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In supersession of all previous Specifications/amendments issued by ESIC Hqrs in respect of Monoplane Cath Lab, please find below **Model Specifications for MII compliant Monoplane Cardiac Cath Lab With Digital Subtraction Angiography:**

This document provides model specification for Monoplane Cath Lab with DSA. Additional terms and conditions for the purpose of tender may be incorporated by respective user units. All Deans/MS's are advised to evaluate the in-house equipment status and modify/ revise the number and requirement of Essential accessories, Additional equipment and component of Turnkey as mentioned in the document while ensuring strict compliance to all statutory Government of India guidelines i.e GFR, GeM, CVC, Make in India guidelines, ESIC Medial Equipment Manual, inter-alia in order to maximize participation, competition and bidding after cost benefit analysis and availability of space, & adequate manpower

TECHNICAL SPECIFICATIONS FOR MONOPLANE CARDIO VASCULAR CATHETERIZATION WITH DIGITAL SUBTRACTION ANGIOGRAPHY LAB :

- Latest state of the art single plane Floor/Ceiling mounted with latest technology cardiovascular angiography and digital imaging system for diagnostic and cardiac & peripheral vascular intervention with latest guidance tools and hemodynamic system.
- The system should have online Digital Subtraction Angiography (DSA) acquisition.
- **The system should be BIS/CDSCO and Make in India compliant.**
- Only the latest machines matching the specifications given below must be quoted.
- Older machines/Models and Re-furbished machines will not be considered.
- Cath Lab System to be quoted by OEM only
- **It is essential that the participating bidder is compliant to the Make in India clause and submits at least one supply order for a recent successfully completed installation at Government Hospital/Medical Colleges for price reasonability along with satisfactory installation/functioning certificate issued by same authority.**

SPECIFICATIONS:

A. MULTI DIRECTIONAL C- ARM/G-ARM POSITIONER

1. Monoplane C arm/G arm should be of latest design.
2. The design should have clear free floor space around the table. It should have Gantry which should be floor/ceiling mounted.
3. The C-Arm should be able to park at the head side away from the working side Gantry position around the table.
4. Monoplane C-arm movement controls should be possible from both sides of the patient (right & left).
5. The C-arm should be able to do head to toe imaging with or without repositioning of the patient.
6. C - arm should have a speed of at least 15 degree/second or more for RAO, LAO and Cranio/Caudal.
7. C arm should automatically be able to go to angulations as described below:
LAO/RAO: at least 100/100 degrees or more
Cranio/Caudal: at least 45 degrees or more
8. C-arm should have good anti-collision prevention and protection.
9. Height of iso-center should be 105cm or more.
10. Gantry depth of C-Arm should be 90 cm or more.
11. Arm design should allow sufficient space around the table during resuscitation and defibrillation.

B. PATIENT TABLE

1. Table shall be floor mounted with carbon fiber tabletop.
2. Table should bear minimum patient weight 150kgs with additional weight for at least 50kgs during resuscitation.
3. Table length should be 270 cm or more, width 45 cm or more.
4. Table should have rotation facility for longitudinal and horizontal movement. The vertical movement of the table should be motorized.
5. Accessories should include:
 - Head fixing aids,
 - Mattress,
 - (04) Radiolucent Carbon fiber arm- supports,
 - Drip stand, and
 - Catheterization arm support

C. X RAY GENERATOR

1. Generator should be latest technology with high frequency type with at least 100kW output.
2. High frequency power unit that provides pulsed fluoroscopy capability.
3. It should have automatic exposure control device for radiographic fluoroscopy and angio mode.

D. X RAY TUBE

1. Powerful and noiseless X-Ray tube should be with a minimum of two focal spots (small & large).
2. Latest technology to prevent radiation leakage and minimize radiation exposure.
3. Anode heat storage capacity of at least 3 MHU or more while ensuring high quality and prevent dysfunction during procedure.
4. Cooling system- oil/water cooling to ensure continuous operation.
5. Anode heat cooling rate should be 3000W/min or more.

E. RADIATION PROTECTION

1. The system should meet all National/International Safety Standards and comply with BARC & AERB guidelines.
2. Should have integrated computer controlled (automatic) X-Ray Beam filtering with copper filters.
3. Display and recording of Radiation dose for each procedure (per fluoroscopy/cine time) should be continuously available.
4. The system should have a facility to remove the anti-scatter grid on the detector for ensuring lower dose in pediatric imaging.
5. Latest dose saving features and Image enhancement features should be provided as standard
6. Lead glass window partition, minimum (200 x 120cm) (as per International radiation protection standard) — can be customized as per requirement.
7. Radiation shield ceiling and table mounted/suspended. (as per International radiation protection standard).
8. OEM should provide the following free of cost:
 - a. Radiation protective apron of high quality with hangers: (Total quantity 20: Front type 10, Wrap around — 6, Two-piece type - 4 and Lead Cap - 4). It should be state of art light weight zero lead with a lead equivalent of 0.5mm of high quality. Lead apron should be zero lead which is high quality.

