



Notice Inviting e-Tender

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Supply and Commissioning of Cath Lab Machine for Department of Cardiology at MCH, Kolkata

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL /NIT-290/2023

Dated-01.06.2023

Amendment-II

Revised Technical specification

Cardiac Catheterization Laboratory (Cath lab)

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	Quoted model should be launched in January 2018 or later (tolerance three month)
1	Description of the expected function: Dedicated flat panel detector single plane angiography system for interventional cardiovascular procedures. The firm without any additional cost should supply any updates of quoted model if available in the market at the time of supply.
2	Operational Requirements with minimum specification: (Main features in brief) State of the art, single plane floor/ ceiling C-Arm/G-Arm cardiovascular digital imaging system with high resolution flat panel detector technology for diagnostic procedures and interventional cardiovascular procedures e.g.

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	coronary angioplasty, balloon valvuloplasty, vascular Angiography, online DSA etc. with following capabilities:
	<ul style="list-style-type: none"> • Should be capable of real time digital angiography acquisition.
	<ul style="list-style-type: none"> • Should be capable of road mapping with zoom, freeze frame and advanced facilities.
	<ul style="list-style-type: none"> • Should be capable of storing fluoroscopy / cine sequences on hard disk and GD for review
	<ul style="list-style-type: none"> • Should be capable of head to toe of standard adult patient coverage for floor /ceiling mounted system.
	<ul style="list-style-type: none"> • Should be user-friendly for quick access and full control of all functionality within the examination room.
	<ul style="list-style-type: none"> • Should be capable of 100% UPS backup for the entire system for at least 30 minutes.
	<ul style="list-style-type: none"> • The system must include all packages for Cardiac applications. System should be complete with pressure injector, Hemodynamic Study Recorder.
	<ul style="list-style-type: none"> • The Cath Lab System should be compatible with all the current models (of standard companies) of IVUS, FFR (Fractional Flow Reserve) / Hyperemia – free ratio and EPS & RFA systems if necessary.
3	C-Arm / GArm Multi-directional Floor / ceiling mounted:

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i)	The system should have Floor /ceiling mounted Gantry allowing the Gantry to position in multiple essential positions of the patient with at least six standard user defined programmed angulations.
ii)	All movements of the gantry should be controllable from the table side.
iii)	The system should have an in-built collision protection.
iv)	The Gantry should have motorized movement for at least LAO/RAO +/-100 degree and 45 degrees CRAN / CAUD.
v)	The gantry should have rotation speed of at least 15 degrees/sec.
vi)	Iso centre to floor distance for frontal C arm should be at least 100 cm or more.
4	Patient Table:
i)	The patient table should have motorized vertical movement with free floating longitudinal & horizontal movements covering at least 100 cm longitudinal and +/-10 cm transverse travel. Table pivot rotation should be available for emergency handling of the patient.
ii)	Table top should be made of radiolucent material (carbon fiber or equivalent) having minimum table length 270 cm & width 45 cm with capacity to bear at least 200 kg weight.
iii)	Standard accessories for the table should be provided include mattress, head fixing aids, radiolucent carbon fiber catheterization and supports, drip stand etc.
5	X-Ray Generator:
i)	Should have 3-phase high frequency X-ray generation unit with at least 100Kw power with integrated overloading protection and pulsed fluoroscopy capability at variable pulse rates.
ii)	Should have minimum Radiographic range 40-120 KVp and fluoroscopy range of 60-120 KVp.
iii)	Should have automatic exposure control for all modes of operation.

