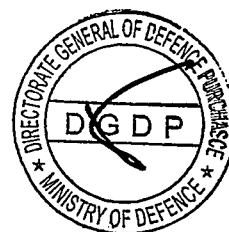


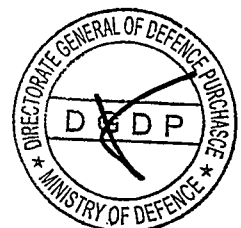
**TECHNICAL SPECIFICATION FOR RADIOFREQUENCY (R.F) GENERATOR FOR E.P ABLATION**  
**QUANTITY-01, (DP-5)**

Ser	Description	Technical specification	To be filled up by the Principal/ Manufacturer
(a)	(b)	(c)	(d)
1.	<b>General Specification:</b> General specifications are as under :		
	a. Nomenclature	Radiofrequency (R.F) generator for E.P ablation, PVMS-271117, Qty-01	
	b. Brand	To be mentioned.	
	c. Model	To be mentioned. <b>Model should be latest.</b>	
	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	<b>Group-A</b> ( 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/ Equipments/ Accessories and Local supplied item to be mentioned specifically.	
2.	<b>Function/Capability:</b> To be mentioned.		
3.	<b>Features/Facilities:</b>		
	a. <b>Recording System</b>		
	(1)	Should have a 12 -Body Surface ECG	
	(2)	Should have unipolar intra cardiac channels up to 120	
	(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 color printer	
	(6)	Operating system should be preferably Windows 10 or latest.	
	(7)	HDD minimum 500 GB and minimum 8GB 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)	Continuous surface ECG visualization	
	(13)	Facility of Split screen display for re-viewing & matching the EGMs	
	(14)	On-line view of real time & review data simultaneously	
	(15)	Selectable amount of data to be stored per patient	
	(16)	Computer based display of RF parameter	
	(17)	Amplifier with 32bit (or more) sample conversation rate at 2KH or more.	
	(18)	Should have option of automatic export of screen page to power point slide	
	(19)	Adequate filtering or good signal quality	
	(20)	User configurable reporting format	
	(21)	Data transfer to PowerPoint, JPEG or similar format	
	(22)	On-line display of RF parameters graphically in the EP software	
	(23)	Aggregate report of RF delivery per case	
	(24)	Only one keyboard to control the complete system.	
	(25)	System should have at least three minimum 23" Monitors	



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	<p><b>b. <u>Stimulator</u></b></p> <table border="1" data-bbox="156 322 1283 517"> <tr><td>(1)</td><td>Must be preferably separate Digital Stimulator Integrated to the Amplifier</td></tr> <tr><td>(2)</td><td>Should have a facility of 4 pacing channels with up to 6 extra stimulation options</td></tr> <tr><td>(3)</td><td>Should have 9 preprogrammed protocol and 10 programmable protocol</td></tr> <tr><td>(4)</td><td>Should have an option of Stimulator Touch screen.</td></tr> <tr><td>(5)</td><td>Stimulation protocols can be controlled through touch screen, keyboard and mouse.</td></tr> </table> <p><b>c. <u>Radio Frequency Ablator System</u></b></p> <p>(1) RF Ablator should be of 100 watt            (2) Must be companies compatible with Thermistor or Thermocouple catheters of all leading            (3) Should have a memory features for ablation parameter storage &amp; recall            (4) Must have auto cut-off intelligence feature in RF ablator            (5) Must have Temperature and Power Control Mode available</p>	(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 options	(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.		
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4.	<p><b><u>Advance 3D Cardiac Electro-Anatomical Mapping System</u></b></p> <p><b>a. <u>Specification</u></b></p> <ul style="list-style-type: none"> <li>(1) Capable of 3D non-fluoroscopic mapping of arrhythmia facilitates radio frequency ablation.</li> <li>(2) Electro anatomic 3D mapping system should be based on location technique using Impedance and Magnetic Field both. System should be capable of creating cardiac maps using any of the above-mentioned location technique independently also based on the user and procedure requirement.</li> <li>(3) Platform based on PC computer</li> <li>(4) The system should be State of Art with capability to create 3D map of multiple Arrhythmias.</li> <li>(5) System should be based upon open Platform allowing the use of any make of regular EP catheters form multiple manufacturers for both 3D Mapping &amp; Ablation.</li> <li>(6) System should have Intuitive Graphical representation of catheters up to 256 Shadows to identify previous position.</li> <li>(7) System should offer both Contact &amp; Advanced Non-Contact Mapping for multiple arrhythmias.</li> <li>(8) System should have the capability of Single Beat Non-Contact Mapping to treat Non- sustained arrhythmias &amp; create Voltage Map from a single PVC beat.</li> <li>(9) System should offer uninterrupted view of unlimited number of EP catheters and minimum 128 Catheter Electrodes in a three-Dimensional Map.</li> <li>(10) System should have the capability to record simultaneously up to 3000 Virtual Unipolar Electro grams &amp; display them as selected by user.</li> <li>(11) System should store permanently at least 10 beats of patient data &amp; have the facility to make a Map from stored ECG in the Review mode</li> <li>(12) System should have Respiration compensation facility by measuring actual change by impedance &amp; modest patient movement should not affect the procedure.</li> <li>(13) System should have the capability of creating Real time geometry from up to 20 electrodes on the catheter.</li> <li>(14) Should be 900 GB or more hard drive storage for data with full disk encryption for patient data.</li> <li>(15) System should be capable of doing pediatric cases as well with pediatric consumables required for pediatric patients</li> <li>(16) System should offer feature of simultaneous Real time and Review Options.</li> </ul>												