- b. Thyroid guards 10 in number with lead equivalent of 0.5mm
- c. Two hanger stands to hold 5 apron each and two wall mounted hangers to hold 5 aprons each.
- d. Lead spectacles 5 in numbers.
- e. Lead lined gloves: Two pairs

F. DYNAMIC FLAT DETECTOR SYSTEM

- 1. Flat detector of current generation for cardiovascular application with excellent spatial and contrast resolution 25cms diagonal or more with pixel size equal or smaller than 200 microns.
- 2. Should have acquisition and display in at least 1024 x 1024 pixels. Any other additional feature/design/technology towards image quality improvement and dose reduction will be preferred.
- 3. Flat detector should have more than 14 bit acquisition with at least 3 levels of acquisition and at least 3 levels of zoom.
- 4. The DQE of detector should be 75% or more for best acquisition efficiency and to minimize loss of radiation energy.
- 5. The system should have capability to acquire the images @ minimum 1 to 30 frames per second for fluoro and cine. For DSA frames rate range should be 1 to 10 fps.

G. MONITORS

- 1. System should be supplied with 04 ceiling suspended Medical Grade TFT/LCD high resolution monitors of at least 19 inches each in the Procedure Room for Live, Reference, Hemodynamics, Stent enhancement, OCT and FFR monitoring etc. or at least 55" Medical grade monitor with split screen.
- 2. System should be supplied with 04 Medical Grade TFT/LCD high resolution monitors of 19 inches each in the Console Room for Live, Reference, Hemodynamics, Stent enhancement, OCT and FFR monitoring, post processing and reporting etc. or 32" or more Medical grade Monitor.
- 3. Facility for sharing some of the monitors for display of stent enhancement images, IVUS, FFR and EP between Procedure room, Console room and work station should be possible.
- 4. The monitors should be suspended from ceiling with railings so that they can be easily moved to either side of the table.
- 5. Console room monitors and work station monitors should be medical grade.

H. WORKSTATIONS

1. At least (02) DICOM workstations to be provided: One each in Console Room and Archival room, with provision to review, post processing and quantifications for coronary and ventricular functions. It should be possible to perform offline post processing in console room even while online acquisition is being performed.
2. The Workstations should be equipped with latest generation Medical Grade monitor of 19" or more with storage capacity of at least 2TB Hard disk, 16 GB RAM, intel i7(Latest generation- 10th) and original licensed version compatible operating system along with latest CD/DVD recorder and Color laser printer.
3. Facility for sharing both the Workstations for display of stent enhancement images, IVUS, FFR and EP with Procedure Room & console room should be possible.

I DIGITAL IMAGE SYSTEM

1. Digital cardiac imaging for acquisition storage and retrieval in high matrix of 1024 x 1024 or more acquisition/ display and storage of image application to give excellent resolution with latest image processing software.
2. Gray scale depth of at least 8-bit pixel should be possible at all frame speeds
3. Image storage capacity of 1,00,000 image at 1024 x 1024 matrix at a minimum of at least 8 bits/pixel on main system hard disk.
4. Cath lab should be supplied with state of art complete coronary ventricular and vascular online & off-line quantifications software which are clinically validated with operation from Procedure room and Console room with facility to operate from procedure room and console room. Auto calibration should be possible.
5. On line acquisition & display of DSA images in 1024 x 1024 matrix with DSA post processing from table side control in Procedure room and Console room. All 2D road mapping /remodeling features should be offered.
6. Should have latest facility for live stent enhancement operable from table side and console room with latest stent enhancement feature, and stent visualization in relation to vessel lumen.
7. Two-way intercom facility between Console room and Procedure room.
8. Cine loop replay facility and last image hold/grab facility during fluoroscope (Fluorosave).

J. ARCHIVAL SYSTEM

1. Digital Archival System capable to review, post-processing and quantifications of coronary and ventricular functions in the Console room. It should be possible to perform simultaneous off-line post processing in Console room.
2. Direct digital archival on compact disk (CD /DVD-recordable) in latest DICOM format preferably in loss less compression.
3. Ability to view CD and post process with clinically validated quantification software.
4. Ability to export DICOM vascular images onto CD/CD/another image recording medium.
5. Archival System should have one Review workstation as defined at point H with DVD combo devices of latest specification with printers.
6. The systems should be fully DICOM ready and fully compliant for connection to PACS system with that being offered by the OEM for Cath lab.
7. Ability to convert the DICOM loops to BMP/JPEG and AVI format to CDR.

