless steel-304 racks which should be completely detachable type.
- The storage unit should be fitted with 5mm thick glass door and mounted flush with the theatre wall.
- The storage unit should be continuously ventilated by positive air in the OT through ventilation holes provided at the bottom and top of opposite sides.

- The dimensions of each storage unitshould not be less than height 1800 - 2100mm x width 900 – 1200 mm x depth 300 - 350mm.

- Must have accessories to keep catheters /Stents and Other cardiology intervention consumables.

13. Distribution Board Electrical Wiring, Conduiting With Fixtures Inside The Operation Theatre

- Electrical Distribution Board should be installed in a separate enclosure. Transformers, Mains, Relays, Circuit protective equipment, for all circuits of Operation theatre shall be installed in the remote cabinet.
- All electrical wiring should be terminated to the connectors mounted on DIN/CE approved rail and labeled with indelible labels.
- Individual fuse and miniature circuit breakers should protect all internal circuits. Complete schematic diagram drawing description should be enclosed with the equipment.

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- Laying of PVC conduits, Modular Switch Boxes, Modular Switches-sockets, Power and Light wiring including earthing wire for all the lighting controls, Pendant and other equipment fixtures and fittings inside the theatre Wiring with low leakage current wires of FRLS wires should be as per requirements.
- 5/15 Amps switched socket outletnot- 2 Nos. shall be equidistant flushed in each wall at 325mm height from FFL of OT. Wiring for 250 volts single phase and earth4 sq.mm and 2.5 sq.mm PVC insulated copper conductor 1100 volts stranded flexible wires should be concealed with conduitfor switch & sockets.
- One switch and socket along with suitable size of wire must be fitted inside the OT for operating other cardiology equipments like IVUS,EP, FFR, Impella,IABP, and Heartlung Machine.
- Installation of all electrical cabling must beof IS: 1554 (As per latest amendment) standard and wiring as per IS: 732 standard and proper earthing of OT and other accessories in the OT room as per standard guidelines of BIS.
- 4 independent chemical earthing must be done by the vendor.

14. Scrub Station(Wall Mounted Type 2 Bay)

- It should manufactured be from Stainless Steel SS 304 Grade Materials. The special designed basin is based on the advanced human engineering which protects from water splashing to keep a dry floor.
- The whole basin base material featured long lasting 304 stainless steel (minimum 1mm. thickness) and to be supported by wall brackets to enable floor cleaning.
- The basins are equipped with latest chrome surfaces, infra red electronic start/stop detection tap which features the water-saving flow time, temperature control ranged from 35°C to 45°C, including an infra-red automated soap dispenser. The front sensors for tap.
- 2 electronic soap dispenser with frontal photocell sensors
- Each sink of the scrub station shall have two soap dispensers and a tap operated with an independent optical sensor. The tap shall have an automatic mixer for hot& cold water through a temperature regulator. Thermostatic mixture inside the Scrub unit should not be offered and Tap should only have the temperature regulatory knob to mix hot & cold water.
- The tap should have time controlled sensor (1min, 2min, etc) and should be operable by knee also.
- The number of sinks will be two in one scrub station

15. Medical Gas Line Installation

- Oxygen, Air (Medical & Surgical), Vacuum, and AGSS supply to Hybrid ot Theatres from the existing manifold system should be provided. The medical gas alarm system shall be installed which fully satisfies the principles of HTM 01-02/NFPA99c and should be compatible with the existing Gas manifold system (MGPS).
- Connection with the main pipelines should be done by the bidder in consultation with the MGPS vendor.
- Adapters in adequate quantity for MGPS or any other equipment will be provided by the bidder.
- Medical graded Copper pipes shall be solid drawn, tempered, seamless, phosphorous deoxidized, non-arsenic and degreased for oxygen service. Copper to Copper joints shall be made on site using silver-copper-phosphorous brazing alloy to BS 1845.
- Copper to brass or gunmetal joints shall not be made on site.

