Date: 02-12- 2024

Tender (Ref: IISc-Med-2024-25/1)

To Whom It May Concern

This Request for Quote (RFQ) seeks proposals for the planning, supply, installation, testing, commissioning, and personnel training for a complete package of medical equipment. The package includes a Single Plane & Digital Subtraction Angiography System (Biplane Cathlab) with Hemodynamic Recorder, High-End Transoesophageal Echocardiograph (TOE) with Post-Processing Workstation and Intra vascular ultrasound. Additionally, the package may include items from other vendors and related components, alongside the equipment from Original Equipment Manufacturers (OEMs) for the specified systems for IISc, Bangalore

At IISc, the planned infrastructure encompasses a wide array of medical equipment to support advanced imaging capabilities, with a particular emphasis on cardiology, essential for patient care, teaching, and research. The vendors are requested to factor this exposure's value into their quotes. Details of IISc can be gleaned from reframe for cardiology perspective.

https://medicine.IISc.ac.in/

A. Procedure:

- Vendors are required to submit a technical proposal and a commercial proposal in two separate sealed envelopes. Only vendors who meet the technical requirement will be considered for the commercial negotiation.
- 2. The deadline for submission of proposals is Dec 23rd, 2024, Monday, 5:30 pm Indian Standard Time.
- 3. Bids in the sealed envelope should arrive at the office of Dean (A & F), Main building, Indian Institute of Science, Bangalore 560012, India, by the above deadline.
- 4. The technical proposal should contain a technical compliance table with 5 columns.
 - a. The first column must list the technical requirements in the order that they are given in the technical requirement below in tender specifications.
 - b. The second column should provide specifications of the equipment against the requirement (please provide quantitative responses wherever possible.)
 - c. The third column should describe your compliance with a "Yes" or "No" only. Ensure that
 - i. the entries in column 2 and column 3 are consistent.
 - d. The fourth column should state the reasons/explanations/context for deviations, if any.
 - i. The fifth column can contain additional remarks from the OEM. You can use this opportunity to highlight technical features and qualify the response of previous columns.

- e. The Sixth column should contain the datasheet Page reference number.
- 5. Vendors are encouraged to highlight the advantages of their equipment over comparable equipment from the competitors
- 6. In the commercial bid, please provide the itemized cost of the equipment and required accessories, etc.
- 7. Please provide itemized cost for any suggested/optional accessories/add-on items that may enhance the equipment usability, capability, accuracy or reliability. Vendors are encouraged to quote for as many add-ons as their product portfolio permits.
- 8. In the quote, you are requested to provide itemized cost for spares, accessories, consumables expected over 2 years of use.
- 9. Please indicate the warranty provided with the equipment
- 10. Any questions or clarifications can be directed to:

Dean (A & F) Main building, Indian Institute of Science, Bangalore 560012 tenders@IISc.ac.in

B. Terms and Conditions

- 1. Only the Original Equipment Manufacturer or their authorized representatives shall participate in the bid.
- 2. The order will be placed only on the bidder who participated in the bid
- 3. The decision of the purchase committee of IISc will be final.
- The vendor is responsible for the planning, supply, installation, testing and commissioning of the equipment & the training of personnel of the installed equipment at the IISc.
- 5. The RFQ must include references to previous installations including the list of all customers where similar systems were installed in past 5 years. Please provide the names and contact addresses of the referees so that the committee can contact them independently. Details of such systems with model numbers and users should be provided. The reference letters can be used to disqualify vendors with poor track records of service, build quality, system performance, or poor availability of spares.
- 6. The vendor should have qualified technical service personnel for the equipment based in India and must assure a response time of <2 hours after receiving a service request. The schedule for periodic preventive maintenance for the equipment and all the items related to OEMs should be provided.
- 7. The indenter reserves the right to withhold placement of the final order and to reject all or any of the quotations and to split up the requirements or relax any or all of the above conditions without assigning any reason.
- 8. Wherever requested in this specifications sheet, data must be supplied along with technical compliance documents. Technical bids without supporting data will be deemed as technically non-compliant.
- 9. Upon request, all guaranteed specifications will have to be demonstrated in an active installation. Failure to demonstrate any promised specifications will be deemed as technical non-compliance.
- 10. Printed literature and published papers to support compliance with the prescribed

specifications may be provided duly authenticated by qualified personnel in the company.

- 11. Technical evaluation by the IISc may include a demonstration to verify the functionalities and capabilities of the equipment quoted. Any discrepancy between the promised and demonstrated specifications will be deemed technical non-compliance. If the need arises, the vendor must be ready to visit IISc for a techno commercial discussion physically.
- 12. The validity of commercial quotations should be at least 90 days from the last date for the submission of tender documents.
- 13. The quotations should be on FOR-IISc Bangalore basis.
- 14. **Payment terms:** LC will be opened with 70% payment on shipment of the documents and remaining 20% on installation, testing & commissioning and 10% on user satisfaction. Insurance coverage should be till the commissioning of equipment.
- 15. The functionalities and capabilities of the equipment to be provided as part of documentation. Any discrepancy in technical specification between what was committed during technical evaluation and demonstrated specification on ground will be deemed technical non-compliance. If the need arises, the vendor must be ready to visit IISc for a techno commercial discussion in person.

C. Other terms

1. Shipment and Delivery Terms

1.1 Partial Shipments

a. Partial shipments are allowed; however, transshipment is strictly prohibited.

1.2 Delivery Confirmation

a. Delivery shall only be made after receiving written confirmation from the IISc purchase team.

1.3 Consignee Details

a. The address of the consignee and the markings on the containers must be clearly stated as per the details provided by IISc.

1.4 Packing Slip and Documentation

a. A packing slip detailing each item and its quantity shall accompany every shipment.

b. The packing slip must be securely attached to the exterior of one of the containers in a visible manner.

c. The purchase order (PO) number must be clearly marked on all packing slips, invoices, and correspondence.

1.5 Missing Items and Substitutions

a. Any items that are not found upon delivery must be clearly noted on the packing slip, and the anticipated availability of such items shall be indicated.

b. Substitutions of items shall not be made without prior written authorization from IISc.

1.6 Packing of Fragile Equipment

a. Fragile equipment shall be packed in wooden boxes to prevent damage during transit.

1.7 Packing of Critical Components

a. Critical components must be packed using foam/bubble wrap and cartons, and securely stuffed within containers to prevent any damage during transit or handling at the site.

1.8 Protection during Transit

a. The Seller shall ensure that all items are securely protected and packed in accordance with best established practices to avoid damage under conditions such as multiple handling, transportation by ship/road, storage, and exposure to heat, moisture, rain, etc.

1.9 Seller's responsibility for damage

a. The Seller shall bear full responsibility for any breakage, damage, or pilferage (including during transit or handling within the hospital) resulting from faulty packing.

1.10 Marking and Packing Slip

a. All packages must be visibly marked with the purchase order (PO) number and name of the Buyer in bold letters.

b. Copies of the packing slip must also be placed inside each package.

2. Insurance and Freight

Cost of all Freight & Insurance Is Included In the-purchase order value will be arranged by supplier. The insurance should be from vendor warehouse to the site till Installation & commissioning at IISc.

- 2.1 Seller Notification for Insurance
 - a. If IISc needs to arrange insurance, the Seller must notify promptly.

3. Warranty Terms

3.1 The equipment along with all the 3rd party items should carry warranty of 12 months from the date of successful commissioning.

3.2 The warranty shall commence from the submission of a duly filled "Medical Equipment Acceptance Sheet Checklist," accompanied by all relevant documents, as per the specifications and requirements.

3.3 After-Sale Service

a. After-sales service will be provided by a service engineer trained by the principal company

b. The credentials and certification of the service engineer shall be shared with IISc for approval.

3.4 Preventive Maintenance and Calibration

a. Preventive maintenance and calibration shall be performed according to the recommendations of the Original Equipment Manufacturer (OEM).b. Preventive maintenance and calibration shall include calibration for any major breakdowns and be conducted in accordance with local rules and regulations, as well as OEM recommendations.

c. Maintenance and calibration shall also be based on the equipment performance history, using calibrated equipment traceable to international or NABL standards, as required.

3.5 Responsibility for Malfunctions

a. The seller shall take full responsibility for any mishaps or malfunctions related to the ordered equipment caused by delayed periodic maintenance or calibration under warranty & subsequently in comprehensive annual maintenance contract.

3.6 Maintenance and Calibration Costs

a. Preventive maintenance and calibration shall be executed free of cost during the warranty and Annual Maintenance Contract (AMC) period.
b. The seller shall clearly inform IISc about the list of consumables or maintenance kits that may incur additional costs (not covered under the maintenance contract) before the equipment is supplied.
c. All accessories, including computer systems, printers, laptops, and software versions, shall be covered free of charge under warranty, rental contracts, and subsequent maintenance agreements.

3.7 Annual Maintenance Contract (AMC) and Comprehensive AMC (CAMC)

The CAMC rate shall be quoted absolute value of the equipment cost per year till nine years post warranty period of equipment. Please refer the template for GENERAL TERMS AND CONDITIONS FOR COMPREHENSIVE/LABOUR MAINTENACE CONTRACT(CMC/AMC)

3.8 No Additional Terms to be imposed

a. The seller shall not impose any additional terms on the buyer when an Annual Maintenance Contract (AMC) is established on a yearly basis.b. All the terms mentioned in the tender and subsequent purchase order shall remain applicable without any modifications.

3.9 Warranty Terms during CAMC

a. The warranty terms, including those for preventive maintenance and calibration, shall remain valid and applicable throughout the duration of the CAMC, as per the terms outlined in the tender and subsequent purchase order

3.10 Payment for AMC and CAMC

a. Payment for CAMC will be made on a quarterly or annual basis.b. Payments will be disbursed upon the successful completion of preventive maintenance and calibration activities, in line with the terms and conditions of the tender and subsequent purchase order.

3.11 Consumables List

a. The vendor shall provide a list of consumables required for the equipment, along with their associated costs, before the supply of the equipment to IISc.

3.12 Equipment Recall and Standby Equipment

a. The vendor shall notify IISc of any recall related to the supplied equipment and ensure proper action is taken as per the buyer's recall terms and policies.b. In the event of an equipment recall, the seller shall provide suitable standby equipment, ensuring the clinical functionality of the buyer is not impacted.

3.13 Adverse Event Reporting

a. Any adverse events associated with the medical devices shall be promptly reported to IISc.

b. The vendor shall ensure that any adverse event is communicated to the National Collaboration Centre-Materiovigilance Programme of India, in accordance with regulatory requirements.

4. Maintenance and Calibration

4.1 Preventive Maintenance and Calibration

a. Preventive maintenance and calibration will be conducted free of charge under the warranty period and any subsequent Annual Maintenance Contracts (AMC).

b. Calibration will be performed in accordance with industry standards and OEM specifications.

