SPECIFICATIONS FOR CARDIOVASCULAR DIGITAL SUBTRACTION ANGIOGRAPHY SYSTEM (CARDIAC CATH LAB)

1. Latest state of the art, single plane floor/ceiling mounted C-arm/G-arm Cardiovascular Angiography system with flat detector technology digital imaging system for diagnostic procedures and interventional cardiovascular procedures - pediatric and adult- structural, coronary and vascular angiography and Digital subtraction angiography.
2. The offer shall be for a single-plane flat-panel digital cardiovascular angiography system and ancillary equipment capable of meeting the essential requirements of a cath lab usable for Cardiology.
3. The platform should be able to accommodate all the up gradations required later (as and when required) to add on more and more special features.
4. The firm should offer the latest high-end model only.
5. All components must be compatible with the main system and with each other.
6. The main Angiography system should be FDA or CE or BIS approved & complies with BARC & AERB guidelines. Copies of certificates should be attached.

Basic points:

1. The original data sheet must support all the specifications quoted by the company. The system must be DICOM3 standard compatible.
2. The system must be configured for higher performance to optimally deal with cardiac interventional procedures. Essential system configuration and capabilities are given below. The bidder should produce an original technical data sheet when required; additional information should be provided as a separate document referring to the specific section in the document.
3. The offer should comprise delivery, installation, official release, and safety acceptance until handover of the system including the accessories necessary for operation. The bidder must be the original manufacturer of the equipment or an authorized dealer with a good track record who has sold, installed, and maintained at least 10 of such equipment during the last ten years in India. All standards software and tools needed for routine and regular use must be part of the system.
4. The technology is changing very fast and new features are added to the system. We accept that by the time of tender floatation, sale, and negotiation for equipment, there may be new features added to the system. So, the bidders should quote the most recently launched system meeting the tender requirement. At the time of negotiation, the latest will be given priority within the constraints of budget allocation. The technical committee will take appropriate decisions regarding the selection of the system.
5. All individual items must be separately priced in the price bid
6. If your system matches fully in most of the important specifications but matches only partly in a few specifications, you may quote your system highlighting these facts and also if your system has alternate features which can compensate for the specification asked.
7. If the specification document refers to technical terms/features which may reflect the product line of a particular manufacturer, the equivalent proved technology/feature can be quoted. If this document does not elaborate on a particular specification, state of art industry standards will be applicable. For all clarifications, refer to state of art industry standards.

Technical Specifications:

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C-Arm /G Arm Multi-directional floor/ceiling mounted, flat panel detector FDA approved

1. C-Arm /**G Arm** Multi-directional should be ceiling-mounted or floor mounted with equivalent maneuverability for unobstructed resuscitation during cardiac arrest, while continuing to do fluro and/or cine at various angulations without any obstruction at the head end. Should be capable of performing coronary angiography and coronary angioplasty and balloon mitral valve and other cardiac interventions.
2. All movements should be motorized with C-Arm angulations of minimum RAO/LAO +110 deg. / -110 deg. CRAN/CAUD +45 deg. at the head end position. With 20 deg. / sec. or more speed for LAO/RAO and 15 deg./sec or more speed for CRAN/CAUD.
3. The system for the user-defined programmed position of the C-arm.
4. Manual/motorized parking of C-Arm in case of catastrophe for resuscitating the patient
5. Motorized peripheral position for peripheral and vascular intervention should be available.
6. It should be possible to position the C-arm on the left side as well as on the right side of the patient.
7. The C arm should have auto collision protection with the patient, monitors, and the table.
8. System should be capable of doing head-to-toe coverage without repositioning the patient.
9. Gantry depth should be more than 100 cm for better groin access
10. Facility for rotational angiography (i.e., without the need of an operator standing near the C arm) should be available. Table side and console side operations should be possible.
11. Roadmap facility with motion compensation: A vessel map is created and superimposed with(un)subtracted live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map.
12. C Arm and table control should be possible from the exam room. The system should have a foot switch in the exam room.