K. HEMODYNAMICS

1. High end latest technology Hemodynamic recorder with at least 1TB storage and 16GB RAM is to be provided by the vendor.
2. It should have the following features: -
 - A. 12 Lead ECG Amplifier with floating input.
 - B. At least 4 pressures with floating inputs.
 - C. Time and amplitude measurement with electronic calipers.
 - D. SP02, Pressure gradient facility, NIBP measurement should be possible.
3. Storage of patient specific data on hard disk and retrieval as and when required.
4. ECG cable and pressure transducers with facility for superimposition of pressure tracings with printing supports inside the operating room- 10 Nos each to be supplied free of cost, and to be quoted separately.
5. High quality Laser Printer.
6. One dual chamber, two single chamber temporary pulse generator of latest technology - to be provided free of cost
7. One High power contrast injector of latest technology with 200 compatible syringes & tubing -to be provided free of cost.
8. Ceiling suspended operation lamp which should be compatible if procedure done from left side of patient.
9. Foot switch for fluoroscopy and acquisition.✓

- L. Suitable Online UPS with 30 minutes battery backup for complete Cath lab. Air Conditioning inside the Cath Lab and Emergency lighting both should be on the UPS.

M. ESSENTIAL ACCESSORIES required for Cath Lab

* *All Deans/MSs are advised to evaluate the in-house equipment status and modify/revise the number and requirement of accessories as mentioned below and procurement to be done at respective Hospitals/Medical Colleges separately as per DOP while ensuring generic specifications following ESIC Medical Equipment Manual and all Public Procurement and Government of India guidelines i.e GFR, GeM, CVC, Make in India guidelines inter-alia.*

S.No	Item	Qty
1	ACT machine with 500 cartridges	01
2	ABG Machine	01
3	ETO sterilizer, compatible to all cardiac catheters, wires, balloons and other surgical items used in Cath lab	01
4	High Quality Defibrillator with external pacer	02
5	High Quality Syringe infusion pump	10
6	High Quality Fumigation machine	01
7	High Quality Dehumidifier	01
8	IABP (latest high end with 10 different size balloon with 2 cylinder)	01

N. Additional Equipment required for Cath Lab

* *specifications to be defined by respective user unit based on specific requirements and procurement to be done at respect Hospital/Medical Colleges separately as per DOP while ensuring generic specifications following ESIC Medical Equipment Manual and all Public Procurement and Government of India guidelines i.e GFR, GeM, CVC, Make in India guidelines inter-alia*

1. OCT
2. IVUS
3. FFR
4. ROTABLATION

O. WARRANTY & CMC

1. The Model offered should be the latest High-end model under current production. Refurbished Units will not be accepted.
 - The Model offered should meet all the approved specifications.
 - The system should be BIS/CDSCO and Make in India compliant.

2. Warranty: 03 (Three) Years- Warranty for 03 years for the complete Cath Lab in toto including items covered in Turnkey project and all items listed within inter-alia.
 3. The equipment should be software and platform protected in the warranty period.
 4. Comprehensive Maintenance Contract for additional 07 years after the completion of 03 years of warranty for the Cath lab.
 5. Confirmation of availability of required spares, X-ray tube, UPS and other essential consumables for Cath Lab in toto including items covered in Turnkey project for 10 years completion of installation to be provided.
 6. Downtime penalty: The equipment must have 95% uptime. The OEM shall extend the CMC by Two times the number of days that the equipment has been not functional in downtime (beyond 95% uptime).
- Bid/Tender should include a clause that availability of Spares/Reagents/ consumables/accessories etc shall be ensured by the bidder for complete lifespan of the equipment or 10 years (whichever is more).

P. INSTALLATION

1. Installation is to be done on turnkey basis, as per DOP/Budget and prevailing guidelines of ESIC issued by PMD Division ESIC Hqs (W-13/13/ARM/SR/2011-PMD dt 12.10.2021) or as updated from time to time.
The vendor is advised to do an on-site visit of the premises of the respective ESIC Hospital/Medical Colleges prior to submission of bids.
2. The whole Cath lab area as per requirement and adhering to the minimum of AERB/BARC shall need to be renovated with high quality false ceiling, floor and wall tiles up to roof level. High quality adequate modular storage racks and necessary furniture like table chair also need to be provided.
3. Payment will be made as per the actual site modification measurements and work done at site.
4. The quotation of turn key work will be given separately beside the Cath lab quotation.
5. Total cost of the Cath Lab along with CMC quotes shall be evaluated for calculation of L1 for the equipment.

SITE MODIFICATION — MSs/Deans are hereby directed to get all infrastructural additions/modifications/changes required for installation of Cath Lab in coordination with the respective agencies/vendor (as per submitted site plan) for equipment & infrastructural changes (as the case may be) in the existing building of the Hospital for establishing Cath Lab as per DOP. Turnkey to be implemented as per prevailing PMD policy, ESIC Hqs New Delhi.

