ANX D TO
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TECHNICAL SPECIFICATION OF COMPLETE CARDIAC ELECTROPHYSIOLOGY LAB WITH 3D SYSTEM AND ICE, QUANTITY-01, (DP-5)

Ser no	Description	Technical specification	To be filled up by the principal/ manufacturer
(a)	(b)	(c)	(d)
1.	**General Specification:** General specifications are as under :		
	a. Nomenclature	**Complete Cardiac Electro physiology Lab with 3D Mapping System and ICE, Qty-01**	
	b. Brand	To be mentioned.	
	c. Model	To be mentioned. **Model should be latest.**	
	d. Name of Manufacture with Complete Address	To be mentioned.	
	e. Name of Principal with Complete Address	To be mentioned.	
	f. Name of Local Agent with Complete Address	To be mentioned.	
	g. Year of Production	Not before the calendar year of contract.	
	h. Country of Origin & Manufacturer	**Group-A** (Bangladesh, Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Indonesia, Ireland, Italy, Japan, Luxemburg, Netherlands, Norway, Singapore, South Korea, Spain, Sweden, Switzerland, Turkey, UK and USA.	
	j. Port of shipment	Same country of manufacture for Main System. Other Items/ Equipment/ Accessories and Local supplied item to be mentioned specifically.	
2.	**Function/Capability:** To be mentioned.		
3.	**Standard Specification**: a. All the components should have FDA & CE certificate as the mark of quality Standard. b. All the interconnection between the spare parts should be through fiber optic cables. c. All the components of EP Lab: Recording System, Stimulator, RF Ablator, 3D Mapping System, irrigation pump & ICE should be from Single Principle/manufacturer.		
4.	**2D CARDIAC ELECTROPHYSIOLOGY RECORDING AND ABLATION SYSTEM**		
	a. **EP Recording system**		
	(1)	Should have a 12 -Body Surface ECG	
	(2)	Should have minimum 120 unipolar intra-cardiac channels	
	(3)	Should have a facility of Invasive pressure recording & display- 2 Channels	
	(4)	Should have a facility of off-line Software/Hardware system to "Review Data" - one installation outside	
	(5)	Must be supplied with compatible laser printer	
	(6)	Operating system shall be preferably Windows 10 or higher.	
	(7)	Should have a HDD of minimum 500 GB and 4GB RAM	
	(8)	Data storage in standard HDD, Patient data writable only DVD/CD	
	(9)	Ease of use with simple commands using one Keyboard	
	(10)	Must have a facility of real time beat by beat display	
	(11)	Should provide retro recording for minimum of 30 sec.	
	(12)	Should have Continuous surface ECG visualization	
	(13)	All the Interconnection between the spare parts shall be through fiber optic cables.	
	(14)	Facility of Split screen display for re-viewing & matching the EGMs.	

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	(15)	On-line View of real time & review data simultaneously	
	(16)	Selectable amount of data to be stored per patient	
	(17)	Computer based display of RF parameter	
	(18)	Amplifier with 32 bit sample conversation rate at 2KHz or more.	
	(19)	Shall have option of automatic export of screen page to power point slide	
	(20)	Adequate filtering for good signal quality	
	(21)	User configurable reporting format	
	(22)	Data transfer to Power Point, JPEG or similar format	
	(23)	Display of RF parameters graphically in the EP software	
	(24)	Aggregate report of RF delivery per case	
	(25)	Only one keyboard to control the complete system.	
	(26)	System shall have at least three 23" Monitors.	
	b.	**Stimulator**	
	(1)	Must be preferably separate Digital Stimulator Integrated to the Amplifier	
	(2)	Should have a facility of 4 pacing channels with up to 6 extra stimulation option	
	(3)	Should have 9 preprogrammed protocol and 10 programmable protocol	
	(4)	Should have an option of Stimulator Touch screen	
	(5)	Stimulation protocols can be controlled through touch screen, keyboard and mouse.	
	c.	**Radiofrequency Ablator System**	
	(1)	RF Ablator shall be of 100 Watt	
	(2)	Must be compatible with Thermistor or Thermocouple catheters of all leading companies	
	(3)	Should have a memory features for ablation parameter storage & recall	
	(4)	Must have auto cutoff intelligence feature in RF ablator	
	(5)	Must have Temperature and Power control Mode available	
	d.	**ADVANCE CARDIAC 3D ELECTRO-ANATOMICAL MAPPING SYSTEM**	
	(1)	Capable of 3D non-fluoroscopic mapping of arrhythmia facilitates radio frequency ablation. 3D EP Navigation System powerful combination of a new system with added magnetic navigation, the unmatched high density mapping capabilities of the Advisor HD Grid Mapping Cath visualization and Tacticath Contact Force sensing.	
	(2)	Electro anatomic 3D mapping system should be based on location technique using both impedance and magnetic field both. The system should be able to create cardiac maps using any of the location techniques independently based on the user and procedure requirement.	
	(3)	The system should allow the physician to switch the location mapping technology throughout the case. The system should be able to do mapping under impedance technology and magnetic technology independently.	
	(4)	Platform based on PC computer	
	(5)	The equipment shall be State of Art with capability to create 3D map of multiple Arrhythmias.	
	(6)	System shall be based upon open Platform allowing the use of any make of regular EP catheters form multiple manufacturers for both 3D Mapping & Ablation.	
	(7)	Intuitive Graphical representation of catheters & up to 256 Shadows to identify previous position.	
	(8)	System shall offer both Contact & Advanced Non-Contact Mapping for multiple arrhythmias.	
	(9)	Shall offer uninterrupted view of unlimited number EP catheters and minimum 128 Catheter Electrodes in a three-Dimensional Map.	
	(10)	Must have the capability to record simultaneously upto 3000 Virtual Unipolar Electro-grams & display them as selected by user.	