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- Except for mechanicaljoints used for components, all metallic pipeline joints shall be brazed or welded. All pipelines shall be routed in such a way that their not exposed to a temperature lessthan 5 deg Celsius above the dew point of the gas distribution pressure.
- The chemical composition shall be as per BS-6017: 1981 Table 2, Cu-DHP grade.
- Distribution Copper Pipe manufactured as per BSEN:13348:2008 Each pipe shall be capped at both ends before supply.
- Pipeline shall be supported at interval to prevent sagging. The supply of pipes shall accompany with manufacturers test certificates for physical properties and chemical composition.
- The supply of pipes shall be further substantiated with inspection certificates from third party such as Llyod and should be KITE marked.
- Medical graded Copper Piping should be laid down from Pendant of OT to the nearby Valve Box outside the Operation Theatre via Surgeon Control Panel.
- They should also distribute to the preop area of OT.

20. View Window(Lead Glass) With Motorized Blinds

- View window with motorized horizontal Venetian blinds sandwiched in two parallel toughened glasses of thickness 5 mm should be complete with FHP Motor Control for 90° rotation.
- The Window frame should be powder coated Aluminium of approved shape flush mounted with wall panelling.
- The entire assembly should be completely sealed and fitted with a proper Aluminium profile. The assembled thickness of the Window should be 33 mm.

21. Exhaust Air Cabinets

The exhaust air cabinets should be openable and cleanable.

- Return air exhaust grill should be provided in the OT.
- These cabinets should have suction from the bottom.
- Designed flow rate should not be less than 1000 m3/hr. Distribution of exhaust air volume should be divided between fluff strainers to maintain the required pressure within the theatre without causing turbulence.
- The Exhaust air cabinet should be manufactured and supplied by the supplier of wall and ceiling system supplies.
- Material Specification of materials and aesthetics should match perfectly with the Wall & ceiling system.

22. Oxygen Flow meter with Humidifier Bottle-2nos

23. Theatre Suction dual jar (2000ml) unit trolley with regulator unit -2nos

24. SPECIFICATION FOR CEILING-MOUNTED DOUBLE DOME OT LIGHT

CEILING-MOUNTED DOUBLE DOME OT LIGHT with an Extended long arm to be installed on one side of the cathlab to avoid the biplane rail movement

1. **General Requirements**
   1. LED surgical lights illuminate the surgical site for optical visualisation of small low contrast objects at verifying depths in incisions and body cavities.
   2. The unit should consist of following items
      a. Double Dome Operating Light
      b. Inbuilt Wi-fi HD Camera in any one dome HD Recorder

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3. The light shall adopt LED Technology to create a homogenous light patch without emitting any infrared rays.
4. The light system shall be Dual light heads, one major and one satellite.
5. Light dome should be round shaped and not Petal/winged-shaped
6. Light dome should be made of aluminium and not ABS material
7. Light should have optical focus through a motorised mechanism adjusted electronically from the control panel
8. All Dome should have 4 colour LED lamps (Cool White & Warm White, Red and Blue/Green light Combination), to achieve high CRI and R9 to get the required shade of light as per different surgical requirements.
9. Operated by following controls
    a. Touch screen control fixed on the light arm
    b. Bluetooth Touch screen control on the OT Wall
    c. Wireless hand control
    d. Gesture control
10. High-power LEDs of 1 watt & above should be used to provide high lumen to watt ratio which leads to lesser energy consumption and low heat at surgical area <2 degree
11. Lights should have higher watts LEDs to achieve a high lumen to watt ratio which leads to lesser energy consumption and low heat at surgical area.
12. Pulse width modulation-controlled LED driving to ensure less heating of LED which increases life of LEDs and no change in Light colour Output and light colour temperature throughout life.
13. Light intensity shall be adjustable between 10% -100% and should have low intensity
14. The light head shall be of a Single round to avoid obstruction to laminar flow on surgical field.
15. The light shall be mountable to ceiling from single center with 360-degree rotation of all arms. Spring arms shall be rotatable at least 360 degrees around their own axis. Each dome head should be rotatable at 360 degrees at connecting joint with spring arm and at least 360 degrees around its own axis. This feature should be applicable with camera mounted dome also.
16. The maximum movement angle of the spring arm shall be at least up 45°and down 50°
17. The thickness of the light head shall be no more than 120mm
18. Each LED shall be replaceable individually to save cost in case of failure, instead of replacing the module with several LED's.
19. The surgical light should be complete with all components for ceiling mount and electrical feed-in, including finalized installation.
20. Detachable & auto cleavable handle (2 nos./dome) for each light should be provided.

