1

Cath Lab

Flat Panel Digital Subtraction Angiography System with Pressure Injector including Accessories

1	Description of Functions	Compatible	Not Compatible	Remark (Fill your Specification)
1.1	A multipurpose flat panel digital subtraction angiography X-ray system for Radiology and Neurology intervention in the Radiology department.			
2	**Operational Requirements**			
2.1	It shall operate on AC power supply.			
3	**System Configurations**			
3.1	Flat panel digital subtraction Angiography X-ray system, 1 unit.			
3.2	CD recording and archival, 1 unit.			
3.3	Integrated 3D Angiography workstation, 1 unit.			
3.4	Ceiling suspended adjustable Lead glass shielding at tableside, 1 unit.			
3.5	Hemodynamic physiology monitor for DSA use, 1 unit.			
3.6	Single head pressure injector suitable for angiography procedures including aortography, 1unit.			
3.7	DICOM dry laser camera minimum 600 dpi resolution, 1 unit.			
3.8	UPS for digital system, capacity sufficient to support 30 minutes of operation time & stabilizer for the complete lab, 1 unit.			
3.9	Lead glass 100cm X 150 cm of 2mm Lead equivalence with suitable frame, 1 piece.			
3.10	Lead apron, 6 pieces.			
3.11	Thyroid shield, 6 pieces.			
3.12	Lead goggles, 3 pieces.			
3.13	Bidder shall indicate brand and model information here and provide technical data document for major components specified above.			
4	**Technical Specifications**			
4.1	Bidders shall offer the most recent advanced high end models from the leading manufacturer only. Any deviation in this regard would make the bid to be rejected technically.			
4.2	**Gantry:**			
4.2.1	Ceiling mounted gantry providing full body coverage without repositioning of patient. Gantry must have 0, 90, -90 deg. working positions for easy operation from 3 sides of the patient.			
	Facility for motorized positioning/rotation of stand from the ceiling pivot by +/-90 degrees for improved workflow and for ease of operation from both left and right side of the patient in addition to zero degree normal head end position. Patient access must be possible from either left or right side. 25 deg. /sec or higher rotation speed with non-contact sensing mechanism (no collision protection switches). Gantry rotation/ angulation +/- 120 deg. and +/- 90 deg.respectively.			
4.2.2	The system must have capability of memorizing at least 2 positions for easy recall of gantry positions for PTAs (Percutaneous transluminal angioplasty or intervention).			
4.2.3	The throat depth of the gantry must be 100cm or more for better groin access.			
4.3	**Table:**			
4.3.1	Motorized up/down, free floating 4 way table top, least radiation attenuation, at least 200 kg + at least 100kgs of additional weight for resuscitation in the metal free overhang area without having to retract the table back on its base.			
4.3.2	Table must have tilt facility to enhance the accuracy and efficiency of gravity-oriented procedures.			
4.3.3	At least +/- 15deg. tilt must be possible.			
4.4	**Detector:**			
4.4.1	A 30 x 40cm rectangular detector that can be rotated by 90 degrees for better flexibility and projection angles depending upon area of interest.			
4.4.2	Flat Detector of latest generation, the digital output of the flat detector must be is 2k x 2.5k image matrix at 14 bits depth for the largest mode.			
4.4.3	System must have at least six imaging modes.			
4.4.4	DQE of the entire detector must be more than 70%, higher preferred.			
4.4.5	Min. pixel pitch of at least 160 micrometre, preferred lower for better resolution.			
4.5	Image Processing & Storage:			
4.5.1	System must have a fully digital 2K image processing for improved detailed visualization of small structures.			
4.5.2	System must have storage capability of at least 50,000 images at matrix size of 1024 x 1024.			
4.5.3	Advanced image processing technique for:			
	⍰ Real Time Edge Enhancement.			
	⍰ Real Time Harmonisation.			
	⍰ Real Time Noise reduction and Dose Correction Algorithms.			
4.5.4	Availability of Vascular analysis software both in examination room and console room.			
4.5.5	System must be capable of virtual collimation of the shutters and wedges in the last image to reduce the x-ray dose.			
4.5.6	4.5.6 Grab function to allow storage and archiving of fluoro image.			
4.6	X- ray Generator and X-ray Tube:			
4.6.1	The system must have microprocessor controlled 100KW high frequency inverter generator.			
4.6.2	Voltage range :40 to 125KV			
4.6.3	Nominal Power: at least 100kW.			
4.6.4	Pulsed X-ray for (subtracted) acquisition up to 6 frames/sec. for vascular applications.			
4.6.5	Fluoroscopy must be possible in low frame rates up to 3.75fr/sec.			
4.6.6	A noise-free, oil cooled, dual focus rotating anode x-ray tube with spiral groove bearing technology and fluid lubricant for faster cooling must be provided.			
4.6.7	Minimum Anode Heat Capacity: 2.4 MHU or more.			
4.6.8	Cooling rate or Anode Heat Dissipation of x-ray tube must be more 500 kHU.			
4.6.9	X-ray tube must have secondary grid switching.			
4.6.10	System must be capable of delivering minimum 3200W continuous fluoro power.			
4.6.11	Additional beam filtration of at least 1.0 mm Cu equivalent. Different filter sizes and types to be freely selectable at the table side for any patient weight for maximum radiation safety to staff and patients.			
4.6.12	Virtual collimation of shutters and filters on the last image to reduce extra radiation for positioning of shutters.			
4.6.13	System must have road mapping facility wherein subtracted roadmap is superimposed on live fluoroscopy. It must be possible to select different roadmap protocols depending upon the anatomy and procedure type.			
4.6.14	Overlaying of live fluoroscopy image over reference image with fade-in and fade-out capability.			
4.6.15	Parallel display of live and roadmap image for optimal guide-wire navigation.			

