Specification for Radiology Department

1. ECG Machine (12 Channel)

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
	12 Channel ECG Machine with Interpretation			
	Manufacturer			
	Brand			
	Type / Model			
	Country of Origin			
1	**Description of Function**			
1.1	ECG Machine is primary equipment to record ECG Signal in various configurations. 12 channels with interpretation are required for recording and analysing the waveforms with special software.			
2	**Operational Requirements**			
2.1	The ECG Machine must be able to acquire all 12 Leads simultaneously and interpret them.			
3	**System Configuration**			
3.1	12 channel ECG machine with interpretation, rechargeable battery, Trolley and other complete accessories.			
4	**Technical Specifications**			
4.1	Must acquire simultaneous 12 lead ECG for both adult and paediatric patients			
4.2	Must have Real time Colour display of ECG waveforms with signal quality indication for each lead			
4.3	Must have Artifact, AC, and low and high pass frequency filters.			
4.4	Must have a storage memory of at least 100 ECGs with easy transfer by optional modem and data card.			
4.5	Must have full screen preview of ECG report for quality assessment checks prior to print.			
4.6	Must have interpretation facility of the amplitudes, durations and morphologies of ECG waveforms and associated rhythm for adult and paediatric patients.			
4.7	Must have alphanumeric Keyboard for patient data Entry **(virtual or hard keys)**			
4.8	Must have High resolution (200 dpix500dpi on 25 mm/sec speed) digital array A4 size printer using thermal sensitive paper.			
4.9	Must have report formats of 3x4; 6x2, Rhythm for up to 12 selected leads; 12 Lead Extended measurements, 1 minute of continuous waveform data for 1 selected lead.			
4.10	Must have battery capacity of at least 30 ECGs or 30 minutes of continuous rhythm recording on single charge.			
4.11	Must be able to be connected to HIS /LAN/Wireless LAN (optional)			
4.12	Must display ECG on LCD/TFT Display of 640x480 pixel resolution.			
4.13	USB Support (optional) for Storage on external portable memories.			
4.14	Must provide a suitable movable Trolley for placing the unit			
5	**Accessories, spares and consumables**			

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
5.1	**Accessories:** • Patient Cable -01 set. • Chest Electrodes Adult-(set of six) -02 sets. • Chest Electrodes Paediatric-(set of six) -01 set. • Limb Electrodes (set of 4)- 02 sets • Thermal Paper A4 Size for 100 patients.			
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).			
6	**Operating Environment**			
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.			
6.2	Power supply: 220 – 240V AC, 50Hz fitted with appropriate plug. The power cable must be at least 3m in length.			
7	**Standards and Safety Requirements**			
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**			
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.			
7.3	Shall meet IEC-60601-1-2:2001 General Requirements of Safety for Electromagnetic Compatibility.			
7.4	Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms.			
8.	**Installation and Commissioning & User Training**			
8.1	Supplier must accomplish proper installation and commissioning of the equipment onsite.			
8.2	Must provide user training (including how to use and maintain the equipment)			
9	**Warranty & Maintenance Service During Warranty Period**			
9.1	Comprehensive warranty for 2 years after installation			
9.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required			
10	**Authorization**			
10.1	Manufacturer's Authorization or Local Distributor Authorization (Manufacturer's Authorization to the main Distributor is also required in case of Local Authorization)			
11	**Documentation**			
11.1	User (Operating) manual in English			
11.2	Service (Technical / Maintenance) manual in English			
11.3	List of important spare parts and accessories with their part numbers and costing.			
11.4	Certificate of calibration and inspection from factory.			
11.5	Shall accomplish all the Qualification Criteria of the bidder mentioned in the main bid document			

2. USG (Colour Doppler) with Echo Probe – Trolley Based

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
	USG (Colour Doppler) with Echo Probe – Trolley Based			
	Manufacturer			
	Brand			
	Type/Mode			
	Country of Origin			
1	**Description of Functions**			
1.1	A fully digital Colour Doppler ultrasound DICOM compatible imaging system for Radiology, OB Gyn, vascular, Cardiac, small parts applications.			
2	**Operational Requirements**			
2.1	It shall operate on mains AC power supply.			
3	**System Configurations**			
3.1	Digital colour Doppler ultrasound machine, 1 unit			
3.2	2-6 MHz. broadband curved array transducer, 1 unit			
3.3	3-12 MHz. broadband linear array transducer, 1 unit			
3.4	Cardiac Probe -Adult - Phased Array 2-5 MHz.			
3.5	B/W Video Thermal printer of latest model, 1 unit.			
3.6	Ultrasound gel warmer, 1 unit			
4	**Technical Specifications**			
4.1	System shall provide all-digital broadband beam forming with maximum display depth shall be at least 30 cm.			
4.2	System shall be performing routine exams and detailed evaluations of obstetrics, gynecology, small organs and cardiology.			
4.3	The system must support broadband Phased array, Convex and Linear array transducers.			
4.4	Digitally controlled, 15-inch or bigger size Flat Panel monitor with tilt & swivel facility.			
4.5	System shall have at least 3 active ports.			
4.6	Full alphanumeric keyboard.			
4.7	Slide pot TGC & LGC gain controls with pre-defined curves.			
4.8	System must be a new generation ergonomically designed to curb minimum injury to sonographer/ physician with keyboard platform rotatable and moveable (up/down).			
4.9	System must support Tissue Harmonic Imaging in Phased Array, Linear Array and convex array transducers.			
4.10	System must have 256 grey shades.			
4.11	Cine memory of 250 frames for cine loop playback.			
4.12	Frame rate: not less than 500fps.			
4.13	Power Doppler for small flow shall be available along with latest technology flow/B Flow/Dynamic flow technology.			
4.14	Colour coded tissue Doppler must be available with quantification for Myo cardiac thickness and strain rate imaging as option			
4.15	ECG triggers facility.			
4.16	Shall have stress echo with ECG gating as option.			