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6	X-Ray Tube:
i)	X-Ray tube should be with high-speed rotating anode, fine focal spot (small & large) and high cooling rate to ensure uninterrupted operation.
ii)	Latest generation tubes with fluoroscopic power of at least 3000 watts with noiseless operation to support long-term use. Pulsed fluoroscopy should be offered with pulse rate of at least 1-30 frames/sec.
iii)	The X-ray tube should have anode heat storage capacity 3.0 MHU or more, with heat dissipation capacity of at least 2900W using advanced efficient cooling mechanism to run continuously for at least 8 hours without shutting off.
iv)	Small focal spot not more than 0.5 mm and large focal spot not more than 1.0mm with a load ability of at least 65 KW tube power.
7	Radiation Safety:
i)	System should meet all National & International safety standards & comply with BARC, AERB and FDA guidelines.
ii)	System should be capable of measuring and displaying radiation dose during the patient examination.
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iv)	Necessary latest software & hardware package for improvement of image quality and dose reduction should be provided.
8	Digital image acquisition chain:
i)	The flat detector should be with a diagonal size of at least 24 cm with a pixel size of not more than 200µm. The smaller pixel size will be preferred. At least three zoom steps to be provided. The DQE should be 70% or more.
ii)	Digital system with acquisition and processing in 1024 X 1024 matrix at 7.5/15/30 fps in both fluoro and digital cine modes
iii)	Digital fluoro loop store/replay facility & Last image hold during fluoroscopy.
iv)	Complete cardiovascular computation software package including clinically validated coronary, ventricular software packages (QCA, LVA), Algorithm / software for real time stent visualization, Stent visualization should be operated and post processing from table side/console side. An easy to operate rapid calculation software for offline coronary quantification should be available. Latest application for stent enhancement in relation to vessel Lumen (fade in fade out).
v)	The full system as per specification mentioned in the tender should have a table side control operation for complete acquisition and post processing capabilities.
vi)	The system should have on-line DSA capabilities in 1024 X 1024 matrix with wide ranges of acquisition frame rates. Angle and distance measurement facility should be available. All advanced 20 road mapping with independent

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	windowing of roadmap and device should be possible for better image viewing. It should be possible to view guide wire and device only without any additional contrast injection
vii)	System should have max opac and min opac facility for iodine contrast.
viii)	Subsequent PACS connectivity should be possible without any additional hardware / software requirement. Auto image transfer facility to PACS should be possible in background mode.
ix)	The complete digital system should be networked and connected to a DICOM compatible camera.
x)	Image processing system with Series exposures with frame rates of 30/15/7.5 fps and pulsed fluoroscopy as standard.
xi)	DICOM facility for patient data acquisition, documentation and archiving.
xii)	Hard disc storage capacity of at least 1,00,000 uncompressed images of 1024 X 1024matrix at a minimum of 8-bit/pixel.
xiii)	Post processing software facilities with real time edge enhancement, positive/negative image display windowing, electronic shuttering, roaming, image reversal, magnifying with text and annotation.
9	Monitors / Display:
i)	Examination room: System should have 55 inch or larger / 4 numbers of 19 inch or more medical grade monitors with two back up monitor (19 inch or more) for display of live image and Reference & Hemodynamics (One Extra monitor for hemodynamic slave display inside the Cath Room).
ii)	Control room: Two LED / LCD monitors for data and image viewing. Brightness should be at least 400 Cd/m ² . These monitors should have the facility for all review post processing and quantification of coronary and ventricular function for training and teaching
iii)	LED / LCD Monitor of Medical Grade for images of Cath Lab Radiography system and Hemodynamic Recording.
10	Digital Archiving:
i)	System should have facility to record images on CD/DVD in DICOM format.
ii)	CDs to have DICOM software embedded for instant review in any PC.
iii)	Ability to record DSA runs in CD.
iv)	Ability to generate single DVD incorporating multiple patient studies capable of review in any PC is desirable.
11	CATHLAB Hemodynamic Recording System: The features needed to be available in the recorder
i)	12 Lead ECG Amplifier with one monitor in examination room and two monitors in Control room.
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iii)	All the Cabling (including that of transducers) of Hermodynamic,