Table:

1. Cardiac Table - Patient table must have radio lucent carbon fiber tabletop or equivalent of high quality with a long-life
2. The table should have longitudinal, horizontal, and vertical travel.
3. It should be possible to swivel the table in case of emergencies (desirable)
4. Table head-to-toe coverage of adult patients without repositioning (desirable)
5. Floor-mounted patient table for all angiographic examinations and interventions.
6. Large unobstructed cantilevered tabletop and wide range of rotations the enable access to patient from all sides and easy transfer and positioning.
7. Table control module for operation of all table full armrest
8. Extendable arm rest both sides and elbow guard.
9. Table height 80 cm to 102 cm, adjustable.
10. Table length 280cm or more, width 45 cm or more
11. Lift speed 2 cm/s or more
12. Table rotation (on pivot) with Head tilt facility
13. Maximum table load 200 kg or more.
14. Thermal mattress & binder for children

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Accessories to be provided for the table:

1. Accessory clamps
2. Detachable radiolucent carbon fibre arm support
3. Drip stand
4. Peripheral filter set
5. Catheterization arm support for Radial angiography
6. Foot support
7. Head end holder (head fixing aids) with support
8. Articulating arm support
9. Long tabletop/mattress: mattress should provide high patient comfort for long interventional procedures, made of slow-recovery foam with ideal density and thickness.

Please provide details:

a) Isocenter to floor distance
b) Focal spot to iso-center distance
c) Source image distance
d) C arm depth
e) Manual and motorized flat detector movement.

3. X-Ray Generator:

1. 100 KW or more with the latest technology high-frequency generator compatible with high-resolution imaging along with the facility to automatically adjust the dose according to the size of the patient
2. Max power at least 100 KW.
3. Cine KVp range to be 40-120 KVp or more. Fluoroscopy KVp range to be 60-120 KVp or more. Output at 100 KVP to be 1000 mA or more.
4. An Should have automatic exposure control device for fluoroscopy mode
   Should have an overloading protection. Provide details
5. Automatic X-ray control system fully automatic calculation and optimization of exposure data based on fluoroscopic value.
6. monitoring the tube load with the date display
7. KV & mA post display on image monitor.

X-Ray Tube

1. X-ray tube should have secondary grid switching/ generator pulsed to deliver pulsed flour to reduce the soft X-ray to patient and Operator.
2. Anode heat dissipation should be 3000 HU/ sec or more
3. Anode heat storage capacity 5 MHU or more, with advanced cooling mechanism. High cooling rate with liquid bearing technology or equivalent for continuous and noiseless operation and capable of pulsed fluoroscopy on both focal spots.
4. The Pulse Fluoroscopy should be offered with pulse rate of 10 frame /sec to 30 frames/sec. Additionally fluoroscopy for paediatric case of 30 frame/sec and more should be provided.
5. At least 3 selectable /programmable cu filters for reducing the dose to the patient in flour or cine mode.

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6. Please provide details:
a. Pulsed fluoroscopy (grid/generator switching)
b. Fluoro power for 20 minutes
c. Maximum heat dissipation of assembly
d. Provide details of filters used
e. X-ray indicator light
f. Leakage radiation
g. List the dose saving measures
h. Radiation dose product in flour and cine

Radiation protection:

1. The System must have radiation safety package like DAP METER or equivalent for radiation safety of operator & patient.
2. The system should have integrated computer controlled (preferably automatic) X-Ray Beam filtering with copper filters of various size from 0.2 mm to 1 mm. Please list the special filters available - pre-programmed.
3. The system should have positioning of collimator blades without radiation.
4. Should have dose measuring capacity.
5. 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. The system should have a facility to remove the anti-scatter grid on the detector for ensuring lower dose in paediatric imaging.
7. System should meet all National & International safety standards & comply with BARC & AERB guidelines.

Collimator:

1. At least one collimator per plane to be provided, preferably with IRIS/square type arrangement
2. Should have facility for dose measurement chamber in order to display the skin radiation dose on the monitors in the lab.
3. Collimator should have facility for copper pre filtration for reducing the x ray dose in floor and cine mode

Digital imaging System:

1. A flat detector with a diagonal size of at least 30cm/12" with at least 3 zoom fields.
2. Acquisition: speed of at least 25 frames per sec. Acquisition speed for DSA should be 0.5 frames/sec to 6 frames/sec or higher
3. Pixel size should be better 180 microns. Matrix at least 1K x 1K, in 16-bit depth
4. Digital system with acquisition and processing in 1024xl024 matrix at 25/30 fps with 16 bit digitization.
5. Detector quantum efficiency at least 75%
6. Image storage capacity of at least 100,000 images in 1024 x 1024 matrix at 16 bits on the main system disk.
7. System should have capability of ECG display on the image monitor.