4.7	Monitors:			
4.7.1	Two monitors of at least 18" size TFT/LCD or Better live reference and subtracted image with high resolution flicker free display must be provided in the examination room . The monitor carriage in the exam room must move over a wide range longitudinally and transversally for better viewing.			
4.7.2	4.7.2 A motorized up-down movement of the monitor carriage will be preferred.			
4.7.3	4.7.3 An at least 18" TFT/LCD slave monitor must be provided in the console room for live images.			
4.7.4	Additional monitor for patient database is must for user friendly patient entry without inhibiting live fluoroscopy viewing on slave monitor.			
4.8	All intervention tools necessary for Radiology and Neurology shall be included. Bidder must indicate all such tools which have been included in the offer here.			
4.9	3D rotational angiography system shall be included.			
4.10	System must have an integrated 3D workstation to for reconstruction of images in 3D and display of 3D images and control in examination with following advanced features:			
	Reconstructive zoom			
	Automated vessel analysis			
	Virtual stenting			
	Aneurysm analysis			
	Catheter tip shaping			
	Calci View			
	Spine View			
4.11	Soft Tissue Imaging: CT option to visualize soft tissue by rotational scan of the cathlab gantry. The CT 3D volume can be viewed in control room and examination room also.			
4.12	Contrast resolution for soft tissue imaging must be up to 5HU.			
4.13	Subtracted Bolus Chase: For visualisation of lower peripheral vessel structures wherein the contrast bolus is followed interactively by a motorized table scan movement.			
4.14	Better Stent Viewing HW and SW or equivalent to significantly improve localized stent visibility in addition to inbuilt software for stent visibility improvement.			
4.15	Stent Boost must have capability of showing fade in-fadeout of lumen for better stent visibility in relation to coronary artery wall.			
4.16	3D road mapping to reduce contrast and time, must allow overlay of real-time 2D fluoro images on the 3D vessel image to see the advancement of the guide wire, catheter and coils on the 3D volume in real time.			
4.17	System must have software to Percutaneous needle guided biopsies, drainages etc. by creating virtual paths on CT datasets. It must be possible to overlay live fluoro in real time on CT image to see the progression of the needle to the target area.			
4.18	It must be possible to do automatic dual axis rotation wherein both rotation and angulation movements are combined in one single scan trajectory to reduce the x-ray dose and contrast required for doing an angio procedure.			
4.19	Electrophysiology tools with the following functions shall be included:			
4.19.1	The system must be capable of providing 3D image of the heart based on both techniques i.e. from pre interventional CT image and also from an actual 3D rotational angiography acquisition in the cathlab.			
4.19.2	The 3D segmentation of different heart structures must be automatic. It must be possible to select the 3D anatomy like left atrium and overlay it on live fluoroscopy image. The 3D image must move in real time and in sync with the x-ray system gantry rotation to help viewing the best projection.			
4.20	CD recording and archival, 1 unit			
4.20.1	DICOM 3.0 based CD recording for recording on CD. CD review of DICOM CD's.			
4.20.2	System must have ability to record DSA runs on the CD and the embedded viewer must support review of these DSA runs at referring physicians PC.			
4.21	Angiography workstation, 1 unit			
4.21.1	The workstation provided must have the ability to view CT and MR images also.			
4.22	Ceiling suspended adjustable Lead glass shielding at tableside, 1 unit			
4.23	Hemodynamic physiology monitor for DSA use, 1 unit			
4.23.1	The monitoring system capable of monitoring 2 invasive pressures and 3 lead ECG. Other functions must include NIBP, SPO2 measurements.			
4.24	Single head pressure injector, 1 unit, suitable for angiography procedures including aortography.			
4.25	DICOM dry laser camera minimum 600 dpi resolution, 1 unit			
4.26	UPS for digital system, 1 unit, capacity sufficient to support 30 minutes of operation time & servo stabilizer for the complete lab.			
5	**Accessories, Spare Parts and Consumables**			
5.1	All standard accessories/consumables/parts required for the proper operation of the above item			
	shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Form.			
5.2	All standard Maintenance tools and cleaning /lubrication materials where applicable shall be included. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Form.			
5.3	Lead Glass 100 x 120 cm, 1 piece.			
5.4	Lead apron, 10 pieces.(lead apron one piece → 5 Pcs , lead apron tow ece → 5 Pcs)			
5.5	Thyroid shield, 10 pieces.			
5.6	Lead goggles, 5 pieces.			
6	**Operating Environment**			
6.1	Power supply: 220 – 240 VAC, 50Hz Single Phase or 380-415VAC 3 phase 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.			
7	Standards & Safety Requirements			
7.1	Must submit ISO 13485:2003/AC: 2007 AND			
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.			
7.3	Shall meet:			
	IEC 60601-1-3 - Part 1: General Requirements for safety - Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.			
	IEC 60601-2-7 - Part 2-7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators.			
	IEC 60601-2-28- Part 2-28: Particular Requirements for the Safety of X-RAY Source Assemblies and X-RAY Tube Assemblies for Medical Diagnosis.			
8	Documentation			
8.1	User (Operating) manual in English.			
8.2	Service (Technical / Maintenance) manual in English.			
8.3	List of important spare parts and accessories with their part numbers and costing.			
8.4	Certificate of calibration and inspection from factory.			
9	QC and software Kits			
10	Manufacturing Date must be less than 6 months before delivery			