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	Electrophysiologic Monitors and RF Ablation System should be such that it does not cause hindrances while doing the Catheterization or other procedures.
iv)	Provision for full hemodynamic analysis
v)	Hemodynamic Recorder (for Cardiac Catheterisation) with 2 pressure and 12 ECG Data entry to include full access to Cath Lab ID Screen, all menus for monitoring of respiration, NIBP, SpO2, 12-lead ECG, at least two invasive pressures, pressure gradient measurements and cardiac output. One additional pair of IBP transducers, ECG lead and SpO2 sensor to be supplied as spare.
vi)	The system should be quoted with NIBP, SpO2, 12-lead ECG, Invasive pressure
vii)	Hardware, SpO2 extension cable, Finger probe, NIBP hose, Adult, paediatric and neonatal Cuffs, ECG trunk cable with standard and radiolucent lead wire set, Cardiac output cable, 17"(or more) colour TFT / LCD monitor for main console 1024 X 1024 or better resolution), 17" (or more) slave TFT Monitor 1024 X 1024 or higher resolution with mountings bracket. Network Laser jet Printer, Appropriate tables for system in control room and for Report generation from system.
12	3D Acquisition and Cross-Sectional Imaging:
	System should have software/hardware package for guidance of valve <ul style="list-style-type: none"> • implantation in TAVI procedure, EVAR, from rotational angiography/ pre-acquired CT/3D rotational Angiography.
	<ul style="list-style-type: none"> • It should be possible to have 3D image reconstruction of vascular structure, Left atrium of heart and aortic arch from rotational subtraction angiography data. The cross-sectional & 3D images should have processing capabilities in the examination room and control room.
	System should have facility of auto positioning of C Arm depending upon <ul style="list-style-type: none"> • image. It should be possible to differentiate between devices like stent and artery in 3D image.
	<ul style="list-style-type: none"> • System should have fusion capability of Ultrasound TEE/CT/MRI images on live fluoro for optimized performance in Structural interventional procedures.
	<ul style="list-style-type: none"> • Latest applications for stent enhancement Clear Stent Dynamic/Stent Boost subtract/ PCI Assist Package/ Stent Boost Stent enhancement for sequentially and separately visualization of stent and vessel outline for assessment of stent deployment. Stent visualization should be operated and post processing from table side/console side.
13	UPS:
i)	Suitable online UPS with at least 30 min. battery backup for complete Cath Lab including cine and fluoroscopy during power interruption. Room emergency lighting should also be on UPS.

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1	System Configuration, Essential Accessories, Spares, Consumables and Services for the Cathlab:
i)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved Multichannel monitor (6 para – ECG, NIBP, SPO2, RR, Temp., IBP) – 2 nos.
ii)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved IVUS system – 1 no.
iii)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved IABP system – 1 no.
iv)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved Rotablator Machine – 1 no.
v)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved Pulse Generator – 2 nos.
vi)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved Biphasic Defibrillator – 1 no.
vii)	European CE (4 digit notified body) / USFDA / BIS / CDSCO approved Syringe Pump - 2 no.
viii)	Footswitch for fluoroscopy and acquisition to be provided.
ix)	Lead Glass: 100 x 150 cm or bigger with lead equivalent as prescribed by ICRP or BARC/AERB recommendations to be fixed between console room and gantry room for radiation protection.
x)	Lead Aprons - Minimum 15 nos. (10 Nos Coat Type & 5 Nos. Skrt Type)
xi)	Thyroid Guard (Good quality) - minimum 15 nos.
xii)	Stand with Hanger – 3 nos.
xiii)	Floor / wall Mounted operation lamp, cool LED type-1 no. Focused floor mounted light with a handle for positioning the light. This handle should be removable.
xiv)	Radiation protection system - 1 no. (As per international radiation protection system).
xv)	Table mounted radiation protection - 1 no. (As per international radiation protection system).
2.	Standards, Safety and Training:
i)	Main Cath lab should be European CE (4 digit notified body) / USFDA / BIS / CDSCO approved product.