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8. Real time image processing algorithm applicable for both fluoroscopy and acquisition. Cine loop replay facility with forward and back ward and fast forward
9. The system should have facility for storage of fluoro loop scene of at least last 10- 20 seconds or previous 450 frames once the fluoro switch is off (backward storage); unlimited and continuous forward fluoro storage facility with excellent quality of stored fluoro images. Facility for storage for adult and paediatric.
10. Road mapping and landscaping facility should be available. Facility for side-by-side still image; road map facility should be provided so as to support all anatomical areas and all interventional procedures with facility to overlay selected reference image with fluoroscopy
11. Dedicated touch pad for review/zoom, play/pause / previous/next image, store/recall /reference images at the table side
12. Post processing software facilities with real time edge enhancement, positive /negative image display windowing, electronic shuttering, roaming, image reversal, zooming and magnifying with text and annotation junctions.
13. There should be facility to enter the patient demographics from the examination room or the console room. The full system should have touch screen control at table side
14. The system should have full table side and console room control operation with complete acquisition and post processing capabilities.
15. System should have on-line & off-line validated coronary analysis and ventricle analysis program.
16. The software should have Auto calibration facility for stenosis measurement with edge enhancement and geometrical and densitometry calculations. The analysis should be possible from table side in the examination room and from the control room.
17. The system should have on-line DSA capabilities in 1024 x 1024 matrix with acquisition frame rate of 0.5 frame/sec to 6 frames/sec. The system should have on-line DSA of excellent quality facility with motorised movements which can be manually controlled.
18. The latest complete software and hardware for visualising stent with extra high resolution from table side control. Should have stent enhancement tool with fade in/fade out facility with all software, hardware, image processing tools for enhancing visualisation of the stent and vessel and should be the latest and most technologically advanced version.
19. The System should be capable to do automatic rotational Coronary angiography to gather more inforacquireith less X-ray and contrast medium dose. The system should acquires simultaneous RAO/LAO cranial-caudal views in just one acquisition run by moving the C arm in a curved trajectory around the patient instead of multiple acquisitions.
20. Selection of stent enhancement and DSA should be possible from the examination room. It should be possible to overlay live fluoro image on reference image on live monitor with fade in and fade out. Angle and distance measurement facility should be available

Monitors / Display:

1. The monitor display system the in examination room should be ceiling suspended and it should be possible to position it on the left or right side of patient table.
2. Display in exam room should be single screen 56-inch 5 megapixel or MORE equivalent monitor to display live and reference images, patient hemodynamic monitoring, stent enhancement monitor / EP tracing and IVUS/ FFR imaging.
3. Two high resolution TFT (Preferably LED) monitors, 19 inch or more for post-processing and reporting in the control room.

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4. One high resolution medical grade TFT/LCD monitor for post-processing and reporting in the workstation.
5. Another monitor in the console room for live scenes. There should be 2 more monitor in console room for live hemodynamic monitoring & Console Monitor for patient registration
1. One colour monitor (Preferably LED) for image viewing/processing in cotrol room.
2. All monitors should be medical grade having:
   a. Flicker free, distortion-free high resolution
   b. High contrast
   c. Wide viewing angle
   d. Brightness at least 500cd / m2
   e. Automatic gain, brightness control

Workstation and Digital Archiving

A state-of-the-art workstation should be provided.

1. Facility for acquired images to be transferred to the workstation seamlessly without interrupting the procedure; there should be 2way digital image communication between the workstation and the procedure room.
2. Should be able to work with the workstation for review of the previously transferred scenes of same patients or other patients while procedure is going on without interruption. Workstation should be able to archive at least 1000 patient data with easy irretrievability search by name, date of procedure or cath number
3. The system should be able to perform QCA facility from the console as well as workstation and facility to transfer the scenes from archive to the procedure room. Full quantitative analysis package should be provided. QCA facility should be also available for recorded CD/DVD.
4. There should be facility to delete selected scenes archived in the workstation
5. On CD/DVD software for reading, with facility for zoom in and out.
6. DVD_R/ CD_R with DICOM Viewer in DICOM 3 format having capability of receive and transfer of images from cath lab to remote review station.
7. Dynamic viewing of CD images at frame rate of 0-25 frames/sec, single frame step by step, fast forward & fast rewind , zoom In or zoom out
8. Image transfer from digital system in background mode without affecting the system operation.
9. USB Interface to copy images to memory disk / external hard disk.
10. There should be facility to connect the workstation to hospital PACS system of any proprietary item for remote viewing and manipulation
11. Should have capability to convert DICOM images into .avi and .mp4 formats with frame editing
12. System should be provided with Image storage server with 10 TB storage and four workstations with medical grade monitor connected to it to fetch and review images (1 in console room, 1 in seminar room, 1 in OPD consultant room and 1 in faculty room). QCA analysis software to be made available at all 4 workstations.