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	(11)	Shall store permanently at least 10 beats of patient data & have the facility to make a Map from stored ECG in the Review mode.	
	(12)	Shall have Respiration compensation facility by measuring actual change by impedance & modest patient movement shall not affect the procedure.	
	(13)	Shall have the capability of creating Real time geometry from upto 20 electrodes on the catheter	
	(14)	Should offer 900 GB hard drive storage data with full disk encription for patient data	
	(15)	Shall offer option of doing pediatric cases as well on the 3D system.	
	(16)	Shall offer feature of simultaneous Real time and review options.	
	(17)	While doing complex fractionated electro-gram (CFE) mapping system shall allow user to define data collection interval from 1-8 seconds.	
	(18)	3D system shall be able to integrate with all the equipment in the cath lab including the existing Recording system and RF Generator (including Cryo).	
	(19)	3D System shall have a minimum of 2 KHz sampling rate for best signal quality.	
	(20)	Shall be CE and USFDA approved as mark of quality standard.	
	(21)	Shall have advanced capability of displaying simultaneous two live maps- Voltage and time maps.	
	(22)	System should be capable to Collect Activation timing & Voltage maps through Bipolar, unipolar and Omnipolar Electrograms	
	(23)	Shall be able to do faster high density mapping by allowing point collection from all electrodes of the catheter.	
	(24)	System should be capable to display Activation map overlayed by the Activation Vector direction of all the activation points collected	
	(25)	System should have a mappling feature where arrows representing activation direction as an overlay to any of the available maps	
	(26)	System should be capable to Display colour coded Waveform Speed (Conduction Velocity) map	
	(27)	System should have the Capability of map type showing the apparent speed at which the depolarization wave travel through the cardiac tissue	
	(28)	System should have a software to eliminate the best possible wrong user collected activation point.	
	(29)	System should be capable of model creation using End Respiration gating algorithm	
	(30)	System should be capable to Visualize the Mapping catheters which looks waveforms in Two direction and chose the true bipolar	
	(31)	System should be able to display the calculated waveform of the optimal bipole (maximum voltage) independent of catheter orientation	
	(32)	System should have the capability to visualize catheter movements from Femoral Vein/Artery during Zero Fluro ablations	
	(33)	Shall provide option of Automatic mapping of the defined area for faster mapping and marking points automatically.	
	(34)	System should have an integrated Contact force technology	
	(35)	System should provide the software and option of remote clinical support	
	(36)	The system should be compatible and completely integrable with the conventional EP Lab.	
	e.	**IRRIGATION PUMP**	
	(1)	The supplier should provide the saline flow irrigation pump (with options for both low and high flow rates) and integration to the RF ablator to facilitate irrigated ablations.	
	(2)	It should be possible to switch between both low and high flow rates automatically (preferably) or manually.	
	(3)	The pump should be able to provide flow rate of up to 40ml/min	
	(4)	It should have bubble detection feature of up to 2µL air bubble detection	
	(5)	It should have alarming features for Bubble detection, communication lost, door open, pressure sensor not connected and occlusion.	
	(6)	Should be USFDA & CE approved.	

