Notice Inviting e-Tender

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Supply and Commissioning of Pediatric Cath Lab Machine at the Neonatology Department of IPGME&R and SSKM Hospital

(Submission of Bid through *online*)

2nd call of Bid Reference No.: WBMSCL/NIT-47/2023; dated-02.02.2023

Bid Reference No.: WBMSCL /NIT-204/2023	Dated–26.04.2023

Amendment-V

REVISED TECHNICAL SPECIFICATIONS

Sl No	Technical Specification
Revised Technical Specification of Bi plane Cath lab for Dedicated Pediatric Cardiology Intervention	
State of the art, Biplane ceiling/floor mounted C-arm/G-arm system for diagnostic and interventional congenital heart therapeutic catheterization lab. All kind of congenital heart therapeutic procedures including 3D-rotational angiography can be performed. The cathlab is dedicated for the management of children with all sorts of cardiac diseases for coronary, structural, functional and rhythm-related problems of the congenital heart. The quoted model should be launched 2017 or later.	
1	MULTI DIRECTIONAL C- ARM/G-ARM POSITIONER

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1.1	The system should have two gantries: One floor mounted and one ceiling suspended providing full body coverage. The lateral plane should have motorized longitudinal C-arm movement.
1. 2	It should be possible to pre-program the gantries for multiple examinations positions.
1.3	All movements of the gantry should be controlled from the controller on the table side.
1.4	The system should have adequate collision protection for safety of the patient.
1.5	The floor mounted C-arm should be able to provide head to toe imaging without re-positioning of the adult patient.
1.6	Both gantries should have fast speed for angulation and positioning. The frontal plane should have a speed of at least 18 degrees/Sec for all positions and the lateral plane should have a speed 08 degrees/sec or more for all positions.
1.7	Frontal Plane Angulation: RAO/LAO should be at least 100/110 degrees and Cranial/caudal should be 30/30 degrees or more. Lateral plane rotation should be 0 to 90 degrees LAO/RAO and cranial and caudal should be 35 degrees or more.
1.8	Gantry angulations in both planes frontal and lateral should be freely user selectable to satisfy clinical imaging needs.
1.9	Both the gantries including and / or table should have an automatic positioning capability dependent on the reference image being selected.
2	PATIENT TABLE
2.1	The table should have motorized vertical and longitudinal and free floating.
2.2	Table should bear minimum patient weight 200 kg or more with additional weight for at least 50 kg during resuscitation.
2.3	Table length should be 270 cm or more, width 45 cm or more
2.4	It should be possible to swivel the table in case of emergencies. Accessories should include head fixing aids, head tabletop with mattress, Radiolucent Carbon fiber arm supports, drip stand and Catheterization arm support. Radial arm board. And head holder clamp device.
3	X RAY GENERATOR

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3.1	Generator should be multi pulse / high frequency for constant output.
3.2	Output should be 100 KW or more Radiography KVP range should be 50 KV -125 KV or more. Output at 100 KV should be 1000 mA or more
3.3	Maximum continuous Flouro power should be 1500W or more for at least 8- 10 hours for long continuous procedures.
3.4	It should have automatic exposure control device for radiographic fluoroscopic and angio mode.
3.5	It should have digital display of KVP and mAs.
3.6	Anatomical programming radiography should be possible.
3.7	It should have overloading protection.
3.8	It should have the facility for pulse fluoroscopy at variable rates for reducing the X-ray dose to the patient during intervention procedure.
4	X RAY TUBE
4.1	Powerful and noise-free rotating anode x ray tube with spiral groove bearing technology and fluid lubricant for faster cooling must be provided. It should be with a minimum of two or more focal spots (small & large). Large focal spot atleast 65 kW or more output for extended runs and small focal spot atleast 30kW or more.
4.2	X-Ray tube should have automatic Copper filtration / secondary grid switch to reduce radiation leakage to patient and automatic exposure control system.
4.3	Anode heat storage capacity of at least 3.0 MHU or more to run continuously for 8-10 hrs without shutting off without deteriorating image quality. Declaration certificate from OEM factory should be submitted for X ray tube anode heat storage capacity MHU value and X ray tube housing assembly capacity.
4.4	Cooling system- oil/water cooling to ensure continuous operation.
4.5	Anode heat cooling rate should be 2900W or more.
5	RADIATION PROTECTION

