

1. TECHNICAL SPECIFICATIONS

Cardiac Catheterization Laboratory (Cath lab)

Quoted model should be launched in January 2014 or later (tolerance one 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 mounted C-Arm/G-Arm cardiovascular digital imaging system with high resolution flat panel detector technology for diagnostic procedures and interventional cardiovascular procedures e.g. coronary angioplasty, balloon valvuloplasty, vascular Angiography, online DSA etc. with following capabilities:

- Should be capable of real time digital angiography acquisition.
- Should be capable of road mapping with zoom, freeze frame and advanced facilities.
- Should be capable of storing fluoroscopy / cine sequences on hard disk and GD for review.
- Should be capable of head to toe of standard adult patient coverage without changing position of the patient.
- Should be user-friendly for quick access and full control of all functionality within the examination room.
- Should be capable of 100% UPS backup for the entire system for at least 30 minutes.
- The system must include all packages for Cardiac applications. System should be complete with pressure injector, Hemodynamic Study Recorder.
- The Cath Lab System should be compatible with all the current models (of standard companies) of IVUS, FFR (Fractional Flow Reserve) and EPS & RFA systems if necessary.

3. C-Arm / GArm Multi-directional floor / ceiling mounted:

(i) The system should have Floor / Ceiling suspended 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 base 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 40-125 KVp and fluoroscopy range of 60-120 KVp.
- (iii) Should have automatic exposure control for all modes of operation.

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.

- (iii) The system should have collimator blade positioning facility without radiation.
- (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 200 μ m. 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 2D road mapping with independent 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 and CO₂ 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: at least two monitors LCD/TFT 19" or more for live and road map images and one monitor for Physio display of the patient. All must be mounted together on a ceiling rail suspension to allow free positioning at any location with weight balanced height adjustment facility.
- (ii) Control room: One / two LCD/TFT monitors for data and image viewing. Brightness should be at least 500 Cd/m². These monitors should have the facility for all review post processing and quantification of coronary and ventricular function for training and teaching.
- (iii) TFT/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.
- (ii) Cardiac catheterization hemodynamic recorder with 4 invasive pressure recording. At least 2 pressures with floating inputs.
- (iii) All the Cabling (including that of transducers) of Hemodynamic, 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 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.

(viii) Viewing Monitor with LAN Connectivity.

12. UPS and DG Set:

- (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.
- (ii) DG set of 200 KVA or more to give electrical support to the entire system including examination & control room and the adjacent rooms of Cath Lab and ACs.

1. System Configuration, Essential Accessories, Spares, Consumables and Services for the Cathlab:

- (i) ICCU bed : 6 (indicative make : Janak / Godrej)
- (ii) European CE and US FDA approved Multichannel monitor (6 para – ECG, NIBP, SPO2, RR, Temp., IBP) – 6 nos.
- (iii) European CE and US FDA 12 channel ECG machine – 2 no.
- (iv) European CE and US FDA approved IABP – 1 no.
- (v) European CE and US FDA Pulse Generator – 6 nos.
- (vi) **European CE and US FDA Biphasic Defibrillator – 2 no.**
- (vii) European CE and US FDA Syringe Pump - 6 no.
- (viii) **European CE and US FDA BIPAP Machine- 2 Nos.**
- (ix) Footswitch for fluoroscopy and acquisition to be provided.
- (x) 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.
- (xi) Lead Aprons - Minimum 15 nos. (10 Nos Coat Type & 5 Nos. Skrt Type)
- (xii) Thyroid Guard (Good quality) - minimum 15 nos.
- (xiii) Stand with Hanger – 3 nos.
- (xiv) 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.
- (xv) State of the art single head high Pressure (minimum 800 PSI) Injector compatible with the machine – One (along with 200 disposable, 150 ml syringes).

- (xvi) Ceiling suspended radiation protection - 1 no. (As per international radiation protection system).
- (xvii) Table mounted radiation protection - 1 no. (As per international radiation protection system).
- (xviii) Laser Network Printer with high resolution – 2nos. (1 nos. color & 1 nos. Black & white)
- (xix) One ALL-IN-ONE desktop computer (windows 10) for reporting purpose with black & white printer.
- (xx) Bed side table – 6 nos.
- (xxi) DVD- 500 Nos.

2. Standards, Safety and Training:

- (i) Main Cath lab should be CE & USFDA approved product.
- (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.

15. Warranty:

Warranty of 2-year minimum to be provided for the complete system. CMC for the system and the accessories should include all the spare parts including X-Ray Tube. Spares support for the entire system must be assured for at least 10 years.

Specifications for Turnkey Work

Site preparation including interiors and Air-conditioning

1. **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.
(Only covered space would be provided to the supplier)

Necessary brick work for compliance (thickening of wall) with AERB requirement should be done by the selected agency.

2. **Height of the room (up to false ceiling):** 3.0 m and above

3. **General**

- a) **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.

- b) **False Ceiling:**

Catheterization Room: Modular type Stainless Steel False Ceiling with raceway for wiring.

Other Areas: Bio-friendly Modular False ceiling system 600x600 mm. Gypsum drop ceiling around the room.

- c) **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.
 - d) **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.
 - e) **Paint:** 2 coats synthetic enamel paints over 2 coats primer over wall putty (if required).
4. **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° 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 online dehumidifier system.
A/C ducting to prepare, if required.

Indicative AC Make: O General/ Hitachi/Mitsubishi

- 5. High quality room LED lighting (up to 400 LUX of luminance)
- 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.
- 8. 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. 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

Furniture to be supplied:

a)	Executive revolving chair with arm rest: 6 Nos. (Godrej/Featherlite)
b)	Steel Almirah with Rack: 3 Nos. (Godrej)
c)	Wooden Shoe Rack: 2 Nos (Godrej)
d)	Crash Cart: 2 No. (Godrej/ Janak)
e)	i) Console table -1 No. ii) Additional Table for workstation size of (1200 x 800) mm- 1 No. (Godrej/Featherlite)
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
h)	LED view box for two films - 2 Nos
i)	Patient trolley with mattress with O2 Cylinder facility: 1 No.
j)	3 Seater patient waiting chair and magazine racks (Godrej / featherlite)-6 nos.
k)	PA system with FM/USB facility (Sony/Philips/Bosch)- 1 No.
l)	Night vision CCTV camera with internet viewing capacity with proper coverage of patient waiting area, entry gate, console & UPS room with storage capacity of 15 days
m)	Fire sensors as per manufacturer specification (Honeywell / jonson or equivalent) and hand held Co2 extinguisher 3 kg – 6 nos.

n)	Catheter Storage Rack (4 ft x6 ft x2 ft) (W x H X D) - 2 Nos.
	Note: The items mentioned above are indicative in nature