4.2 Report of Maintenance and Calibration

a. The Seller shall provide report of maintenance and calibration with details of the work performed, including calibration standards and methods.

4.3 Qualification of Engineers

a. The Seller must ensure the trained engineers are certified and qualified for preventive maintenance and calibration.

5. Spare Parts

5.1 Supply of Spare Parts

a. The Seller shall supply spare parts for the entire lifetime of the equipment and guarantee availability for a minimum of 10 years from the date of commissioning of equipment.

5.2 Price of Spare Parts

a. The Seller will provide the prices of major spare parts, which should not exceed 30% of the total equipment value.

b. A list of critical spare parts and their estimated prices shall be submitted with the tender as part of commercial bid.

5.3 Spare Parts Availability

a. The Seller must maintain a minimum stock of spare parts to ensure quick availability for repairs.

5.4 Spare Parts Pricing

a. The prices of spares shall be firm for 5 years, after which adjustments can be negotiated considering inflation and exchange variations.

6. Uptime and Compensation

6.1 Uptime Requirement

a. The bidder must ensure a minimum uptime of 97% based on a 365-day working year.

b. In case the uptime falls below the specified 97%, the Warranty/CAMC shall be extended by a ratio of 1:5 days for every additional day of downtime.

6.2 Compensation for Test Failures or Erroneous Results

a. The seller shall be liable to compensate the buyer for any test failures or erroneous results generated by the ordered equipment.

b. The compensation amount will be mutually agreed upon by both parties, and this provision will be legally binding.

7. Software and Support Services

7.1 Software Licenses

a. All software supplied as part of the equipment must come with the necessary licenses for use in India.

b. The seller shall provide a copy of the software license along with proof of ownership.

The supplied application & operating system software will be kept updated in the form of Free of cost as & when they are released by factory.

However, for new application software any additional hardware is needed, the cost will be borne by IISc management at negotiated special price.

7.2 Software Support Services

a. Any software updates or bug-fixing services will be free of charge during the lifetime of equipment.

8. Integration with Clients HIS & PACS-RIS

8.1 Integration Requirement

a. The Seller must integrate the equipment with clients Hospital Information System (HIS) & PACS-RIS at no extra cost.

9. Confidentiality and Ownership Transfer

9.1 Confidentiality

a. The service provider must not acquire or retain any confidential data from IISc.

9.2 Ownership Transfer

a. Any change in the ownership of the principal company must honour all existing agreements with IISc.

10. Recall of Equipment

10.1 Equipment Recall

a. In the event of any recall of equipment, the Seller shall promptly inform IISc in writing.

b. During the period when the equipment is under recall, the Seller shall provide suitable standby equipment of similar or higher specifications to IISc, at no cost

11. Force Majeure

If either Party Is unable to carry out his obligations under this Contract due to an Act of God, war, riot, blockade, strike (I.e. national/ state or city), lockout, flood or earthquake or Government orders/ restrictions not within the control of the parties hereto which results In an Inability, In spite of due diligence of either party in performing its obligation In time, this Contract shall remain effective, but the obligation which the affected party Is unable to carry out shall be suspended for a period equal to the duration of the relevant circumstances provided that : The non-performing party shall give the other Party prior written notice describing particulars of the Inability including but not limited to the nature of occurrence with its expected duration and the steps which the non-performing parties is taking to fulfil its obligation.

Upon receipt of such notice the other party shall discuss the matter with the nonperforming party with a view to helping the non-performing party to fulfil obligations. This clause does not envisage financial assistance.

If In any event the Force Majeure situation continues for a period of three weeks both the parties shall meet again and discuss whether the Contract can be amended to overcome the Force Majeure situation so the Project can proceed further.

Notwithstanding anything contained to the contrary it is clarified that economic hardship, non-- availability of material, labour and transport shall not constitute Force Majeure. The overall responsibilities and obligations of the parties shall not be excused by reasons of Force Majeure situation.

Notwithstanding the above If the Force Majeure continues for a period of three months or more In that event without prejudice to the rights of the parties, the Buyer shall have the right thereafter to terminate this contract.

12. Seller's Personnel at Buyer's Premises

12.1 Adherence to Safety Regulations

a. Seller's personnel on IISc premises must adhere to all IISc safety regulations and protocols.

8.2 Seller's Responsibility for Personnel's Safety

a. The Seller is responsible for their personnel's safety and health while on IISc premises and shall indemnify IISc for any accidents or injuries.

13. Site Evaluation

a. The Seller must conduct a site evaluation including transportation path, power, air conditioning and other requirements before equipment installation.

b. The Seller shall submit detailed drawings, specifications, and colour codes for all ordered items for Buyer review and approval via email or other methods. Manufacturing shall commence only after drawing approval and joint inspection of the proposed site.

14. Skilled & trained Engineer for Installation

a. Installation must be carried out by skilled engineer and is considered complete only when the equipment is fully operational as per the tender specification.

15. Inspection and Quality Plan

15.1 New Equipment Requirement

a. Only brand-new equipment will be accepted, and it must be accompanied by quality conformance and manufacturer test certificates.

15.2 Training

a. Hands-on training for IISc engineers and technicians must be provided at no extra cost.

16.Marketing Support

a. The Seller shall provide marketing support to IISc as mutually agreed upon.

b. The Seller's personnel shall coordinate their activities with Buyer's and construction contractors working to prepare the Installation Site (as hereinafter defined) for receipt of the Equipment. A pre-installation instruction manual to be provided to Buyer by seller.

TEMPLATE FOR ACCEPTANCE OF MEDICAL EQUIPMENT FOR CLINICAL USAGE

| | MEDICAL EQUIPMENT PRE-COMMISSIONING CHECK-LIST (To be filled during commissioning | | | |
|--------|--|--|--|--|
| Sr.No. | handover) Vendor to fill the details | | | |
| 1 | Equipment name | | | |
| 2 | Main Unit Model & Serial No | | | |
| 3 | Date of receipt of equipment at site | | | |
| 4 | Goods opening report (item wise) | | | |
| 5 | Principal Company name | | | |
| 6 | Dealer/ Vendor name | | | |
| 7 | Vendor contact details including email address | | | |
| 8 | Equipment Model name | | | |
| 9 | User Department name | | | |
| 10 | End User (Head of Dept) Signature | | | |
| 11 | Clinical Engineers name | | | |
| 12 | Clinical Engineers Signature | | | |
| 13 | Service Engineers name and Contact number | | | |

| 14 | Application specialist name and contact number | | |
|---|---|---|--|
| | Main Unit - hardware as per Purchase Order (Vendor- | | |
| | signed PO and list of items supplied as per PO with | | |
| | invoice) to be enclosed as part of the commissioning | | |
| 15 | | | |
| | Main Unit - software as per Purchase Order (Vendor- | | |
| | signed PO and list of software supplied as per PO | | |
| | with invoice) to be enclosed as part of the | | |
| 16 | commissioning documentation. | | |
| | OEM items as per Purchase Order (Vendor-signed | | |
| | PO and list of items supplied as per PO with invoice) | | |
| | to be enclosed as part of the commissioning | | |
| 17 | documentation. | | |
| | Accessories as per Purchase Order (Vendor-signed | | |
| | PO and list of items supplied as per PO with invoice) | | |
| | to be enclosed as part of the commissioning | | |
| 18 | documentation. | | |
| | Consumables as per Purchase order- (Vendor signed | | |
| | PO and List of items supplied as per PO with | | |
| | invoiced) to be enclosed as part of commissioning | | |
| 19 | documentation | | |
| | Brochure of equipment to be enclosed as part of the | | |
| 20 | commissioning documentation. | | |
| | Technical Data Sheet to be enclosed as part of the | | |
| 21 | commissioning documentation. | | |
| | Set of service manuals (1 hard copy & 1 PDF soft | | |
| | copy) to be handed over to the Clinical Engineering | | |
| 22 | Dept. | | |
| | Set of instruction manuals - Two copies (1 hard copy | | |
| | and 1 PDF) to be handed over to the Clinical | | |
| 23 | Engineering Dept. | | |
| | List of spares & additional accessories with re- | | |
| | ordering codes and costs used along with the | | |
| 24 | equipment as a standard package (PDF). | | |
| | Equipment demo training information materials like | | |
| 05 | PPT/Video to be handed over to the Clinical | | |
| 25 | Engineering department. | | |
| | Duly signed letter from the vendor organization head | | |
| | (MD/CEO) stating that the supplied unit, accessories | | |
| | & OEM items are brand new from the factory, to be | | |
| 26 | enclosed as part of the commissioning documentation. | | |
| 20 | Quality test certificate of equipment from the factory, | | |
| | duly signed by the factory production in-charge, to be | | |
| | enclosed as part of the commissioning | | |
| 27 | documentation. | | |
| ~1 | Software license document (PDF); including OS, | | |
| | system and application software, and commitment to | | |
| support over the lifetime of the equipment, to be | | | |
| | enclosed as part of the commissioning | | |
| 28 | documentation. | | |
| 20 | All cables from the equipment should have proper | | |
| 29 | cable management, i.e., cable labeling. | | |
| | | 1 | |

| I | 28 and HIRA (Hazard Identification and Rick | | | |
|-------|--|---|--|--|
| | 2S and HIRA (Hazard Identification and Risk Assessment) to be conducted during preventive | | | |
| | naintenance wherever applicable to keep the working | | | |
| 30 | area clean. | | | |
| 30 | | | | |
| 31 | First-level training to Clinical Engineering (training certificate). | | | |
| 51 | | | | |
| 22 | Application training to the end-user on all functions | | | |
| 32 | demonstrated (training certificate). Do's and Don'ts for the equipment for the user group | + | | |
| | to be provided as part of the training module, to be | | | |
| | | | | |
| 33 | enclosed as part of the commissioning documentation. | | | |
| 33 | Preventive maintenance frequency calculated based | | | |
| | on Equipment Risk Classification, Usage and | | | |
| | Operational Intensity, Manufacturer's | | | |
| | Recommendations, Historical Performance, and | | | |
| 34 | Failure Data. | | | |
| 54 | Preventive maintenance (PM) checklist to be | | | |
| | predefined & duly filled during preventive | | | |
| | maintenance, to be enclosed as part of the | | | |
| 35 | commissioning documentation. | | | |
| 55 | Preventive maintenance kit specification & details to | | | |
| | be shared in advance, to be enclosed as part of the | | | |
| 36 | commissioning documentation. | | | |
| 30 | Preventive maintenance schedule should be done | | | |
| | during non-clinical work operational hours based on | | | |
| 37 | prior approval from the user. | | | |
| 37 | Calibration schedules should be based on | | | |
| | Manufacturer's Recommendations and after every | | | |
| 38 | major equipment breakdown servicing. | | | |
| 50 | The calibration process should follow NABL 126 | | | |
| 39 | guidelines. | | | |
| 00 | With each maintenance work, the service provider | | | |
| | should hand over two physical copies of the service | | | |
| | report (one for the user and one for the Clinical | | | |
| | Engineering Dept.) along with a duly filled PM | | | |
| | checklist. If physical copies are not available, soft | | | |
| | copies should be provided to both the user and the | | | |
| | Clinical Engineering Dept. Accepted downtime in | | | |
| | hours & accepted equipment breakdown frequency as | | | |
| | per PO terms should be understood by the service | | | |
| 40 | team, including downtime penalty | | | |
| _ · • | Accepted Downtime in hours & accepted equipment | | | |
| | breakdown frequency as per PO terms are | | | |
| | understood by service team including downtime time | | | |
| 41 | penalty. | | | |
| | The service provider should maintain a logbook of | | | |
| 42 | maintenance at the user site. | | | |
| | Shelf-life details of critical | | | |
| | spares/accessories/consumables to be provided, to | | | |
| | be enclosed as part of the commissioning | | | |
| 43 | documentation. | | | |
| 10 | | | | |