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ii)	Electrical safety conforms to standards for electrical safety IEC-60601-General Requirements.
iii)	Manufacturer should have ISO certification for quality standards.
iv)	Shall comply with AERB and BARC guidelines.
Technical specification IVUS	
	<p>IVUS offers direct, accurate, real-time, topographically-oriented 360-degree images not just of the vessel lumen, but of the vessel wall itself and any lesions it might contain. This enables clinicians to qualitatively and quantitatively characterize atherosclerotic plaque morphology, assess the extent of vascular remodeling or distortion, and determine the luminal cross-sectional area available for blood flow.</p> <p>Therefore, it helps in the assessment of plaque morphology, total plaque volume, and the degree of vascular remodeling or distortion and also to calculate cross-sectional Luminal/Vessel Area or Diameter.</p>
1	Latest Generation Intra Vascular Ultrasound System.
2	Monitor-SVGA LCD Monitor-Minimum 19".
3	Area & length measurements graphics in the cross-sectional and long view images.
4	ECG and Audio signals capturing enabled.
5	Ease to eyes by coloring IVUS images.
6	Sterile field control option.
7	Compatibility with Coronary (9-60 MHz), Peripheral (9-60 MHz) and Intra Cardiac Echo (ICE) (9-60 MHz) catheters .
8	FFR Ready
9	Automated lumen and vessel measurement to aid in diagnosis and planning
10	Dynamic review feature (blood flow, plaque morphology, dissections and stent

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	apposition)
11	Long view and cross-sectional imaging.
12	Coronary IVUS catheter with single Rotating/Mechanical transducer driven by a flexible drive cable with minimum 9-60 MHz frequency.
13	High storage capacity with removable hard disk and minimum of 25 cases storage.
14	Archiving options: CD ROM, 16X DVD, Removable Hard Disk and Network.
15	Minimum 30 GB hard disk with an option of removable storage with minimum storage of 25 cases.
16	DICOM storage & image formatting.
17	Digital Frame Grabber.
18	Data Entry: Touch Screen, Mouse
19	Multiple image screen format.
20	Automatic & manual pull back options. Automated vessel and lumen measurements/detection with manual correction option.
21	Printer to print IVUS images.
22	Clinical support for training of staff.
23	Technical back up for maintenance of machine
Technical specification of Rotablator	
1	Latest version state of art Rotablator to be supplied with the cathlab machine launched within last 3 (three) years
Technical specification of Intra-aortic Balloon Pump (IABP)	
1	Latest version state of art IABP to be supplied with the cathlab machine launched within last 5 (five) years