P(A) SCOPE OF MS/DEAN

1. Power for Air Conditioning and space requirement for installation will be provided by the hospital for coordinated planning and execution of the work.
2. Site preparation should be time bound and completed before shipment of the equipment and time to installation of the machine after arrival should not be more than four weeks (total time 90 days).

P(B) SCOPE OF TURNKEY

Turnkey would include dismantling and disposal of redundant fixtures and execution of all necessary civil, electrical, plumbing and air conditioning work at site.

Site Modification -Cath Lab

1. The scope of work includes complete civil work, electrical, plumbing, furnishing, air conditioning and fire fighting for the construction of complete Cath lab.
2. Scope of work for site modification Cath lab system: the Cath lab site shall consist of the following rooms
 - a) Main Cath lab room/Procedure room
 - b) Console room
 - c) Equipment / panel room
 - d) Changing room with toilet (minimum 03)
 - e) Scrub area and catheter wash area
 - f) Post Cath patient observation room
 - g) Patient waiting area
 - h) Doctor's Room
3. The bidders will have to quote the unit rates of the following components of turnkey work: -
 - a) Civil works
 - b) Electrical Work
 - c) Plumbing and sanitary fittings
 - d) Air conditioning
 - e) Interior furnishing and furniture
 - f) Miscellaneous like Scrub, catheter wash station etc.
4. While preparing the plan the following aspects have to be addressed: -
 - a) Care should be taken to provide easy negotiation of the patient stretchers / trolleys through corridor and doors.
 - b) Radiation shielding for doors, walls, Windows etc.
 - c) Furniture like desk, chairs, shelves etc.

Civil Work

- a) Civil construction work including construction of brick wall if any plastering, flooring as per the approved plan and equipment layout plan.
- b) Partition between the respective areas will be made with high quality products.
- c) Concrete platform/ bed at Cath lab equipment area.
- d) Platform for unloading and shifting the Cath lab should be provided if necessary.
- e) Cable tray, trench and channel -necessary trenches, cable tray and channels at required location will be provided.
- f) All the construction work to be done as per the final plan approved by consignee.
- g) One hand free automatic and sensor-based scrub station and one manual scrub station with disinfectant and soap dispenser.
- h) Central oxygen suction, Nitrous Oxide line integration and connection in Cath lab and patient observation room
- Wall, Flooring, Painting, False Ceiling & Plumbing: To be done as per as per AERB/BARC standards (in case of Cath lab area is yet to constructed however if Cath lab area is already having flooring then only modification cost will be considered)

Electrical Work

- a) The supplier shall be required to specify the total load requirement for the Cath lab Centre including the load of air conditioning, room lighting and for the accessories, if any.
- b) The supply line will be provided by the institute up to one point within the Cath lab Centre the distribution panel shall be provided by the vendor. Few lights in each room shall be connected to the UPS to provide emergency lighting.
- c) The electrical work shall include the following: -
 - I. **Wiring:** All interior electrical wiring with main distribution panel board, necessary MCBs DB joint box switch box etc. The wires shall be of copper of different capacity as per the load and should be renowned make.
 - II. Light switches, power points, and illumination should as per prescribed standards.

Air Conditioning

- a) Ductable package air conditioners and split AC units may be used according to room requirement and suitability. Humidity control should be effective to eliminate moisture condensation on equipment surface. The Air condition should be designed with standby provision to function 24 hours a day.
- b) The outdoor units of AC should be installed by vendor.
- c) Ventilation is required in the toilet with exhaust fitting (if already not present).

ENVIRONMENTAL SPECIFICATIONS

- a) Temperature and Relative humidity ranges to be maintained as per prescribed standards.
- b) Air conditioning load: The heat load calculations and maintaining the desired temperature and humidity in the Cath Lab in toto shall be the responsibility of the bidder.

FURNITURE

All furniture items should be of standard make

S.No	Item	Qty
a	Revolving chairs height adjustable, medium-back with hand rest in the console room	04 Nos
b	Tables for Console and Workstation	As required
c	Modular design wall cabinets (highest quality) for safe keeping and storage of drugs, catheters, interventional items, manuals, procedure sets, linen, trays etc. under lock and key	06 Nos
d	Cupboard with laminate door shutter for storage of spare parts and accessories and records as per requirements	04 Nos
e	Instrument trolleys	02 Nos
f	Patient foot step	01
g	Drug trolley	01
h	Patient trolley with rubber foam mattress to be kept in the patient preparation room	02 Nos
i	Changing room should have change lockers and dressing tables	02 Nos
j	Dustbins with plastic lid	04 Nos
k	One stainless steel stand with 10 hangers to keep the lead aprons to be provided near the scrub area	details in accessories section
l	Steel Lockers	as per requirement