| I | Commissioning report should include (IQ/PQ/OQ) as | |
|----|--|--|
| | part of equipment commissioning documents, duly | |
| | signed by the user group, to be enclosed as part of | |
| 44 | the commissioning documentation. | |
| | Cleaning & disinfection methodology, including the | |
| | material used, to be provided at the time of | |
| | commissioning of equipment, to be enclosed as part | |
| 45 | of the commissioning documentation. | |
| | User application training schedule to be provided | |
| 46 | along with the PM schedule. | |
| | Training materials soft copy (PPT/Video) to be shared | |
| 47 | for installation sign-off. | |
| | Letter from the principal manufacturer stating their | |
| | commitment to IISc for support of equipment for the | |
| | coming years as per Purchase Order terms to be | |
| 48 | provided. | |
| 40 | CE/FDA/CDSCO Certificate to be enclosed as part of | |
| 49 | the commissioning documentation. | |
| | The single-phase power cord supplied along with the | |
| 50 | equipment should have a 3-pin plug (Neutral, Phase, Earth) for Indian usage. | |
| 50 | Warranty card and details of the warranty to be | |
| | enclosed as part of the commissioning | |
| 51 | documentation. | |
| 01 | Short shipped items (if any) with quantity. The | |
| | warranty will start only after full supply, installation, | |
| | testing, and commissioning of hardware, application | |
| | software, and third-party equipment supplied along | |
| 52 | with the main equipment. | |
| | OEM and Dealer Sales and Service Escalation | |
| | contact details, including CEO/MD, to be enclosed as | |
| 53 | part of the commissioning documentation. | |
| | Life of the equipment as committed during technical | |
| | discussions to be provided with maintenance and | |
| | spare support during the course of the year, | |
| | irrespective of dealer change, as per PO terms and | |
| | conditions, to be given on the OEM letterhead. In | |
| | case the OEM stops service support during the sales- | |
| | committed life, the vendor is expected to compensate with the depreciated cost of equipment or provide | |
| | buyback or upgrade options according to the | |
| 54 | hospital's requirements. | |
| 57 | Any adverse events and recalls related to the | |
| | equipment, if reported, need to be intimated to IISC in | |
| | a timely manner to ensure patient & staff safety by the | |
| 55 | vendor. | |
| | Signature: User Dept Head | |
| | Head-Clinical Engineering | |
| | Date and Time | |
| | | |

All these highlighted details should be given in spiral bound document by vendor to IISc

EQUIPMENT WARRANTY WILL START ONLY AFTER FULL COMPLIANCE OF ABOVE FORM

GENERAL TERMS AND CONDITIONS FOR COMPREHENSIVE/LABOUR MAINTENACE CONTRACT(CMC/AMC)

| 00 | | | |
|----|---|--|--|
| 1) | ALL TERMS AND CONDITIONS REMAIN UNCHANGED AS PER SALES PO | | |
| 2) | AMC & CMC VALID FROM TO | | |
| 3) | THIS CONTRACT INCLUDES | | |
| 1 | All equipment and items supplied by the OEM are covered under service contracts and must be replaced /repaired free of cost under CMC. | | |
| 2 | All equipment must be serviced by trained, authorized service engineers. The training certificate of the engineer must be submitted to the IISC Clinical Engineering Team in advance. | | |
| 3 | Preventive maintenance frequency is calculated based on equipment risk classification, usage, operational intensity, manufacturer's recommendations, historical performance, and failure data. | | |
| 4 | The equipment preventive maintenance must be performed according to the predefined checklist provided in the service manual. | | |
| 5 | Operating system and anti-virus updates are an integral part of preventive maintenance. | | |
| 6 | The vendor will not allow their service engineer to train junior staff on our equipment. | | |
| 7 | Vendor to attend unlimited breakdown calls. | | |
| 8 | Call response time of two hours to be maintained; response time to attend calls within 4 hours is applicable, including holidays and non-working hours. | | |
| 9 | Breakdown frequency should not exceed twice the frequency of preventive maintenance. | | |
| 10 | Vendor must submit soft copies of all reports in two copies. | | |
| 11 | Vendor must maintain a service logbook at the user department. | | |
| 12 | Yearly downtime and breakdown frequency will be calculated based on the call logbook. | | |
| 13 | Any damage to hospital property during maintenance by the company engineer should be compensated to the hospital. | | |
| 14 | Vendor must ensure two preventive maintenance visits per year before the due date. Any malfunction or harm to the patient due to delayed preventive maintenance or calibration will be the sole responsibility of the vendor, including legal compensation. Preventive maintenance and calibration must be mandatory after repair or replacement of any spare parts, and necessary kits are to be provided FOC. | | |
| 15 | A copy of the preventive maintenance report with a checklist and a soft copy of calibration, if applicable, is to be shared within one day of execution. The preventive maintenance and calibration label, with done and due dates, must be affixed to the machine without fail, along with the clinical engineer. | | |
| 16 | Periodic training to clinical engineers and end-users, as and when applicable, is mandatory. Training documents must be provided for all concerned staff prior to the renewal of the contract. It is the vendor's responsibility to ensure training, including application training for all staff, without fail. Relevant training materials like PPT/Video must be submitted to the clinical engineering team prior to any training. | | |

| 17 | Vendor should provide the cleaning and disinfection protocol for the equipment, carry out necessary training periodically, and ensure that all concerned members are trained on the same. | | |
|----|--|--|--|
| 18 | Any recall related to the above equipment must be notified in writing, and required corrective actions must be carried out FOC. Necessary training must be provided to concerned staff. | | |
| 19 | Any adverse event reported must be intimated to the Materiovigilance department, and corrective action must be shared within one working day with the hospital. | | |
| 20 | Complete breakdown details, including downtime and preventive maintenance/calibration history, must be shared before the renewal of the next contract. Any downtime of more than 48 hours must include root cause analysis and corrective & preventive action with due diligence. Service reports must be legible and include call received, call attended, and call closed (including date & time) accurately. Any report missing this information will be deemed incomplete. | | |
| 21 | Unlimited spare support must be provided, except for consumables (filters). All accessories and parts are covered and included in the contract. Spares must be ordered and moved immediately after diagnosis, including during holidays and non-working hours. | | |
| 22 | Uptime must be maintained at 97%, including holidays and non-working hours. | | |
| 23 | Uptime is defined by the machine working for its intended purpose without compromising patient care or revenue. Any deviation will count as downtime, and for any additional downtime, the contract will be extended by 1:5 days. | | |
| 24 | A maximum of two breakdowns per preventive maintenance frequency is permitted. Any deviation will increase the preventive maintenance frequency in the subsequent year with no cost escalation. | | |
| 25 | Standby equipment must be provided within a day if the issue cannot be resolved for movable equipment like pressure injector. | | |
| 26 | The vendor escalation matrix, including sales and service contact details (mobile numbers & email IDs), must be provided without fail. | | |
| 27 | First-level service training must be provided for the concerned equipment, and the training report must be provided to the clinical engineering team members. | | |
| 28 | Preventive maintenance must not be executed during peak working hours and must be carried out as per the user's convenience. The preventive maintenance kit is included in the CMC and must be replaced during preventive maintenance. | | |
| 29 | The AMC bill will only be cleared after the submission of the equipment log report, which must include details of downtime and preventive maintenance (PM) or calibration history. This report must be provided prior to the renewal of the contract. | | |
| 30 | For equipment under AMC, the quotation for spare parts must be provided within one day of the service engineer's recommendation in the service report. | | |
| 31 | For equipment under AMC, no cannibalization of spare parts from working equipment by the service engineer is allowed. | | |
| 32 | Any spare part ordered for equipment under CMC must reach the hospital site within 120 hours. | | |
| 33 | If the equipment remains non-functional after spare part installation, the concerned service engineer must be replaced from the IISC site. | | |
| 34 | All defective spare parts under labour AMC will be retained by the hospital. For equipment under Comprehensive AMC, IISC will mark the spare part as defective, and a non-returnable gate pass will be issued. | | |

| TECHNI | CAL SPECIFICATION FOR SINGLE PLANE CARDIAC CATH LAB | |
|--------|---|--|
| Lound | | |
| Sr.No | State-of-the-art, ceiling-mounted single-plane cardiovascular angiography system with flat-panel detector technology for high-quality digital imaging. The system must be suitable for both diagnostic and interventional cardiovascular procedures, as well as advanced structural heart interventions. It should be equipped with the latest guidance tools and a hemodynamic recording system for precise patient monitoring. Additionally, the system must support real-time Digital Subtraction Angiography (DSA) acquisition and offer 3D rotational angiography capabilities. The system should have the following essential specifications. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) | |
| А | Multi-Directional C-Arm/G-Arm Positioner – Single Plane | |
| 1 | The monoplane C-arm/G-arm should be of the latest design, ensuring clear, free floor space. The gantry should be ceiling mounted. | |
| 2 | The C-arm should be able to park at the head side, away from the working side. The gantry should move +/- 90 degrees around the table at the head side. | |
| 3 | The C-arm should be able to perform head-to-toe imaging without repositioning the patient. | |
| 4 | Both C-arm/G-arm movement controls should be possible from either side of the table. The control panel should be modular and usable on both sides of the table. | |
| 5 | The gantry should have fast speed for angulation and positioning. The C-arm/G-arm should have a speed of at least 25 degrees/sec for LAO and RAO and 18 degrees/sec for Cranial and Caudal. | |
| 6 | The C-arm/G-arm should have angulation: RAO/LAO = At least 120/120 degrees and Cranial/Caudal should be 45/45 degrees or more. | |
| 7 | Patient collision prevention and protection are necessary. Non-contact patient sensing or any other advanced technique/design offering added advantage towards patient safety should be provided. | |
| 8 | The arm design should allow sufficient space around the table during resuscitation and defibrillation. | |
| В | Patient Table | |
| 1 | The table shall be floor-mounted, with a carbon-fiber tabletop and pivot capability of 120 degrees. | |
| 2 | Maximum patient weight = 250 kg or higher, with additional weight capacity for at least 50 kg during resuscitation. | |
| 3 | The table length should be sufficient to accommodate long catheters and hardware. | |
| 4 | The table should have a head-side tilt facility as standard. | |
| 5 | Table should have swivel as standard. | |
| 6 | Table should have Craddle as standard. | |
| С | X-Ray Generator | |