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	f.	**The specs for ICE system are as follows:**		
	(1)	A fully versatile echo imaging platform that utilizes intra cardiac electrocardiography (ICE) technology in invasive setting to visualize cardiac structures and blood flow.		
	(2)	It provides digital image acquisition and display of images from the **intra cardiac** probe inserted into the heart through intravascular access.		
	(3)	Tissue Harmonic Imaging with patented Pulse Inversion Technology.		
	(4)	Imaging Modes: 2-D, M-Mode, PW & CW Doppler, Color Flow Doppler, Tissue Doppler		
	(5)	DICOM Networking Compatibility		
	(6)	CD, DVD, thumb drive and PC format export capability		
	(7)	TEE and surface probe compatible		
	(8)	Interface capability with Conventional EP Lab platform.		
	(9)	Should provide increased consistence from user to user and should adjust imaging parameters with the push of a button.		
	(10)	Should provide fully articulating flicker free 19-inch-high resolution flat panel display with nearly infinite positioning adjustments.		
	(11)	Support for up to three on-board peripherals or probes		
	(12)	On board patient reporting with embedded images.		
	(13)	Adaptive image processing for noise and artifact reduction to improve tissue conspicuity.		
	(14)	System should CE and USFDA Approved		
	(15)	System should have a standalone ICE technology. It can be used individually in different types of cases like during ASD/VSD/PDA devices and Electrophysiology procedures both.		
	(16)	The Consumables and the system should be from the same manufacturer.		
	g.	**Catheters:**		
	Ser No	**Description**	**Qty**	
	(1)	Supreme Quadripolar Fixed Carve JSN	10	
	(2)	Supreme Quadripolar Fixed Carve CRD	5	
	(3)	Supreme Quadripolar Fixed Carve CRD 2	10	
	(4)	Connector for Quadripolar	10	
	(5)	Inquiry Steerable Decapolar Catheter	15	
	(6)	Connector for Inquiry Steerable Decapolar Catheter	3	
	(7)	Therapy Ablation Small	5	
	(8)	Therapy Ablation Medium	10	
	(9)	Therapy Ablation Large	3	
	(10)	Connector for Therapy Ablation	3	
	(11)	FlexAbility Asymmetric Bi directional Irrigation tip Ablation Catheter	3	
	(12)	Optima Plus PV mapping Catheter	5	
	(13)	Connecting Cable for optima	1	
	(14)	Livewire BDB duo deca Cathter	3	
	(15)	Connecting Cable for Livewire BDB duo deca catheter	1	
	(16)	Ensite X Patch	15	
	(17)	Agilis Sheath Small curve Bidirectional	2	
	(18)	Agilis Sheath Medium curve Bidirectional	3	
	(19)	Agilis Sheath Large curve Bidirectional	1	
	(20)	Swartz Sheath SR0	5	

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	(21)	Swartz Sheath SR1	5	
	(22)	Swartz Sheath SL0	10	
	(23)	Swartz Sheath SL1	10	
	(24)	BRK Needle	5	
	(25)	Cool point Pump Circuit	10	
	(26)	Advisor HD Grid Mapping Catheter	3	
	(27)	Advisor HD Grid Mapping Cath Cable	1	
	(28)	Tacticath Contact Force Sensing Catheter	3	
	(29)	ICE Catheters	5	
5.	**Standard accessories:** To be mentioned			
6.	Power Supply	220 VAC ± 10%, 50 Hz		
7.	**Complete BOQ/BOM.** All Foreign & Local supplied items to be listed separately for full range of operation of the equipment as per following table:			

Ser	Name of item	Qty	Brand	Model	Country of Origin	Country of Manufacturer	Remarks

8.	**Foreign Training**		
	a. Operational Training	Clinical training for 2 (two) physicians from respective user Department (EP Lab Related). 1 (one) technician from EP department for 2 weeks.	
	b. Repair/Maintenance Training	Not required	
9.	**Local Training**		
	a. Operational Training	02x physicians from respective user Department (EP Lab Related) for 01 week.	
	b. Repair/Maintenance Training	02x EM Tech for 02 weeks.	
10.	Warranty	05 (Five) years from the date of issuance of Inspection Note (I/Note).	
11.	After sales service	10 (Ten) years from the date of installation	
12.	Certificate of quality	US-FDA and CE Certificate must be submitted with offer.	
13	Books and Publication	**Following books and publication will be supplied in English along with the stores free of cost.** a. Operational manual – 03 Copies (01x Original & 02x Photocopies) b. Repair/Maint/Service manual including details circuit/ Schematic diagrams– 03 Copies (01x Original & 02x Photocopies) c. Parts Catalogue/Master Parts list– 03 Copies (01x Original & 02x Photocopies) d. 100% Spare Parts list with price – 02 x Original copies **Note:** In addition to hard copy, a soft copy CD/DVD containing all books and publications will be supplied by the supplier free of cost.	
14.	Other feature/items not listed above but required for full range of operation of the offered equipment to be mentioned and to be supplied with main equipment.		