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
4.17	System Shall offer Contrast harmonic imaging and must have optimization settings to detect contrast agents. Please specify other advanced technologies to perform better contrast harmonic imaging			
4.18	Exhaustive software for Cardiovascular applications with report formats.			
4.19	System must be DICOM ready and capable of being interfaced with HIS/RIS/PACS.			
4.20	Following transducers or similar frequency range to be quoted as standard: • 2-6 MHz. broadband curved array transducer. • 3-12 MHz. broadband linear array transducer. • Cardiac Probe -Adult - Phased Array 2-5 MHz.			
4.21	To ensure maximum clinical utility, the manufacturer must demonstrate the capability of the system to successfully perform in the following types of applications: • Abdominal • Small parts and superficial • Paediatric • Musculoskeletal • Obstetrical • Gynaecological and fertility • Cardiac • Prostate • Vascular (Peripheral, Cerebrovascular, and Intraoperative)			
4.22	The system architecture shall be designed to simultaneously process the entire bandwidth of broadband transducer received frequencies from 1 to 15 MHz			
5	**Accessories, Spare Parts and Consumables**			
5.1	**Accessories:** • Black and white video thermal printer with 10 rolls of high density recording paper: 01 no. • Desktop PC System with Colour printer: 01 no. • Ultrasound gel warmer: 02 bottles.			
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).			
6	**Operating Environment**			
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.			
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.			
6.3	Shall provide UPS of suitable rating with voltage regulation and spike protection for 30 minutes back-up.			
7	**Standards & Safety Requirements**			
7.1	Must submit ISO 13485:2003/AC: 2007 **AND**			

S.N.	Purchaser's Specifications	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
7.2	CE (93/42 EEC Directives) and USFDA approved product certificate.			
7.3	Electrical safety conforms to standards for Electrical Safety IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.			
8.	**Installation and Commissioning & User Training**			
8.1	Supplier must accomplish proper installation and commissioning of the equipment onsite.			
8.2	Must provide user training (including how to use and maintain the equipment)			
9	**Warranty & Maintenance Service During Warranty Period**			
9.1	Comprehensive warranty for 2 years after installation			
9.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required			
10	**Authorization**			
10.1	Manufacturer's Authorization or Local Distributor Authorization (Manufacturer's Authorization to the main Distributor is also required in case of Local Authorization)			
11	**Documentation**			
11.1	User (Operating) manual in English			
11.2	Service (Technical / Maintenance) manual in English			
11.3	List of important spare parts and accessories with their part numbers and costing.			
11.4	Certificate of calibration and inspection from factory.			
11.5	Shall accomplish all the Qualification Criteria of the bidder mentioned in the main bid document			

3. Lead Apron

S.N.	Purchaser's specification	Bidder's Compliance (Yes / No)	Reference Page No.	Remarks
	Lead Apron			
	Manufacturer			
	Brand			
	Type/Model			
	Country of Origin			
1	**Description of Function**			
1.1	Lead Apron is used to protect radiographer from direct contact with X-Ray Radiation			
2	**Operational requirements**			
2.1	Lead Apron for Radiation protection			
3	**System Configurations**			
3.1	Lead Apron, adult type			
4	**Technical Specifications**			
4.1	Adult type			
6	**Operating Environment**			
6.1	Not applicable			
7	**Standards & Safety Requirements**			
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**			
7.2	CE (93/42 EEC Directives) or USFDA or BIS approved product certificate.			
8	**Installation and Commissioning & User Training**			
8.1	Not Applicable			
9	**Warranty & Maintenance Service During Warranty Period**			
9.1	Comprehensive warranty for 1 year after acceptance			
10	**Authorization**			
10.1	Manufacturer's Authorization or Local Distributor Authorization (Manufacturer's Authorization to the main Distributor is also required in case of Local Authorization)			
11	**Documentation**			
11.1	User (Operating) manual in English			
11.2	Certificate of calibration and inspection from factory.			
11.3	Shall accomplish all the Qualification Criteria of the bidder mentioned in the main bid document			