| 1 | The generator should be of the latest technology, high-frequency type, with at least 100 kW output at maximum factors. | | |
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| 2 | The generator should have overloading protection. | | |
| D | X-Ray Tubes | | |
| 1 | The powerful X-ray tube should have a minimum of two focal spots (small & large). | | |
| 2 | Anode heat storage capacity = At least 5.0 MHU. | | |
| 3 | Maximum heat dissipation = At least 20000 W or more, with a maximum anode cooling rate of 1700 KHU/min or more. | | |
| 4 | Cooling system = High oil/water cooling rate to ensure continuous operation. | | |
| 5 | A secondary grid-switch should be available in the tube to reduce scatter radiation. | | |
| 6 | Automatic spectral filtration/pre-program mechanism for eliminating soft radiations should be provided. | | |
| 7 | The X-ray tube should operate with minimal noise and have a high anode heat storage capacity to support long interventional procedures without interruption. | | |
| 8 | It should be possible to position the table without fluoroscopy, using graphics on the last image hold. | | |
| Е | Dynamic Flat Detector System | | |
| 1 | Detector: | | |
| a) | Detector size: 12 inches or more diagonally. | | |
| b) | 16-bit or more digitization should be available. | | |
| 2 | Refresh light for artifact-free imaging should be available. | | |
| 3 | Pixel size of the flat detector should be 160 microns or less. Smaller sizes are preferred for the visualization of the smallest details. | | |
| 4 | The system should have acquisition and display in at least 1024x1024 resolution, and any additional feature/design/technology towards image quality improvement and dose reduction will be preferred. | | |
| 5 | Advanced low radiation safety features and top-of-the-line packages for the safety of patients and operators should be offered as standard features. | | |
| F | Digital Imaging System | | |
| 1 | The digital cardiac imaging system should support acquisition, storage, and retrieval in a high matrix of 1024x1024 or more for excellent resolution. | | |
| 2 | Gray scale depth of at least 12-bit pixel should be possible at all frame speeds. | | |
| 3 | Image storage capacity of 100,000 images at 1024x1024 on the main system hard disk. | | |
| 4 | Examination Room: The system should be supplied with a single display of at least 55 inches medical-grade monitor to display images/waveforms. The contrast resolution should be 4000:1. Monitors should have a high refresh rate for flicker-free viewing of images. | | |
| 5 | Console Room: The system should be offered with two monitors of 2MP resolution each to review live and review/Reference images. Also, it should be possible to perform the post-processing, and quantifications of coronary and ventricular functions on the review monitor. | | |
| 6 | Vendor should also provide two backup medical-grade monitors of 19 inches each in the examination room. | | |

| 7 | The system should have the facility to review live and previously recorded images of the patient without stopping the live fluoroscopy or interrupting the main operator in the exam room. | |
|----|---|--|
| 8 | At least one DICOM 2MP workstation (19 inches or more) should be provided in the console room, capable of all review, post-processing. It should be possible to perform simultaneous offline post-processing in the control room even while online acquisition is being performed. | |
| 9 | The Cath Lab should be supplied with state-of-the-art, complete coronary and ventricular online/offline quantification software programs, which are clinically validated. Auto calibration should be possible. | |
| 10 | The system should allow recall of stored images in fast-slow-still modes to select images at the tableside itself. | |
| 11 | Cine loops replay facility and preferably last image hold facility during fluoroscopy. | |
| 12 | Integrated intercom facility between control room and examination room. An additional control module must be offered in the console room for all geometrical positions of the gantry. A wireless foot paddle in the examination room for fluoroscopy. | |
| 13 | The system should have an online DSA facility with all road mapping features. | |
| 14 | Facilities for better stent visualization features with instantaneous processing, eliminating the need to wait for new images before stent repositioning. Stent visualization features must provide real-time images clearly showing the balloon position in relation to the deployed stent, allowing the interventional cardiologist to properly position the balloon to the proximal diagonal branch prior to dilation. | |
| G | Digital Archival System | |
| 1 | One additional fully loaded PC-based CD review station with DVD combo devices of the latest specifications. It must have a DVD writing facility. | |
| 2 | Ability to view CD and post-process with clinically validated quantification software. | |
| 3 | Ability to export DICOM vascular images to a CD or other image recording medium. | |
| 4 | Direct digital archival on compact disk (CD-recordable) in the latest DICOM. The main system should have the facility to record the CD/DVD. | |
| 5 | The system should be fully DICOM (DICOM-3) ready and fully compliant for connection to a PACS system of any make. | |
| Н | Additional Requirements | |
| a) | Facilities for importing CT & MRI fusion package data on live fluoroscopy for structural heart interventions should be available. | |
| b) | Facility for pre-acquired CT data on live fluoroscopy for structural heart interventions should be offered as standard, i.e., TAVI/TAVR. The C-arm should be automatically aligned with the roadmap image. It must provide automatic distance, diameter, area, and perimeter measurements for TAVI. It must provide calcium segmentation and visualization. | |

| c) | The system must provide transseptal puncture guidance based on heart models and provide live echo/fluoro fusion imaging with 3D TEE. | | |
|-----|--|--|--|
| d) | The system must have the facility to create a dynamic, motion-compensated, real-time view of the coronary arteries. The system overlays a highlighted coronary angiogram on a 2D fluoroscopic image, creating a coloured map that adjusts automatically, providing continuous and specific visual feedback. | | |
| e) | The system must be offered with 60 frames/second for paediatric cases. | | |
| f) | The system should be capable of imaging of the coronary tree anatomical view in a single run. The system should be capable of performing automatic dual-axis rotational coronary angiography to gather more information with less X-ray and contrast medium dose. | | |
| | Essential Accessories | | |
| 1 | A high-end, latest technology hemodynamic recorder with at least 1 TB storage, >1 GB RAM is to be provided by the vendor. It should have the following features: | | |
| 1a) | Multichannel (>12 channels), modular recorder with software for recording, calculating (valve area, etc.), and archiving in the hard disk. | | |
| 1b) | Should have a laser printer for printing high-quality traces. | | |
| 1c) | Should have high-resolution, medical grade, >18" monitors (1 in the console room, display of hemodynamic on a large screen in the exam room), separate for recording and printing. | | |
| 1d) | Should be able to display ECG, pressure waveforms, respiration, non-invasive oxygen saturation, skin temperature, end-tidal CO2, etc. | | |
| 1e) | Should be provided with an original table, housing cabinet. | | |
| 1f) | Two sets of accessories such as radiolucent ECG cables, transducers, transducer cables, saturation probes, and cables (for neonates, infants, children, and adults; both reusable and disposable) should be provided with the machine, and all accessories must be quoted separately for future supply orders. | | |
| 2 | Lead glass (200x100 cm). | | |
| 3 | Radiation shield - ceiling and table-mounted/suspended. | | |
| 4 | High power contrast injector of the latest technology: (Qty-1). 10 syringes to be supplied along with the injector. | | |
| 5 | Suitable online UPS of at least 120 KVA capacity, with 30 minutes battery backup for the complete cathlab including cine and fluoroscopy. Emergency lighting in the exam room should also be on UPS. | | |
| 6 | 10 units of Protective Zero Lead Apron which are lightweight, along with wall hangers (2 Units). Thyroid guard lead-free - 10 units, headgear - 10 units, radiation protection glasses - 10 units. | | |
| 7 | Dehumidifier (Qty-1). | | |
| 8 | One Laser Network Printer of high resolution (at least 1200 dots per inch) with a minimum of 128 MB memory and 1200 dpi for high-quality image printing. | | |
| 9 | Operating system & antivirus: The system should be offered with a license validity until the lifecycle of 10 years for the unit, operator console, and workstation. | | |

| 10 | Console table to be provided by the supplier (Qty-2). | | |
|----|--|--|--|
| 11 | Radial Arm Rest (Qty-1), Head Side Arm Holders/Grab Bars (Qty-1), Detachable Radiolucent Carbon Fiber Arm Support (Qty-4), Catheterization Arm Support for Radial Angiography (Qty-1), Head Support (Qty-1), IV set with drip stand (Qty-1). | | |
| J | Facility management and 97% uptime guarantee: The vendor should provide all post- warranty maintenance and spares, including the tube and all accessories. | | |
| К | Fully Automated Daily Quality Control and Calibration: Fully automated daily quality control and calibration should be available | | |
| L | The system should be compliant with IEC, ISO, CDSCO or similar quality standards for medical devices. | | |
| М | The system should be offered with license validity till the lifecycle of 10 years for Unit, Operator Console, and Workstation. | | |
| N | Operating System & Antivirus: The system should be offered with license validity till the lifecycle of 10 years for Unit, Operator Console, and Workstation. | | |
| 0 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards | | |
| Ρ | Material Supplied from or having a country of origin from a country which shares a land border with India are not accepted. | | |
| Q | Should have import / manufacturing license from central licensing Authority or state licensing authority of CDSCO for medical devices and a copy of valid license should be submitted for the quoted model. | | |
| R | The system should be AERB type approved, and the copy of E-LORA listing should be submitted along with the bid. if the quoted model has not been yet installed In India, vender should submit NOC from AERB. | | |
| S | Regular QA according to AREB norms will be the responsibility of the bidder during warranty and CMC period. | | |
| Т | Medical equipment must comply with Indian standards and operate at 230V+/-10% single phase or 415V +/-10% three phase,50 Hz +/-1% | | |
| U | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards | | |
| V | Further to this, the system should include all the necessary accessories and consumables supplied as standard | | |
| W | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. | | |
| Х | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. | | |
| Y | The portal for integration with the building management system should be provided at no additional cost. | | |