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5.1	The system should meet all National/International Safety Standards and comply with BARC & AERB guidelines.
5.2	Should have integrated computer controlled automatic X-Ray Beam filtering with Copper filtration / secondary grid switch.
5.3	Display and recording of Radiation dose for each procedure (per fluoroscopy/cine time) should be continuously available.
5.4	The system should have a facility to remove the anti-scatter grid on the detector for ensuring lower dose in pediatric imaging.
6	DYNAMIC FLAT DETECTOR SYSTEM
6.1	Both planes should have flat panel detectors with diagonal size of at least 40 cm or more for frontal plane and at least 25 cm or more for lateral plane. The pixel size should have 200 microns or less for both frontal and lateral planes.
6.2	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.
6.3	Flat detector should have 14 bit acquisition with at least 3 levels of acquisition and at least 3 levels of zoom for both planes.
6.4	The DQE of detector should be 75% or more for best acquisition efficiency and to minimize loss of radiation energy.
6.5	The system should have capability to acquire the images @ minimum 3.75 to 30 frames per second for fluoro and cine and 30 frames per second or more for pediatrics. For DSA frames rate range should be 0.5 to 6.0 fps.
6.6	Acquisition mode for pediatric acquisitions with additional 30 f/s or more acquisition and should display in $1k^2$ matrix and storage in $0.5k^2$ matrix at least.
7.	MONITORS
7.1	System should be supplied single integrated large display of 55 inch or more medical grade TFT/LCD high resolution monitors with back up monitors in the Procedure room for Live, Reference, Hemodynamics, Stent enhancement, 3D acquisition imaging and images for other sources like CT/MR etc.

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7.2	System should be supplied with at least 05 Medical Grade TFT/LCD high resolution monitors of 19 inches or more each display monitor in the Console Room for display of Live, Reference, Hemodynamics, Stent enhancement, 3D workstation and for each planes.
7.3	The monitors inside the lab should be suspended from ceiling with railings so that they can be easily moved to either side of the table.
8	WORKSTATIONS
8.1	DICOM workstation to be provided in Console Room with provision to review. It should be possible to perform post processing in console room even while online acquisition is being performed.
8.2	The Workstations should be equipped with latest generation computer with 19"TFT monitor with storage capacity of at least 1 TB Hard disk, 16 GB RAM, latest generation processor and original licensed version compatible operating system along with latest CD/DVD recorder.
9	DIGITAL IMAGE SYSTEM
9.1	DSA 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.
9.2	Gray scale depth of at least 12-bit pixel should be possible at all frame speeds.
9.3	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.
9.4	Cath lab should be supplied with state of art complete 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.
9.5	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 and 3D road mapping / remodelling features should be offered.
9.6	Two-way intercom facility between Console room and Procedure room.
9.7	Cine loop replay facility and last image hold/grab facility during fluoroscope (Fluoro save)
9.8	3D RA subtraction facility and 3D workstation with Fusion capabilities from Rotation angiography, Pre acquired CT, MR datasets and 3D Roadmap guidance package with and/or facility to perform CT like imaging for heart chambers in the