2. Technical Requirements of both Domes:

1. Should have 4 Color LED lamps, Yellow, White, Red and Blue/Green
2. Central Illuminance should be 160,000 lux
3. Light field Diameter should be adjustable from 150mm to 300mm
4. Color temperature (K), adjustable from 3800-5100K
5. Color rendering index should be 98 or more
6. Depth of illumination should be 1200mm.
7. Dimming range should be between 25-100%
8. Endoscopy mode illumination should be less than 5% of 160,000 lux and option of Blue/Green light should be available.

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9. Following controls should be available in control panel and wall control unit
    a. Power on/off
    b. 10 steps Intensity adjustment or Continuous adjustment
    c. 5 grade variable color temperature
    d. Endo mode
    e. 5 pre-defined lighting settings for various surgeries
    f. Intensity Focus In/Out
    g. LED usage counter
    h. Camera Controls
10. Number of LED bulbs in each light head should not be more than 50-60
11. LED Service life should be a minimum of 60000 hrs. with LED usage counter
12. Light Head Dimension Should be 550mm (+/- 20mm)
13. Max. Power consumption of each dome should be less than 75W.
14. Power supply should be 100-240V AC, 50-60Hz

3. Standards

1. ISO 9001:2008
2. ISO 13485:2003 from the CDSCO notify body,
3. European CE certificate issued by a European notified body and US FDA registered
4. Must have CDSCO License for quoted model.
5. Should have compliance with: IEC 60601-1, IEC 60601-2, IEC 60601-2-41, Certified from any NABL accredited lab / any lab from country of origin for imported brands to be submitted.

4.Recording Systems

1. Wi-fi HD Camera System in any one dome and should have a wireless recorder
2. Image Sensor:1/2.8" Progressive Scan CMOS
3. Resolution: 1920x1080
4. Zoom: 30x optical zoom
5. Camera signal output - only wireless
6. 24" Medical grade monitor should be provided in 3rd arm below the second dome
7. The HD Recorder should be mounted below the monitor
8. Recording capacity should be at least 1TB
9. Should have the facility to export the videos from the recorder
10. 2 ports of USB 2.0 should be available
11. A mouse with a pad should be provided
12. The handle for positioning the monitor and recorder should be provided below the recorder.

23.HVAC :

- SITC Air-conditioning of Tonnage 20 TR (including standby unit(11.5 & 8.5) With AHU and DX unit with VRF must be included with all the ducting for supply & return air, Insulation, Control PCB, Integration controller Including all pre-filters to achieve OT temp from 16-22 deg C

.The AHU design should allow a minimum of 20 air changes per hour including 4 fresh air changes according to NABH guidelines

- A separate adequate capacity of AC units(minimum 4 ton) is to be provided for the UPS room and Equipment room.

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- All the cabling and electrical components required for the installation of the HVAC unit must be included

Specification For Biplane DSA has been adopted from approved specification circulated by MoHFW vide no Z-28016/35/2024-PMSSY-Iv(8285627)& for modular OT from ,AIIMS,New Delhi