TECHNICAL SPECIFICATION FOR BI PLANE CATHLAB

| SN | The system must be the latest generation, with the latest market introduction. It should be a state-of-the-art biplane floor and ceiling-mounted C-arm/G-arm DSA system with flat detector technology, digital imaging system for adult and paediatric diagnostic and interventional radiology procedures, including vascular angiography applications and online DSA. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) | | |
|-----|---|---|--|
| 1 | System Gantry | The system should have two 'C/G' arm gantries: one floor- mounted and one ceiling-suspended, providing full body coverage. Both gantry movements should be rapid, motorized, and collision-proof. Manual override by the operator should be possible. | |
| 1.2 | Pre- Programmed Positions | It should be possible to pre-program the gantry positions, angulations, and rotations for at least 50 user-defined examination positions. | |
| 1.3 | Gantry Control | All movements of the gantries should be controlled from the joystick at the table-side as well as in the console room. | |
| 1.4 | Speed of Gantry Movements | Both gantries should have fast speed for angulations and positioning. The frontal system should have a speed of at least 10 degrees/second for all positions lateral system should have a speed of at least 8 degrees/second for all positions. The lateral arm must be offered with a fast parking speed of 15 cm/sec. User notification feature must be available in the system to notify that 3D acquisition can be started without collision. | |
| 1.5 | User-Selectable Angulations | Gantry angulations and rotations in both planes (frontal and lateral) should be freely user-selectable to satisfy clinical imaging needs. | |
| 1.6 | Automatic Positioning | Both gantries should have an automatic positioning capability, as projected from a relevant reference image. The Image Beam Rotation for oriented images in every angulation. | |
| 1.7 | Single Plane Coverage | Head-to-toe coverage with a single plane without repositioning the patient. The frontal arm must have extended range to 135 degrees on the nurse's side to allow access to the patient's head whether to place a head holder, perform anaesthesia, or stabilize the patient. | |
| 1.8 | Oblique Angulations | The gantry and detector placement for oblique angulations should be possible without any compromise. Systems with uniform and better oblique angulations along the side of the detector will be preferred. | |
| 1.9 | Double C-Arc | The system must be offered with a lateral double C-arc to ensure angulation always perpendicular to the X-ray beam, enabling true free projections. | |

| 2 | Table | |
|-----|---------------------------|---|
| 2.1 | Table Design | Floor-mounted long table with carbon fiber tabletop, easy patient transportation capability, and must have a head-side tilt facility. |
| 2.2 | Swivel Functionality | For easy patient transfer, the table should have a swivel of at least +/- 90 degrees as standard. |
| 2.3 | Motorized Movements | Motorized up-down movements and floating longitudinal and transverse movement with a locking facility. CPR should be possible at any position. |
| 2.4 | Cradle | Table should have cradle function as standard |
| 3 | X-Ray Generator | |
| 3.1 | Generator Power | The system should have generator Power of 100 KW or more, compatible with high-resolution imaging. |
| 4 | X-Ray Tube | |
| 4.1 | Tube Specifications | X-Ray tube should have a fine focal spot (small & large) with a high cooling rate to ensure continuous operation, capable of pulsed fluoroscopy on both focal spots. The pulsed fluoroscopy should be offered with a pulse rate of 7.5 frames/second to 30 frames/second. |
| 4.2 | Anode Heat Capacity | The X-Ray tube should have an anode heat storage capacity of at least 5.0 MHU or more to run continuously for 6-8 hours without shutting off, with an appropriate anode heat dissipation rate of 20,000 W or more. The maximum anode cooling rate should be 1750 KHU/min or more. |
| 4.3 | Grid Switching | X-ray tube must have secondary grid switching at the tube side to reduce scattered radiation. |
| 5 | Radiation Protection | |
| 5.1 | X-Ray Beam Filtering | The system should have integrated computer-controlled (preferably automatic) X-Ray beam filtering with copper filters of various sizes from 0.2 mm to 0.9 mm/1mm in fluoro and acquisition mode. Please list the special filters available. |
| 5.2 | Collimator Positioning | The system should allow positioning of collimator blades without radiation. |
| 5.3 | X-Ray Dose Monitoring | The system should have monitoring and display of X-ray dose during the patient examination. It should be possible to create a DICOM-based dose report of the patient. |
| 6 | Digital Imaging System | |
| 6.1 | Flat Panel Detectors | The system should have flat panel detectors with a diagonal size of at least 46 cm for the frontal plane and 39 cm for the lateral plane. Both detectors must be offered with 16-bit digitization. |
| 6.2 | Image Processing | Digital system with acquisition and processing in a 1024x1024 matrix up to 25/30 fps with the latest image processing software and hardware. |
| 6.3 | Cine Loop Replay | Cine loop replay facility and last image hold facility during fluoroscopy should be available. |
| 6.4 | Image Storage Capacity | Image storage capacity of at least 50,000 images in a 1024x1024 matrix at 10/12 bits on the main system disk. |

| 8.1 | Image Transfer | Image transfer from the digital system in background mode without affecting the system operation. |
|------|----------------------------------|--|
| 8 | DICOM Interface | Image transfer from the digital system in background reads |
| | System | control room and examination room should be available. |
| 7.6 | Communication | Integrated two-way communication system between the |
| 7.5 | Additional Workstation | One additional workstation to be provided in the cath lab with 1 high-resolution 18/19-inch medical-grade monitor for parallel viewing of images. The system must have the facility for recording images on DVD/CD-R with DICOM Viewer in DICOM 3 format, with the capability to receive and transfer images from the cath lab. |
| 7.4 | Post-Processing Monitor | High-resolution 18/19 inch medical-grade monitor for post- processing and reporting in the control room with the main console - 1 Nos. |
| 7.3 | Control Room Monitors | The control room shall have at least 2 wide-screen medical- grade 24 inch monitors for the display of live, playback, and reference images of each plane. |
| 7.2 | Standby Monitor | A standby high-resolution medical-grade TFT/LCD monitor of at least 24 inches along with a large display is to be offered - 2 Nos. |
| 7.1 | Monitor Display | The medical-grade monitor display should be offered with a single TFT/LCD monitor of 55" or more, with a minimum 8-megapixel resolution. Facility for simultaneous display of at least 8 image source inputs (analog/digital) should be available to display reference images, patient hemodynamic monitoring, 3D acquisitions imaging, and images from other sources like CT/MR. The monitor display system should be ceiling-suspended and should allow flexibility in having different image layouts in desired/different format sizes. |
| 7 | Monitors / Display | |
| 6.11 | Real-Time Image Processing | Real-time image processing software and overlay of road map on fluoroscopy images for vascular interventions should be available. |
| 6.10 | Collision Protection | The system should have a patient collision protection facility with software and hardware. |
| 6.9 | Fluoro Loop Storage | The system should have the facility for storage of the fluoro loop scene of at least 10 seconds. |
| 6.8 | Rotational Angiography | The system should have the facility for rotational angiography. |
| 6.7 | Online DSA Capabilities | The system should have online DSA capabilities in a 1024x1024 matrix with an acquisition frame rate of 1 frame/second to 6 frames/second or more with 2D road mapping capabilities. The system must be offered with bolus chase reconstruction. |
| 6.6 | Table-Side Control | The full system should have table-side control operation with complete acquisition and post-processing capabilities. |
| 6.5 | Vascular Analysis Program | software should have an auto-calibration facility for stenosis measurement with geometrical and densitometry calculations. The analysis should be possible from the table side in the examination room and from the control room. |
| | | The system should have a vascular analysis program. The |

| 8.2 | USB Interface | USB interface to copy images to memory disk / external hard disk. |
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| 8.3 | DICOM Protocols | The system should have complete DICOM send, DICOM storage commitment, DICOM query retrieve, DICOM worklist, DICOM MPPS, DICOM print, and other DICOM protocols and interfaces for PACS, HIS/RIS. |
| 9 | 3D Acquisition and Cross- Sectional Imaging | |
| 9.1 | 3D Acquisition | The 3D Acquisition should offer: |
| 9.1. a | 3D Reconstruction | 3D Reconstruction and visualization in real time of a volume using volume rendering technique. It must be possible to Control 3D acquisitions using a touch screen in the ER room with the help of Touch Screen module. System must be offered with the Iso-Centring tool to isocentre the head precisely for optimal image quality. |
| 9.1. b | MPR & MIP | Multiplanar reconstruction (MPR) & Maximum intensity projection (MIP). |
| 9.1.c | 3D Road Mapping | 3D Road Mapping with overlay facility of 3D Roadmap over live fluoroscopy. |
| 9.1. d | Dynamic 3D Road Mapping | Dynamic 3D Road Mapping with automatic updating of 3D Roadmap with changes in C-arm position, zoom, and source-to-image distance. |
| 9.2 | Cross-Sectional Imaging | The cross-sectional CT-like imaging based on rotational Angiography must be offered for visualization of bleeding, and the ventricular system of the brain. It must be offered with Metal Artifact Reduction and Patient motion artefact correction. |
| 9.2. a | Image Merging | Capability to merge/fade live images with 3D segmentation should be available on the 3D workstation in the control room and parallel display in the exam room. Cross-sectional & 3D images should have processing capabilities in the examination room. |
| 9.2. b | Fusion of 3D Data | Fusion of 3D CT data with 3D Angio to combine high- resolution vessel images, with display capability in the examination room. |
| 10 | Advanced Applications | |
| 10.a | Blood Flow Visualization | The system should have capability to visualize blood flow patterns in the parent vessel and aneurysm sac, quantify blood flow rates, and calculate the change in Mean Aneurysm Flow Amplitude (MAFA value) before and after the procedure. |
| 10.b | Real-Time Image Guided Needle Intervention | The system must be offered with real-time image-guided needle intervention application. |
| 10.c | Liver Nodule Identification | Identification/Segmentation of liver nodules in 3D, automatic analysis of lesion vasculature, suggested feeder vessels based on catheter tip position, and live image guidance to |

| | | reach verified feeders for selective or super-selective embolization. |
|---------|---|--|
| 10.d | Paediatric Cardiac Cases | The system must be offered with 60 Frames/sec for paediatric cardiac cases. |
| 10.e | Coronary Quantification Software | The cathlab should be supplied with state-of-the-art, complete coronary and ventricular online/offline quantification software programs, which are clinically validated. Auto-calibration should be possible. |
| 10.f | Stent Enhancement Software | System must be offered with stent enhancement software. |
| 11 | Hemodynamic Recorder | A high-end, latest technology hemodynamic recorder with at least 1 TB storage, >1 GB RAM is to be provided by the vendor. It should have the following features |
| 11.1 | | Multichannel (>12 channels), modular recorder with software for recording, calculating (valve area, etc.), and archiving in the hard disk. |
| 11.1. a | Multipara Monitor Features | The following features should be available in the multipara monitor: |
| 11.1. b | ECG Display | Display of 10-lead ECG on screen with 5-lead ECG connectivity. |
| 11.1.c | NIBP Module | NIBP module with necessary cables and consumables. |
| 11.1. d | SpO2 Module | SpO2 module with necessary cables and consumables. |
| 11.1. e | Pressure Inputs | At least 2 pressure inputs with floating inputs. |
| 11.1. f | Time Measurement | Time measurement capability. |
| 11.1. g | Laser Network Printer | One Laser Network Printer of high resolution (at least 1200 dots per inch) with minimum 128MB memory and 1200 dpi for high-quality image printing on A4 paper – 5 reams of glossy printing papers to be supplied. |
| 11.2 | Patient Connection Box | The patient connection box should be easy to install at the patient table in the examination room. |
| 11.3 | Colour Waveform Monitor | 18/19" colour waveform monitors with programmable layout and digital monitoring readout – 1 Nos. |
| 11.4 | Interface and Viewing Facility | Necessary interface and viewing facility with a minimum 55" display monitor in the examination room and console room. |
| 11.5 | ECG Cables and Pressure Transducers | ECG cables and reusable pressure transducers - 10 each. |
| 12 | UPS | |
| 12.1 | UPS Capacity | Suitable online UPS of at least 120 KVA capacity, with 30 minutes battery backup for the complete cath lab including cine and fluoroscopy. Emergency lighting in the exam room should also be on UPS. |
| 13 | Accessories | |
| 13.1 | Foot Switch | Foot switch for fluoroscopy and acquisition. |