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	Cath lab.
9.9	The 3D volume as well as important markings or measurements can be overlaid on the live fluoroscopy image for easier orientation and guidance through the procedure.
9.10	With uncompromised registration in real time 2D fluoroscopy with 3D anatomy from CT, MR data sets
9.11	Advanced image processing technique for: -
9.12	Real time edge enhancement
9.13	Positioning of patient on Last image hold without radiation.
9.14	Real time harmonization
9.15	Real time noise reduction and dose correction algorhythms.
9.16	Real time pixel shift to reduce the motion artifacts
10	ARCHIVAL SYSTEM
10.1	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.
10.2	Direct digital archival on compact disk (CD /DVD-recordable) in latest DICOM format preferably in loss less compression.
10.3	Ability to view CD and post process with quantification.
10.4	Ability to export DICOM cardiovascular images onto CD/DVD/another image recording medium.
10.5	Archival System should have one Review workstation with DVD/ combo devices of latest specification with printers.
10.6	The systems should have live streaming for conference and workshop and also be fully DICOM ready and fully compliant for connection to PACS system with that

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	being offered by the OEM for Cath lab
10.7	Ability to convert the DICOM loops to BMP/JPEG and AVI / Mp4i format
11	**Hemodynamic Recorder:**
a)	12 channel ECG waveform display
b)	Atleast 4 Invasive pressure display and necessary transducers and connectors.
c)	FFR License
d)	SPO2, Non-invasive BP display and necessary equipment.
e)	Accessories kit for measuring non-invasive BP in neo-natal
f)	Storage of ECG/Pressure recording on CD
g)	Storage on hard disk: specify storage capacity
h)	Conversion of hemodynamic reports into DICOM 3compatible image data format
i)	Pressure calculation
j)	Gradient calculation
k)	Rate of pressure change(dP/dt max)
l)	Shunt calculation
m)	Cardiac output
n)	Valve area
o)	Cardiac Index, Flow & Stroke volume
12	**WARRANTY & CMC**

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12.1	The Model offered should be the latest High-end model under current production. Refurbished Units will not be accepted. The model offered should have BIS,US FDA &European CE approval
12.2	Warranty: Warranty for 2 years for the complete Cath Lab including Local accessories and Turnkey.
12.3	The equipment should be software and platform protected in the warranty period.
12.5	Confirmation of availability of required spares, X-ray tube, UPS and other essential items for Cath Lab including items covered in turnkey project for 2+8 years from completion of installation to be provided.
13	Accessories:
	The following essential accessories to be provided with the unit--
13.1	UPS with 30 minutes battery backup for complete Cath lab. Emergency lighting both should be on the UPS.
13.5	Lead glass 100x 150 cm for console room.
13.7	Focused ceiling mounted light with a handle for positioning the light.
13.11	Wired Foot switch for fluoroscopy and acquisition.
13.12	Infusion bottle holder
13.13	State of the art Single head high Pressure nonionic contrast Injector compatible with the machine – One (along with 200 disposable, 150 ml syringes)
13.14	Syringe Pump – 5 Nos. (European CE (4 digit notified body) & USFDA).
13.15	High end 12 Channel ECG Machine, 12 channel Printout -2 No (European CE (4 digit notified body) & USFDA) (ECG Cable – 3 set to be supplied extra)

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13.16	6 Para Multipara Monitor (ECG, NIBP, SPo2, Temp, RR, IBP) - 1 No (European CE (4 digit notified body) & USFDA); NIBP Cuff – 3 sets (adult – 2 sets; Paediatric – 1 set) to be supplied extra
13.17	Single chamber Pulse Generator-1 No (European CE (4 digit notified body) & USFDA). This can be used for temporary pacing purpose
13.18	European CE (4 digit notified body) and US FDA Defibrillator – 1 no.
13.19	Lead Aprons - Minimum 20 nos. (10 nos Coat Type & 10 Nos. Skrt Type)
13.20	Stand with Hanger – 4 nos.
13.21	Eye Glasses, neck collar, Head guard & Gonad shield- 15 nos. Each
13.22	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.
13.23	Ceiling suspended radiation protection - 1 no. (As per international radiation protection system).
13.24	Table mounted radiation protection - 1 no. (As per international radiation protection system).
13.25	Laser Network Printer with high resolution – 2nos. (1 nos. color & 1 nos. Black & white)
13.26	One ALL-IN-ONE desktop computer and 2 CD/DVD Writer with PACS compatibility software facility for intra-facility transfer and transmission.