Specifications for Turnkey Work

Site preparation including interiors and Air-conditioning

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1.	<p>Area to be prepared including interiors: Carpet area of 1500 sq. feet approx. The area should have properly lead shielded wherever required as per BARC norms. If the carpet area 1500 sq. ft is not available at the site, the payment for the turnkey work will be deducted as per the area available at the proposed site.</p> <p>(Only covered space would be provided to the supplier including ceiling, flooring & wall)</p> <p>Necessary brick work for compliance (thickening of wall) with AERB requirement should be done by the selected agency.</p>
2	Height of the room (up to false ceiling): 3.0 m and above
3	General
a)	<p>Floor: Floor (except of Catheterization room) should be of premier quality double charged joint less Glazed vitrified tiles of size (800 x 800) mm. High quality Antistatic floor suitable for operation theatre for Catheterization room. (kajaria/Nitco/Jhonson)</p>
b)	<p>False Ceiling:</p> <p>Catheterization Room: Modular type Stainless Steel False Ceiling with raceway for wiring.</p> <p>Other Areas: Bio-friendly Modular False ceiling system 600x600 mm. Gypsum drop ceiling around the room</p>
c)	<p>Wall: should be of premier quality double charged joint less Glazed ceramic tiles of size (600 x 300) mm up to ceiling high. Wall specification should be as per BARC norms. All corners should filled and finished with matching colour silicon. All visible edges up to a height of 1200 mm to be fixed with mat finish SS corner guard. The same to be flushed with tiles surface.</p>
d)	<p>Door for Cathlab Room: Wooden (with lead shielding as per AERB norms) for Cath Lab room door. Heavy duty double leaf Stainless Steel for Main Entrance door and UPS room door with locking facility with 1 hour fire rating. Both metal doors shall be Stainless Steel finish.</p>
e)	<p>Paint: 2 coats synthetic enamel paints over 2 coats primer over wall putty (if required).</p>
4	<p>Air-conditioning machine: The entire carpet area should be air-conditioned with AC machines of appropriate tonnage and with 100% back up. AC machines with 5 star rating having appropriate capacity to bring down and maintain room temperature up to 20° to 22° Celsius as per requirement. There should be sufficient number of the AC machines to run the service round the clock and uninterrupted in case of breakdown of any of the AC machine(s). HVAC Machine for Cath Lab room, consol room and Technical room should have standalone dehumidifier system.</p> <p>A/C ducting to prepare, if required.</p>
	Indicative AC Make: O General/ Hitachi/Mitsubishi/Diakin
5	High quality room LED lighting (up to 400 LUX of luminance)

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6	Moveable Skylight or equivalent complete ambient interior whichever is applicable
7	Gas Pipelines etc with 4 terminations – 3 at patient waiting area & other at Catheterization room – imported terminals to be supplied.
	The bidders to submit drawing layout plan of the interior. At least 15 -20 patient holding positions has to be mentioned in the drawing layout plan. Sufficient furniture to be supplied for the console room and patient waiting
9	Wiring System:
a)	Light, Fan, 5 Amp Plug: 3 X 1.5 sq. mm copper conductor FRLS wire should be provided.
b)	Power Plug (15 Amp): 2 X 2.5 + 1 X 1.5 sq. mm copper conductor FRLS wire should be provided.
c)	Split AC wiring: 2 X 4 + 1 X 2.5 sq. mm copper conductor FRLS wire should be provided
10	Earthing: 4(Four) nos. Copper plate earthing as per PWD schedule.
11	Dress Changing room with mirror and storage shelf as per requirement.
12	Toilet for Doctors and officials:
	Plumbing – Kohler / Jaquar / Roca Sanitary system for WC and Urinals- Cera / Hindware / Parryware –with tornedo technology).
13	Toilet for patients:
	Plumbing – kohler / jaquar / roca Sanitary- cera / hindware / parryware – tornedo technology)
14	Scrub station – Full SS-304 body with 2 sink scrub station (warm and cold water) with paddle operating facility (Modular). Necessary water RO plant to be supplied with scrub system.
15	Misc supply items during warranty & CMC period:
a)	3 nos - 80 liter Waste bins as per color code with adequate supply waste bags for Waste Bins
b)	6 nos- 20 liter Waste bins as per colour code with adequate supply of waste bags
16	Heavy duty R/O water treatment and SS 40 liter water cooler facility to be provided
Note: The items mentioned above are indicative in nature	
<u>Furniture to be supplied:</u>	
a)	Executive revolving chair with arm rest: 2 Nos. (Godrej/Janak/Geeken)
b)	Steel Almirah with Rack: 2 Nos. (Godrej/Janak/Geeken)
c)	Wooden Shoe Rack: 1 Nos (Godrej/Janak/Geeken)
d)	Crash Cart: 1 No. (Godrej/Janak/Geeken)
e)	i) Console table -1 No. ii) Additional Table for workstation size of (1200 x 800) mm- 1 No.

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	(Godrej/Janak/Geeken)
f)	Mirror in change Room with small storage rack and clothes Hook, Curtain with SS rods and Hooks- 1 No
g)	Wheel chair: 1 No