| 13.2 | Ceiling | Ceiling suspended operation lamp. |
|-------|---|---|
| - | Suspended | |
| | Operation Lamp | |
| 13.3 | Lead Glass | Lead glass (200 x 100 cm) as per international radiation protection standard. |
| 13.4 | Radiation Shield | Radiation shield ceiling and table-mounted/suspended as per |
| | | international radiation protection standard. |
| 13.5 | Contrast Injector | High power contrast injector (floor/ceiling mounted) with 20 syringes. |
| 13.6 | Radiation Protective Aprons | Lead-free, lightweight radiation protective aprons of high quality – Total quantity 10. |
| 13.7 | Apron Hanger Stands | Two hanger stands to hold 5 aprons each. |
| 13.8 | Thyroid Shields | Thyroid shields – Qty 10. |
| 13.9 | Lead Spectacles | Lead spectacles – Qty 10 and headgear – Qty 10. |
| 13.10 | Console Tables | Console tables – Qty 2. |
| 13.11 | Intercom | Intercom between examination room and control room. |
| 13.12 | Laser Network Printer | One Laser Network Printer of high resolution (at least 1200 dots per inch) with minimum 128MB memory and 1200 dpi for high-quality image printing. |
| 13.13 | Door Bulb Alarm Interface | System must be provided with a door bulb alarm interface with radiation signage. |
| 13.14 | Dehumidifier | Dehumidifier – Qty 1. |
| 13.15 | Radiolucent Accessories | Detachable Radiolucent Carbon Fiber Arm Support – Qty 4, Radial Arm Support – Qty 1, Head Side Arm Holders/Grab Bars – Qty 1, Mattress – Qty 1, Footswitch – Qty 1, Accessory Clamp – Qty 1, Drip Stand – Qty 1, Catheterization Arm Support for Radial Angiography – Qty 1, Foot Support/Step – Qty 1, Head End Holder – Qty 1, Handle with Support – Qty 1, Articulating Arm Support – Qty 1, IV Set Holder – Qty 1, Temperature Humidity Monitor – Qty 1. |
| 14 | Facility management and 97% uptime guarantee. | The vendor should provide all post-warranty maintenance and spares, including the tube and all accessories. |
| 15 | Fully Automated Daily Quality Control and Calibration: | Fully automated daily quality control and calibration should be available |
| 16 | Compliance with Standards: | The system should be compliant with IEC, ISO, CDSCO or similar quality standards for medical devices. |
| 17 | License Validity: | The system should be offered with license validity till the lifecycle of 10 years for Unit, Operator Console, and Workstation. |
| 18 | Operating System & Antivirus | The system should be offered with license validity till the lifecycle of 10 years for Unit, Operator Console, and Workstation. |
| 19 | eliminating the nee | d include rapid switching between 2D and 3D imaging, ed to park the lateral plane in an extreme position for 3D ring enhanced workflow efficiency |

| 20 | The system should include Sinusoidal Scanning, which eliminates fossa artifacts caused by the skull base, thereby improving image clarity and diagnostic accuracy. |
|----|---|
| 21 | The system should include 6D fusion capabilities. This feature will enable advanced imaging and treatment planning by allowing the merging of two 3D volumes, with the ability to separately colour-mark vessels for enhanced visualization and clinical precision. |
| 22 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 23 | Material Supplied from or having a country of origin from a country which shares a land border with India are not accepted. |
| 24 | Should have import / manufacturing license from central licensing Authority or state licensing authority of CDSCO for medical devices and a copy of valid license should be submitted for the quoted model. |
| 25 | The system should be AERB type approved, and the copy of E-LORA listing should be submitted along with the bid. if the quoted model has not been yet installed In India, vender should submit NOC from AERB. |
| 26 | Regular QA according to AREB norms will be the responsibility of bidder during warranty and CMC period. |
| 27 | Medical equipment must comply with Indian standards and operate at 230V+/- 10% single phase or 415V +/-10% three phase,50 Hz +/-1% |
| 28 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 29 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 30 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |
| 31 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
| 32 | The portal for integration with the building management system should be provided at no additional cost. |

| Sr.No | TECHNICAL SPECIFICATIONS OF PREMIUM TOP OF THE LINE ECHOCARDIGRAPHY MACHINE |
|-------|--|
| | Department: Cardiology OPD (1) |
| 1 | System should be US FDA/European CE/ISO approved. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) |

| 2 | The system must be a latest-generation, top-of-the-line, technologically advanced digital 4D (Live 3D) echocardiography system for transthoracic and transoesophageal adult, paediatric, and neonatal examinations. |
|----|---|
| 3 | System should have frame rate ≥2800fps |
| 4 | The system must offer digitally processed channels of ≥7 million. |
| 5 | The system must be offered with a minimum of a ≥22-inch OLED or higher high- resolution monitor with infinite position adjustments |
| 6 | The system must have a transducer with broadband technology or equivalent for excellent grayscale image quality on difficult-to-image patients. Please specify the technology used in the transducer |
| 7 | The system should have at least four active imaging probe ports with electronic switching capability from the keyboard, without the need for a probe adapter. |
| 8 | The system should support second-generation 4D (Live 3D) matrix TEE transducers capable of exceptional 4D (Live 3D) Echo and 4D (Live 3D) zoom. |
| 9 | The system should support broadband probes spanning a frequency range of ≥1-22 MHz |
| 10 | Image storage should be available on a built-in hard disk with a capacity of 1TB. The system should offer extensive image management capabilities, including thumbnail review, cine loop editing etc. |
| 11 | The system must be offered with speckle reduction imaging, an image processing technique designed to remove speckles and clutter artifacts. |
| 12 | The system should be capable of scanning at a minimum depth of 40 cm. The scanning depth must be clearly mentioned in the technical quote. |
| 13 | The system should feature multiple line acquisition capable of achieving very high frame rates, at least 2500 frames per second or more. It must allow frame-by-frame review. |
| 14 | The system must be offered with a user-friendly, high-resolution user interface touch panel of at least 12.0 inches, or an intuitive keyboard. User-friendliness will be given preference. |
| 15 | The system should include state-of-the-art transmit real-time compound imaging technology with multiple transmitted lines of sight, where multiple coplanar images from different viewing angles are combined into a single compound image at real-time frame rates for improved visualization. |
| 16 | Live Zoom, Zoom, and Flexible 3D Zoom should be available. |
| 17 | The system should feature a light source and transparent view to enhance visual resolution and simulate the true texture of cardiac tissue. |
| | |

| 18 | The system must include cardiac auto Doppler with artificial intelligence. |
|----|---|
| 19 | Strain measurement should be offered as standard in the system. |
| 20 | System should be offered with tomographic representation for Mitral Valve. |
| 21 | The system should provide multislice imaging from 4D with up to 12 slices. |
| 22 | Mitral valve analysis using AI should be available, designed to take a live 3D volume of the mitral valve and convert it into an easy-to-interpret model through guided steps, offering access to a comprehensive list of MV measurements and calculations. |
| 23 | The system should be offered with 2D-based strain quantification. |
| 24 | The system should automatically fuse live 3D TEE with live imaging when moved inside the cathlab in real time, providing intuitive guidance of the device in 3D space. Markings placed on soft tissue in the echo should automatically appear in the X-ray image. |
| 25 | Following latest Transducers should be supplied with the system |
| A | Live 3D Matrix transducer with 3000 elements, compact size, for adult echocardiography (Range 1-5 MHz ±1 MHz). |
| В | 2D transthoracic echo transducer for paediatric echocardiography (Range 2-9 MHz ±1 MHz). |
| С | 2D transthoracic echo transducer for neonatal echocardiography with a footprint of less than 10 mm (Range 3-12 MHz ±1 MHz). |
| D | Linear transducer for vascular and carotid scans offering 14 cm depth (Range 2-12 MHz ±1 MHz). |
| 26 | ACCESSORIES: Online UPS |
| 27 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 28 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 29 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |
| 30 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
| 31 | The portal for integration with the building management system should be provided at no additional cost. |

| Sr No | TECHNICAL SPECIFICATIONS OF HIGH-END ECHO MACHINE |
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| | Department: Cardiology OPD (2) |
|----|--|
| 1 | The system should have US FDA/European CE/ISO certification. |
| 2 | The system must be a latest-generation, top-of-the-line, technologically advanced Digital 4D (Live 3D) echocardiography system for transthoracic in adults, paediatrics and neonates. and transoesophageal examinations in adult and paediatrics. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) |
| 3 | The system should have a high frame rate of 1900 fps or more. |
| 4 | The system must offer digitally processed channels with \geq 4.7 million images. |
| 5 | The system must be offered with a minimum 21-inch or higher high-resolution monitor with infinite position adjustments. |
| 6 | The system must have an adult cardiology transducer with broadband technology or equivalent for excellent grayscale image quality on difficult-to-image patients. Please mention the technology used in the transducer. |
| 7 | The system should have at least three imaging active probe ports with an electronic switching facility from the keyboard without a probe adapter. |
| 8 | The system should support broadband probes spanning a frequency range of 1-22 MHz. |
| 9 | The system should have an image storage facility on a built-in hard disk with a capacity of 500GB. It should offer extensive image management capabilities, including thumbnail review, cine loop editing, etc. |
| 10 | The system must be offered with speckle reduction imaging, an image processing technique to remove speckles and clutter artifacts. |
| 11 | The system should be capable of scanning to a depth of at least 40 cm. The scanning depth should be clearly mentioned in the technical quote. |
| 12 | The system should have multiple line acquisition capable of achieving very high frame rates, at least 1900 frames per second or more. |
| 13 | The system should have automated/semi-automated 2D tools for LA volume and EF assessment. |
| 14 | The system must allow frame-by-frame review. |
| 15 | The system must be offered with a user-friendly, high-resolution user interface touch panel of at least 12.0 inches, or an intuitive keyboard. User friendliness will be given preference. |
| 16 | The system should have state-of-the-art transmit real-time compound imaging technology with multiple transmitted lines of sight, wherein multiple coplanar images from different viewing angles are obtained and combined into a single compound |