Detail BOQ for Biplane DSA & Modular OT(Hybrid Cath lab)			
Sl. No.	**Description of Stores /Items**	**Quantity**	**Units**
1	DIGITAL SUBTRACTION ANGIOGRAPHY UNIT (BIPLANE) with hemodynamic Monitor & accessories	1	Pieces
2	Anaesthesia workstation with monitor & e charting system	1	Pieces
3	Cardiac Monitor with Defibrillator with AED pads	1	Pieces
~~4~~	~~IABP machine~~	~~1~~	~~Pieces~~
~~5~~	~~Radiation Protection Equipment~~	~~1~~	~~Pieces~~
6	Fully Modular Low heat outputOnline UPS SYSTEM -160 Kva with 30 mins backup for the entire Cathlab	1	Pieces
~~7~~	~~Dual Chamber Temporary Pacemaker~~	~~1~~	~~Pieces~~
~~8~~	~~Syringe infusion Pump~~	~~1~~	~~Pieces~~
~~9~~	~~Handheld Non Invasive Cardiac Output Monitor~~	~~1~~	~~Pieces~~
~~10~~	~~FFR console~~	~~1~~	~~Pieces~~
11	**Modular Ot & Its components**	**1**	**As below**
11.10	Truly Modular Wall Panel System (Factory Finished)with Sub Structure, including backed gypsum and lead lining	100	sq meter
11.11	Suspended Ceiling System (Factory Finished)	100	sq meter
11.12	Sealing gaskets/ Silicon sealants	125	meter
11.13	Laminar Air Flow Ceiling System(To be installed in centre/Periferry depending on the roof rails)	1	Pieces/Set

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11.14	Operation Theatre Flooring (Antistatic Conductive Pvc Roll)	100	sq meter
11.15	Doors And Frames (Automatic Hermetically Sealed Sliding Doors) - Automated Sliding Large Door(ASL)	2	pieces
11.16	Doors And Frames (Automatic Hermetically Sealed Sliding Doors) - Automated Sliding Small Door(ASS)	1	pieces
11.17	Doors And Frames Manual Doors (Hinged)	3	pieces
11.18	Pressure Relief Dampers	2	pieces
11.19	Internal Ducting Inside Ot With Insulation	1	set
11.20	Exhaust Air Cabinets	6	pieces
11.21	Peripheral Light Cum Clean Room Luminaries	20	pieces
11.22	Surgeon Control Panel – Touchscreen	1	pieces
11.23	Adjustable Movable Boom Arm Systems -Retractable Surgeon Pendant System:	1	pieces
11.24	Adjustable Movable Boom Arm Systems -ii. Retractable Persfusion /Anaesthesia Boom System	1	pieces
11.25	X-RAY FILM VIEWER	1	pieces
11.26	Ceramic WRITING BOARD (OPERATING LIST BOARD)	1	pieces
11.27	Built-In Storage Unit	3	pieces
11.28	Scrub Station(Wall Mounted Type 2 Bay)	1	pieces
11.29	Medical Gas Line Installation	1	Set
11.30	Oxygen Flow meter with Humidifier Bottle-2nos	2	pieces
11.31	Theatre Suction dual jar (2000ml) unit trolley with regulator unit	2	pieces
11.32	View Window(Lead Glass) With Motorized Blinds(1200*1500)	1	pieces
11.33	CEILING-MOUNTED DOUBLE DOME OT LIGHT with Extended long arm to be install one side of the cathlab to avoid the the biplane rail movement &must having input routing signals to the big display	1	pieces
11.34	HVAC systemwith VFD with AHU with variable flow including ducting electrical panels and HVAC controller including Temp & humidity sensor	1	Set
11.35	Cassate ACs for UPS and Equipment room	2	pieces
11.36	Separate exhaust ducting line with inline silent fans in UPS room	2	pieces

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11.37	Ceiling Lights	16	pieces
11.38	PVC/ Wall Cladding -for corridors	100	Sq meter
11.39	Glass Cabinets for catheters	4	pieces
11.40	Wall Equipment & Accessories - Flat Monitor (43 inches)flushed with wall panel with tempered glass	1	pieces
11.41	Distribution Board Electrical Wiring, Conduiting With Fixtures & LAN Networking with L3 switch	1	set
11.42	Electrical Switches& socket Inside the Cathlab and auxiliary room	20	pieces
11.43	ANESTHESIA GAS SCAVENGING SYSTEM (AGSS) with blower	1	set
11.44	Additional Civil Works(Painting ,Celing etc)	150	Sqmtr
11.45	Additional Electrical Work (Electrical cabling)-225 Sqmm(Suppling, laying & Installation)	480	meter
11.46	Additional Electrical Work (Electrical panel with all the components like Breaker, MCCB, MCB,Busbar Etc)	2	Pieces
11.47	Installation & Turnkey	1	Lumpsum

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