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3D Acquisition and cross section imaging (optional)

The 3D Acquisition should offer:

1. 3D Reconstruction and visualization in real time of volume in volume rendering technique (VRT), MPR & MIP.
2. Rotational angiography facility at a speed of at least 45 degrees per second with acquisition frame rate of at least 25 frames per second in 1 k matrix with facility for display of subtracted and un subtracted images in the examination room. The possibility of acquiring 3D Coronary Arteriography package along with the stent enhancement package. Stent enhancement with lumen subtraction facility will be preferred.
3. It should be possible to create 3D image of left atrium of heart and aortic arch. It should be possible to overlay line fluro image on this 3D image of left atrium for catheter guidance in EP procedure.
4. The facility should offer auto segmentation of ventricles / vessels of the entire heart (especially the left atrium with visualization of the pulmonary veins) in automatically performed one step.
5. The system should have TAVI guidance package with overlay and auto landmarking from rotational angio data of cath lab

ACCESSORIES

1. Lead aprons: of standard state of the art make, light weight, with a lead equivalent of 0.5mm. Should be double sided, 12 such aprons to be provided 6 of which should be two piece and 6 should be single piece with wrap around. Should be FDA approved
2. Two wall mounted lead hangers for 6 lead aprons each
3. Goldshield - 5, Head Cap radiation protection - 05, Radiation protection Lead spectacles 6 Neck protection radiation shield covering front and side -12.
4. Hemodynamic Recorder (for Cardiac Catheterisation) with 2 pressure and 12 ECG . State of the art Hemo and EP system to be offered as integrated or separate system. System should have the following features

    - Proven signal processing technology for signals of enhanced accuracy and quality
        - 22-bit analog/digital converter or higher
        - 2000 Hz or higher sampling rate for better signals
        - 4 invasive pressure inputs (Range 10 to 400 mmHg)
        - Integrated vital signs alarms for HR, NBP, SPO2 and respiration rate
    - Visible and audible alarm during cath lab examinations.
    - Resizable split-screen mode, printable, for pre-post treatment comparison.
    - FFR measurement facility
    - Integrated measurement/calculation of cardiac output (thermodilution, Fick)
    - Customized workflow support programs:
        - fast setting of pressure parameters, support for more standardized procedures; for e.g. left heart, right left heart, pediatric examinations.

Virtual pullback and pullback sequence.
Calculation of systolic area index for constrictive pericarditis.
ECG Electrodes should be: R, L, F, N and C1 to C6
Available leads should be: I, II, III, aVR, -aVR, aVF, aVL, V1-V6

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Heart rate detection range 15 – 300 beats/min
Cycle length 200 – 4000 ms

Sensitivity range from 1 to 1000 mm/Mv
Sweep speed Real-time: 5 to 400 mm/s

I. One ETO sterilizer of approved make 4.5 Cu ft
II. One movable lead glass barrier with 2.0 mm Lead equivalent to be provided approximately size 75" H x 30" W, Depth 25".
III. Integrated two-way communication systems between control room and examination room.
IV. Camera system to display live cases in cath lab to departmental conference room.
V. FDA/CE approved CO2 angiography system.

VI. Lead lined gloves: Two pairs to be provided

VII. Ceiling-suspended operation lamp, cool LED type- 1 no. Focused ceiling mounted light with a handle for positioning the light. This handle should be removable.
VIII. Fire alarm guard
IX. Instrument Table – 2Nos (Length: 100cm, width-45cm, Height-80cm (top span from floor), with 2 span(rack) with side rail on three sides, wheel size- diameter not less than 10cm)
X. State of the art High Pressure Injector compatible with the machine – One (along with 5 reusable & 200 disposable, 150 ml syringes)
XI. Ceiling suspended radiation protection - 1 no. (as per international radiation protection system)
XII. Table mounted radiation protection - 1 no. (as per international radiation protection system)
XIII. Foot swith for fluoroscopy, cine and DSA to be provided.
XIV. UPS Backup of all electric ports for at least 30 min
XV. 2 SINGLE chamber external pacemaker with 10 temporary pacing wires
XVI. IABP – state of art intra-aortic balloon pump, latest imported model with hemodynamic pressure recorder AND 4 IABP BALLOON.
XVII. FDA approved integrated with Cath-lab High Definition IVUS System with Dual/Higher frequency 45 MHz IVUS Imaging capability with 10 IVUS Catheter.