| | image at real-time frame rates for improved visualization. It should demonstrate and show multiple transmitted lines of sight in linear probes. |
|----|---|
| 17 | The system should include cardiac auto Doppler with artificial intelligence. |
| 18 | 2D AI-based measurement should be offered. |
| 19 | Automatic strain measurement for the left ventricle should be available in the workstation. |
| 20 | The following latest transducers should be supplied with the system: |
| | a. 2D single crystal/purewave transducer for adult echo. |
| | b. 2D paediatric phased array transducer for paediatric echo. |
| | c. Linear transducer for vascular applications. |
| 21 | The system should be supplied with an online UPS as an accessory. |
| 22 | The system should be compatible with a paediatric TEE transducer suitable for patients >3.5 kg. |
| 23 | The system should be compatible with a neonatal transthoracic transducer with a footprint <10 mm, suitable for neonatal echo and neurosonography. |
| 24 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 25 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 26 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |
| 27 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
| 28 | The portal for integration with the building management system should be provided at no additional cost. |
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| Sr No | TECHNICAL SPECIFICATIONS OF PREMIUM TOP OF THE LINE ECHOCARDIGRAPHY MACHINE |
|-------|--|
| | Department: Cardiology: Cathlab |
| 1 | The system should have US FDA/European CE/ISO certification. |

| 2 | The system must be the latest generation, top-of-the-line, technologically advanced |
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| | Digital 4D (Live 3D) echocardiography system for transthoracic and transoesophageal adult, pediatric, and neonatal examinations. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) |
| 3 | The system should have a frame rate of ≥2800 fps. |
| 4 | The system must offer digitally processed channels of \geq 7 million. |
| 5 | The system must be offered with a ≥22-inch OLED or higher high-resolution monitor with infinite position adjustments. |
| 6 | The system must have an adult cardiology transducer with broadband technology or equivalent for excellent grayscale image quality on difficult-to-image patients. Please mention the technology used in the transducer. |
| 7 | The system should have at least four imaging active probe ports with an electronic switching facility from the keyboard without a probe adapter. |
| 8 | The system should be capable of supporting a second-generation 4D (Live 3D) matrix TEE transducer capable of exceptional 4D (Live 3D) echo and 4D (Live 3D) zoom. |
| 9 | The system should support broadband probes spanning a frequency range of ≥1-22 MHz. |
| 10 | The system should have an image storage facility on a built-in hard disk with a capacity of 1TB and extensive image management capabilities, including thumbnail review, cine loop editing, etc. |
| 11 | The system must be offered with speckle reduction imaging, an image processing technique to remove speckles and clutter artifacts. |
| 12 | The system should be capable of scanning to a depth of at least 40 cm. The scanning depth should be clearly mentioned in the technical quote. |
| 13 | The system should have multiple line acquisition capable of achieving very high frame rates, at least 2800 frames per second or more. |
| 14 | The system must allow frame-by-frame review. |
| 15 | The system must be offered with a user-friendly, high-resolution user interface touch panel of at least 12 inches or an intuitive keyboard. User friendliness will be given preference. |
| 16 | The system should have upgradability to 4D transthoracic imaging. |
| 17 | The system should have state-of-the-art transmit real-time compound imaging technology with multiple transmitted lines of sight, wherein multiple coplanar images from different viewing angles are obtained and combined into a single compound image at real-time frame rates for improved visualization. It should demonstrate multiple transmitted lines of sight in linear probes. |

| 18 | The system should have the ability to auto-acquire the LAA ostium size quickly in 3D (for technical evaluation only, quote in optional items). |
|----|--|
| 19 | Live zoom, zoom, and flexible 3D zoom should be available. |
| 20 | The system should have a light source and transparent view to increase visual resolution and simulate the true texture of cardiac tissue. |
| 21 | The system should include cardiac auto-Doppler with artificial intelligence. |
| 22 | The system should be offered with software beamforming technology. |
| 23 | Strain measurement should be offered as standard in the system. |
| 24 | The system should be offered with tomographic representation for the mitral valve. |
| 25 | The system should offer multislice imaging from 4D with up to 12 slices. |
| 26 | The system should offer mitral valve analysis using AI, designed to take a live 3D volume of the mitral valve and turn it into an easy-to-interpret model with guided steps, providing access to a comprehensive list of mitral valve measurements and calculations. |
| 27 | The system should be lightweight and easy to move for cathlab environments. |
| 28 | a. Fusion imaging for echo navigation: The system should automatically fuse live 3D TEE and live cath lab/CT in real time for intuitive guidance of the device in 3D space. Markings placed on soft tissue in echo should automatically appear in the X-ray image. b. Synchronization of echo and X-ray images should be possible when the C-arm is repositioned. |
| | c. TEE perspectives of the anatomy should be simultaneously displayed in real-time. |
| 29 | The 3D TEE field of view should be visible on the X-ray image for additional reference. |
| 30 | The following latest transducers should be supplied with the system: |
| | a. Single crystal/purewave 2D transducer for adult echocardiography. |
| | b. 3D/2D TEE matrix transducer for adult TEE applications with customizable buttons. |
| | c. Linear probe for vascular applications. |
| 31 | Accessories: Online UPS. |
| 32 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 33 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 34 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |

| 35 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
|----|---|
| 36 | The portal for integration with the building management system should be provided at no additional cost. |

| Sr No | TECHNICAL SPECIFICATIONS OF HIGH-END ECHO MACHINE |
|-------|---|
| | Department: Cardiothoracic Surgery: Cardiac OT: |
| 1 | The system should be US FDA/European CE/ISO certified. |
| 2 | The system must be the latest generation, top-of-the-line, technologically advanced Digital 4D (Live 3D) echocardiography system for transthoracic and transoesophageal adult, pediatric, and neonatal examinations. The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) |
| 3 | The system should have a high frame rate of ≥1900 fps. |
| 4 | The system must offer digitally processed channels of ≥4.7 million. |
| 5 | The system must be offered with a minimum of a 21-inch or higher high-resolution monitor with infinite position adjustments. |
| 6 | The system must have an adult cardiology transducer with broadband technology or equivalent for excellent grayscale image quality on difficult-to-image patients. Please mention the technology used in the transducer. |
| 7 | The system should have at least three imaging active probe ports with an electronic switching facility from the keyboard without a probe adapter. |
| 8 | The system should be capable of supporting a second-generation 4D (Live 3D) matrix TEE transducer capable of exceptional 4D (Live 3D) echo and 4D (Live 3D) zoom. |
| 9 | The system should support broadband probes spanning a frequency range of 1-22 MHz. |
| 10 | The system should have an image storage facility on a built-in hard disk with a capacity of 500GB and extensive image management capabilities, including thumbnail review, cine loop editing, etc. |

| 11 | The system must be offered with speckle reduction imaging, an image processing technique to remove speckles and clutter artifacts. |
|----|---|
| 12 | The system should be capable of scanning to a depth of at least 40 cm. The scanning depth should be clearly mentioned in the technical quote. |
| 13 | The system should have multiple line acquisition capable of achieving very high frame rates, at least 1900 frames per second or more. |
| 14 | The system must allow frame-by-frame review. |
| 15 | The system must be offered with a user-friendly, high-resolution user interface touch panel of at least 12 inches or an intuitive keyboard. User friendliness will be given preference. |
| 16 | The system should have state-of-the-art transmit real-time compound imaging technology with multiple transmitted lines of sight, wherein multiple coplanar images from different viewing angles are obtained and combined into a single compound image at real-time frame rates for improved visualization. It should demonstrate multiple transmitted lines of sight in linear probes. |
| 17 | The system should have the upgrade capability to auto-acquire the LAA ostium size quickly in 3D when connected to a 3D TEE transducer (optional—please specify if an equivalent is available). |
| 18 | Live zoom, zoom, and flexible 3D zoom should be available. |
| 19 | The system should be offered with software beamforming technology. |
| 20 | 2D Al-based measurement should be offered. |
| 21 | Strain measurement should be offered as standard in the system. |
| 22 | The system should have future capability for tomographic representation of the mitral valve. |
| 23 | The system should offer multislice imaging from 4D with up to 12 slices on a 3D TEE transducer. |
| 24 | The following latest transducers should be supplied with the system: |
| | a. 2D phased array probe for adult echo. |
| | b. 3D/2D TEE matrix transducer for TEE applications. |
| | c. Paediatric TEE transducer for TEE applications, suitable for patients weighing more than 3.5 kg. |
| | d. Neonatal TEE transducer for TEE applications, suitable for patients weighing more than 2.5 kg. |
| | e. Linear transducer for vascular applications. |
| 25 | Accessories: Online UPS and integrated DVD/CD writer (1 Nos.). |

| 26 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
|----|---|
| 27 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 28 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |
| 29 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
| 30 | The portal for integration with the building management system should be provided at no additional cost. |

| Sr No | |
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| | TECHNICAL SPECIFICATIONS OF OFF-CART WORKSTATION |
| | Department: Cardiology: OPD (1): The manufacturer should also confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) be available for up to three echocardiography systems. |
| 1 | Viewing of ultrasound (US) exams should be available for up to five echocardiography systems. |
| 2 | Viewing of prior studies and comparison with current examinations should be available. The system should have comprehensive features for reviewing still and multi-frame images. |
| 3 | It should be offered with query and retrieve DICOM connectivity services that allow the workstation to query/retrieve a PACS to import exams, as well as the ability to save secondary capture images and SR measurements back to a PACS. |
| 4 | Clinical Applications |
| 4.A | 2D Quantification |
| 4.A.i | A simple and fast workflow for robust and reproducible global longitudinal strain measurements should be available at a single click. The user should receive immediate results based on automated proposals for view labels and LV endocardial border definitions based on speckle tracking. |
| 4.A.ii | A strain analysis tool for RV function assessment should be available. |
| 4.A.iii | A strain analysis tool for LA function assessment should be available. |
| 4.A.iv | An application for measurement of strain analysis of the left ventricle (LV) based on short-axis views should be available to assess cardiac function. |

| 4.B | 3D Quantification |
|----------|--|
| 4.B.i | Display and crop manipulation of dynamic three-dimensional rendering and left ventricular (LV) volumes should be available. |
| 4.B.ii | Multiplanar Reconstruction (MPR) views should be available to provide unlimited anatomical planes from the 3D volume. |
| 4.B.iii | Measurement of LV endocardial volumes, stroke volume (SV), and 3D ejection fraction (EF) using semi-automated border detection in 3D space should be available. |
| 4.B.iv | Global and regional LV volumes based on the ACC 17-segment model should be available, displaying global LV volume waveform and providing selective display of 17 regional volume waveforms. |
| 4.B.v | Timing assessment for each of the 17 minimal regional volumes and determination of a synchronicity index for all volume segments or a user-selectable group of volume segments should be available. |
| 4.B.vi | A comprehensive report with a summary of synchronicity indexes should be available, displaying regional timing and radial excursion parametric images in a bull's-eye representation. |
| 4.B.vii | Live 3D, 3D zoom, full volume, and 3D color datasets should be available. Bi-plane LV volume, ejection fraction (EF), and LV mass calculations should be available. |
| 5 | AI-based 3D quantification should be available to automatically detect, segment, and quantify the left ventricle (LV) and left atrium (LA) from a live 3D volume. It should provide automated 2D views and reproducible quantification across users over time. |
| 6.A | Reporting Tool |
| 6.A.i | An Adult Echo Report for a comprehensive structured reporting package should be offered for standardized echocardiography reports. |
| 6.A.ii | Measurements should be automatically transferred from the ultrasound modality. |
| 6.A.iii | - Graphical Wall Motion Scoring should be available. |
| 6.A.iv | - Population from prior studies should be available. |
| 6.A.v | - Measurement mapping for all major brands of ultrasound systems should be available. |
| 6.A.vi | - Automated and configurable norm value range check based on ASE standards should be offered. |
| 6.A.vii | - Automated quality assessment of the measurements based on IAC Echocardiography standards should be offered. |
| 6.A.viii | - An auto summary should be available. |
| 6.A.ix | - A side-by-side dynamic preview of the report content should be available. |
| 6.A.x | - Drag-and-drop of images should be available. |
| | |

| 6.A.xi | - User-specific customization options at various levels should be offered. |
|--------|---|
| 6.B | Paediatric reporting with a Z score should be available. |
| 7 | Other Accessories |
| 7.A | PC & Laser printer for reporting |
| 8 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 9 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 10 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |
| 11 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |

| Sr No | TECHNICAL SPECIFICATIONS OF FOR INTRA VASCULAR ULTRASOUND AND FRACTIONAL FLOW RESERVE WITH IFR & CO-REGISTRATION TOOLS |
|-------|---|
| 1 | The system model should be the state-of-the-art, new generation and latest model manufactured by the company. Old or discontinued models will not be acceptable. The manufacturer should confirm End of Life service for 10 years from the date of installation. (Document proof from the manufacturer should be attached) |
| 2 | The system should include a sterile touch screen control integrated into the patient table. An additional control interface should be available at the console for operational flexibility. |
| 3 | The system should avoid multiple patient data entry steps and facilitate automatic data transfer directly from the catheterization laboratory (Cath Lab). |
| 4 | The system must support data archiving via DVD, Blu-ray, or PACS (Picture Archiving and Communication System) network integration. |
| 5 | The system should be capable of advanced colour mapping to distinguish between lumen, dissection, and stent apposition. This functionality should provide qualitative blood flow information for both coronary and peripheral vasculature. Additionally, the flow information should complement existing methods of estimating blood flow and tissue perfusion, ensuring comprehensive diagnostic and interventional support. |
| 6.1 | The system should be capable of offering evidence-based iFR and FFR modalities for the quick assessment of ischemia. |
| 6.2 | The system should support physiology assessment with both FFR and iFR modalities, as recommended in global guidelines. |

| 7 | The system should support iFR waveform analysis for the measurement of diffused lesion graphs. |
|----|--|
| 8 | The system should include a broad portfolio of coronary and peripheral applications, supported by catheter technology such as rotational or digital/phased array catheters. |
| 9 | The IVUS imaging system should provide high-resolution images with advanced imaging technology operating at a frequency above 20 MHz. |
| 10 | It should have a digital IVUS field of view of 60 mm specifically for venous procedures. |
| 11 | The system should include a permanent patient interface module without the need for add-on sledges as consumables, avoiding additional costs. |
| 12 | The system should be equipped with IVUS catheters featuring a 2.5 mm tip-to-imaging distance, designed to improve vessel assessment by providing enhanced visibility and imaging precision. This design should offer better deliverability, particularly in complex cases such as CTO (Chronic Total Occlusion) and bifurcation procedures |
| 13 | IVUS Co-Registration: The system should support localization of IVUS images with angiographic co-registration, designed to help reduce the risk of geographic miss during interventions. |
| 14 | iFR Co-Registration: The system should enable localization of physiology measurements (iFR) within the angiogram during the decide and confirm stages of a PCI procedure, ensuring accurate assessment. |
| 15 | Physiology and IVUS Tri-Registration: The system should allow direct length measurement on the angiogram, providing both anatomical measurements and physiological calculations. This measurement should assess the treatment impact on the area and display the results, including an iFR estimate, for comprehensive evaluation. |
| 16 | The system should be equipped with remote service capability, integrated with the Hospital Information System (HIS), to enable efficient support and troubleshooting. |
| 17 | System should have real-time QCA, vessel enhancement, device positioning, and device enhancement features, along with imaging and physiology to reduce radiation and contrast. |
| 18 | The system should include a CPU with the latest operating system, a 19" or larger monitor kit, mouse, keyboard, and cable kit. |
| 19 | It should have a CPU with a minimum specification of 2.3GHz, 12 cores total, and a 2400 MHz BUS. |
| 20 | The system should include at least 32 GB of RAM, a 1 TB SSD SATA hard drive, DVD drive, and DICOM Network capabilities (including worklist management and DICOM Store). |
| 21 | It should be compatible with disposable catheters and pressure wires. |
| 22 | The system should have certification from a reputed regulatory body. |
| 23 | If any software is being used for operations of this equipment, then it should be: interfaceable with the hospital EMR/HIS using HL7/ FHIR standards |
| 24 | Further to this, the system should include all the necessary accessories and consumables supplied as standard |
| 25 | The software should also be compliant with the requirements of the National Health stack and should have undergone ABDM sandbox testing if indicated in the NHA guidelines. |

| 26 | For all patient related data which may be generated in the equipment, guidelines given in the DPDP act are to be followed. |
|----|---|
| 27 | The portal for integration with the building management system should be provided at no additional cost. |
| 28 | All the required consumable required to make system completely function to be quoted as standard like IVUS catheter & IFR pressure guide wire |

| Others | Coronary laser atherectomy device to be quoted as an optional |
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Scope of work

| SI | Scope of work Matrix involved for cathlab | Scope of work |
|--------|--|------------------------------------|
| N O | | |
| 1 | a) Drawing as per IEC 60601-2-33 b) Approval of Drawing | (a) service provider (b) Client |
| 2 | Civil works: Floor level: a) Finished floor level at the cathlab examination room to be at perfect level. Permissible Tolerance in mm is to be defined as per pre installation requirement of service provider b) The finished floor level inside cathlab area is to be as defined in the pre installation requirement. | (a) Client (b) Client |
| | c) 9-inch brick wall as per AERB guidelines | C) Client |
| 3 | Transportation route: a) Transportation Dimensions b) Defining The equipment transportation route | (a) service provider (b) Client |
| 4 | a) Dedicated Earth requirements to be provided b) Providing Earth pit | (a) service provider (b) Client |
| 5 | a) Lead shielding glass window between Cath lab and examination room | (a) service provider (b) Client |
| | b) Lead shielded door -as per site requirement | |

| 6 | Power supply: | |
|--------|--|----------------------------------|
| | a) Power supply: 415 V, 3 Phase, 50 Hz, Power supply has to be provided for cathlab unit as per pre installation requirement. | (a) Client |
| | b) Mains Distribution Panel: | (b) Client |
| | To be provided & Installed as per Line diagram in drawing. c) Power Cable: | (c) Client |
| | The mains cable has to be terminated in a mains switch at the | |
| | mains panel in the equipment room. d) Earth Connections: | |
| | As per pre installation requirement. | (d) Client |
| 7 | LIGHTING | |
| | a. Uniform diffused lighting in all rooms 2 no. spotlights with dimmer control may be provided in | (a) Client |
| | the console room | |
| | b. Radiation ON switch connected to cathlab | (b) Client & Service provider |
| | | |
| 8 | Concrete bed: Concrete bed of examination room as per the pre installation | Client |
| | requirement must be provided | |
| 9 | UPS, Power Panel for MR a) Supply of 120 KVA UPS | (a) Client |
| | b) cathlab Power Panel, SLD attached | (b) Client |
| | c) DC power supply panel for lighting if applicable | (c) Client |
| | d) Cables for connecting the UPS and power panel from Mains switch | (d) Client |
| | e) Cables from the cathlab Power panel to cathlab unit | (e) Client |
| 1 | False ceiling: | |
| 0 | False ceiling to be provided by the customer in the Air- | Client |
| | conditioned areas. False ceiling height: 2.7 metres from the finished floor level | |
| | | |
| 1 | False ceiling inside the exam area to house the DC lamps after any railing works as applicable | Client |
| 1 | | |
| | Floor finishing with appropriate materials | |
| 1 2 | Cupboards: | |
| 2 | Cupboards/racks to be provided a) For keeping accessories | (a) Client |
| | b) For keeping the manuals and software discs and special tools | (b) Client |
| | (With locking facility) | |
| 1 | Change room & reception: | Client |
| 3 | Preparation of change room, Reception, cubicles etc. | |
| 1 4 | Painting: Painting, tile work etc. | Client |
| -+ | | <u> </u> |

| 1 5 | A/C Note: -Ducting and termination a) The HVAC ducts that enter or leave the cathlab room must have laminar airflow b) Temperature: as per pre installation requirement of service provider Rel. Humidity: as per pre installation requirement of service provider c)Shopfloor drawing incorporating laminar airflow location | (a)Client (b)Client (c) service provider |
|------------------|--|---|
| 1 6 | Intercom and Communication System | Service provider |
| 1 7 | Cleanliness of site and dust free environment: a) Cleaning up and Site fully ready to receive the equipment at site b) Arrival of Special tools at site for unloading | (a) Client (b) service provider |
| 1 8 | Equipment arrival and unloading: a) Equipment arrival at Site b) Arrangement of Crane for unloading c) Unloading of equipment d)Platform for unloading as per vendor pre installation requirement e) Confirmation of structural strength for unloading platform and rigging route | (a)service provider (b) service provider (c) service provider (d)Client (e)Client |
| 1 9 | Mechanical installation: Installation of cathlab &Certification from AERB approval | Service provider |
| 2 0 2 1 | a) Closing of wall opened for moving in cathlab if applicable b) Providing cable tray inside Functioning of A/C: A/C to be switched ON, DUST FREE ENVIRONMENT, Digital Thermometer with temp and humidity display to be provided | (a) Client (b) Client Client |
| 2 2 | in the examination room and console room a) Flooring (Anti-static) to be provided in the examination room (after the mechanical installation of cathlab and patient table. b) Flooring (Anti-static) to be provided in the Console room. | (a)Client (b) Client |
| 2 3 | Wall sockets: a) Required no. wall sockets of 5A/15 A rating to be provided near the Console of cathlab unit as per service provider b) Wall sockets of 5A/15A rating in Equipment room as per service provider. c)MGPS outlets | (a) Client (b) Client (c) Client |
| 2 | a) Cabling of the cathlab unit | (a) service provider |
| 4 | b) False Ceiling and Interior finishing of exam room | (b) Client |
| 2 5 | Coordination with Modular OT vendor for integration as required and other service providers as required | Service provider |
| 2 6 | Power ON: UPS Engineers also to be available | Service provider |

| 2 | Application Training & Patient trials | Service provider |
|---|---|------------------|
| 7 | | |
| 2 | Handing over of the cathlab Unit after QA | Service provider |
| 8 | | |