Warranty.

The complete system, including the accessories, X-Ray tube, computer system, air-conditioning with accessories to be under warranty for five years. The entire turnkey project, including the building and furniture, is to be maintained during the period of warranty, to the satisfaction of the hospital commandant.

The warranty will start after the successful and complete installation of the Cardiac lab.

- Thereafter, a comprehensive maintenance contract (including repair/ replacement of the parts including X-ray tube) of the entire turnkey project inclusive of the complete system, all accessories, computers and printers, building, furniture, air-conditioning, DG set, and all other items supplied/ installed should be offended for five years.

- Warranty of tube to be given separately.

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Turnkey site preparation.

ANNEXURE 1

Comprehensive turnkey site preparation and detailed layout plan suitable to the existing site and ambient conditions at the center to be submitted by all the agencies before offering their price bids. Turnkey would include dismantling and disposal of redundant fixtures and execution of all necessary civil, electrical and air conditioning work at site. Site preparation should be time bound and completed before shipment of the equipment and time to installation of the machine no more than 4 weeks (total time 90 days).

Proper care to taken to install Cath-lab systems to reduce noise, proper grounding and avoid interference.

One movable lead glass barrier with 2.0 mm Lead equivalent to be provided approximately size 75" H x 30" W, Depth 25".

Essential site preparation requirements include the following:

A. Civil Work

1. Dismantling / Brick works.
2. Dismantling of walls floor (if any)
3. Dismantle all electrical & furniture fittings.
4. Disposal of all debris from the site.
5. Door/window work-P/F aluminium or wooden door with frame & lead lining as per the AERB requirements. Sensor based automatic door opening to avoid cross infection by hand or fomites in all the working areas.
6. Wall/ ceiling repair work-repairing the cement/plaster. Leakage site to be identified first and fixed permanently with proper water proofing.
7. Redesigning the site (to be approved by department committee) for housing the system, control, electronics etc. **(the control panels be preferably housed in a low height aluminium partition enclosure)** the fixtures should be from branded company and best. Optimally all fixtures should be wall mounted.
8. Floor, walls, roof and false ceiling should be aesthetically designed and prepared for use for the life of the equipment and easily maintainable. Flooring work: providing and fixing highest quality vitrified tiles. False ceiling: providing and fixing perforated AI ceiling. Constructions of walls as per AERB requirements.
9. *Lead partition of approx. 180x90 cm between control rooms, side window to have lead glass approx. 115x80 cm, the sliding door to have lead glass approx. 125x80(two in number) and 70x80 cm (two in number).*

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B. Examination room and console room

1. Wall panelling glass wall panelling on the wall from 5 feet height above floor till ceiling height. Ceramic tiles/High quality marble on wall up to 5 feet height from the floor up to the glass panel. Tile should be at least 2 X2 or more in dimensions and of highest quality (grade 5)

2. Redesigning the site for the controls, monitors, electronics etc. Walls to be covered with highest quality tiles in its entire heights. Flooring work provide and fix highest quality vitrified tiles (at least 2 X2 or better, grade 5)/high quality marble

3. Appropriate designing of the examination room to provide for the safe operation and parking of the C-arms, TV stand, Patient Trolley, instrument trolley (modular design, high quality) and anaesthesia work station, patient monitoring system, infusion pumps, syringe pumps to be done.

4. Modular design wall cabinets (highest quality) for safe keeping and storage of drugs, catheters, interventional items, manuals procedures sets, linen, trays etc. under lock and key. Specify the material, brand and area to be covered.

5. Wall-mounted hangers for suspended lead-free aprons, film viewer (N-2, flat panel design) for the display of images and billboard for memos should be provided.

6. Instrument trolleys, height adjustable operator chairs, patient footstep, ergonomically designed chairs with wheels for control room personnel, wall counters for medications, consumables, anaesthesia equipment and emergencies drugs to be provided.
7. The whole area should be waterproof, fire safe and designed to prevent posts and rodents and kept functional all the time. Wall mounted clocks and rooms thermometers (wet and dry), pest repellent devices and fire extinguishers are to be provided in all the rooms. The area should be properly designed to keep particularly the operating area and the electronics cabinet dust-free and leakage free. As far as possible the floor should be free from encumbrances for ease of cleaning.
8. Drainage for water from account condensate should be provided and the whole area should be free of flooding. Special care should be taken to reinforce the roof, joints and all potential points of water leakage during monsoon or accidental water logging on the roof. Full facility for piped medical grade gas and vacuum supply to multiple points in the angio suit should be provided. This facility should confirm to existing fire/ explosion safety standard.

C. Electrical and air conditioning work

1. Appropriate UPS with 30 min battery backup for the entire system including all accessories using maintenance free dry batteries should be provided with 95% up time warranty.
2. All electrical panels, switches, distribution boards, cables should be of the highest quality for safe and trouble-free operation. Adequate number of voltmeters, ammeters and frequency meters as well as circuit breakers, fire extinguishers, alarm system and low battery indicator to be provided. Proper grounding to be provided. All points of entry and exit of cable, ducts etc. to the site should be sealed to prevent entry of pastes and rodents.
3. All entry and exit points of the examination room should have lead lined doors and X- Rays on light with radiation area symbol. All cable channel and conduits to be properly covered and sealed

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to protect from rodents and be easy to access for maintenance. Air conditioning blowers/ diffusers should be located appropriately and be provided with effective regulators to control the environment in the examination room to meet the requirements of the patient including infants and neonates.

4. Ceiling mounted booms will be preferred for EP equipment. For rooms that are not equipped with ceiling-mounted equipment booms, the conduits should be at least two runs of 4-in.-diameter tubes that connect the procedure room to the control room through the floor, dedicated solely to EP equipment cabling (separate from X-ray equipment and power receptacle requirements).This conduit should be conductive and bonded to equipotential grounding.
5. Floor openings or ports should be concealed by an enclosure that should be fluid tight with protective grommets that will prevent cable insulation damage. The length/reach is dependent on the location of each cable termination linking the equipment, as specified by the EP representative who oversees the room project and design.
6. For rooms equipped with ceiling-mounted equipment booms, cabling runs through ceiling trays connecting the control room to the procedure room boom. The trays can be used in conjunction with other equipment that terminates at the equipment boom as long as there is enough separation between power lines and data transmission lines to prevent electromagnetic interference (EMI) induced by adjacent power lines running in parallel. Open trays are preferable for ease of access above the ceiling and should be conductive and bonded to equipotential grounding. The length/reach is dependent on the location of each cable termination linking the equipment.
7. Power lines and data lines should be run separately and isolated from each other in different conduits to prevent EMI from power line wiring induced through data line wiring that could affect the optimal performance of the EP equipment.
8. Interface cables between the patient and the equipment (e.g., ECG cables and intracardiac catheter cables) should not dangle by the X-ray tube and should be kept neatly arranged by the side of the patient to provide easy access for
9. troubleshooting purposes during the procedure
10. The UPS may be integrated into the power for the entire suite, or individual UPS may be placed in line for each central processing unit.
11. The main purpose of the UPS is to prevent the EP system, mapping system, or other critical imaging or monitoring system from going through a hard shutdown and full reboot procedure in case of a transient power outage or surge.

Furniture

1. Work station table (high quality or modular).
2. Executive chairs 2 (Height adjustable, high quality or better)
3. Table top storage 15 X2 6 X2 preferable of metal /modular design and highest quality for the examination room.
4. Storage cabinet (modular design) in nurse s room, examination room and console room if possible. Redesigning the area in front of the lab for usage as changing room or housing the sterilizer equipment.

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Documentation.

1. User manual in English
2. Service manual in English
3. List of important spare parts and accessories with their part number and costing
4. Certificate of Calibration and inspection from the factory
5. Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelled list of Equipment available for providing calibration and routine
6. maintenance support as per manufacturer documentation in service / technical manual.

Other requirements:

1. Model should be latest generation
2. Should have local service facility. Response time in case of breakdown must be < 24 hrs.
3. Comprehensive warranty of the main cath lab system and third-party items for 5yrs and CMC of the main cath lab system and third-party items for the next 5 years to be provided by the cath lab unit supplier
4. Availability of the spares to be ensured for minimum 10 years
5. Demonstration is must before approval and also working demonstration after installation

Conditions for tender:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.

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6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last

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financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).

19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6th, 7th, 8th, 9th and 10th years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6th to 10th year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

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