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	<p>(17) While doing complex fractionated electro gram (CFE) mapping system should allow user to define data collection interval from 1-8 seconds.</p> <p>(18) System should be able to integrate with EP Recording system, RF Generators (including Cryo).</p> <p>(19) System should have a minimum of 2 KHz sampling rate for best signal quality.</p> <p>(20) System should be CE and USFDA approved as mark of quality standard. System should provide the software and option of Remote clinical support</p> <p>(21) System should have advanced capability of displaying simultaneous two live maps- Voltage and time maps.</p> <p>(22) System should display both Bipolar and Unipolar maps for enhanced visualization.</p> <p>(23) System should be able to do faster high-density mapping by allowing point collection from all electrodes of the catheter.</p> <p>(24) System should be capable of doing automatic mapping of the defined area for faster mapping and marking points automatically.</p> <p>(25) System should have an integrated contact force technology.</p> <p>(26) System should be able to display the calculated waveform of the optimal bi pole (maximum voltage) independent of catheter orientation.</p> <p>(27) System should have a mapping feature where arrows representing activation direction as an overlay to any of the available maps.</p> <p>(28) System should have the capability of map type showing the apparent speed at which the depolarization wave travel through the cardiac tissue.</p> <p><b>b. Irrigation Pump:</b></p> <p>(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.</p> <p>(2) It should be possible to switch between both low and high flow rates automatically (preferably) or manually.</p> <p>(3) The pump should be able to provide flow rate of up to 40ml/min</p> <p>(4) It should have bubble detection feature of up to 2µL air bubble detection</p> <p>(5) It should have alarming features for bubble detection, communication lost, door open, pressure sensor not connected and occlusion.</p> <p>(6) Should be US FDA &amp; CE approved.</p>		



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5.	<p><b><u>Technical Specifications for Intra Cardiac Echocardiography</u></b></p> <p>a. A fully versatile echo imaging platform that utilizes intra cardiac electrocardiography (ICE) technology in invasive setting to visualize cardiac structures and blood flow.</p> <p>b. It provides digital image acquisition and display of images from the intra-cardiac probe inserted into the heart through intravascular access.</p> <p>c. Tissue Harmonic Imaging with patented Zone Sonography Technology.</p> <p>d. Imaging Modes: 2-D, M-Mode, PW &amp; CW Doppler, Color Flow Doppler, Tissue Doppler</p> <p>e. DICOM Networking Compatibility.</p> <p>f. CD, DVD, thumb drive and PC format export capability.</p> <p>g. Should provide increased consistence from user to user and should adjust imaging parameters with the push of a button.</p> <p>h. Should provide fully articulating flicker free min 19-inch-high resolution flat panel display with nearly infinite positioning adjustments.</p> <p>J. Support for up to three on-board peripherals or vascular probes. On board patient reporting with embedded images.</p> <p>k. Adaptive image processing for noise and artifact reduction to improve tissue conspicuity.</p> <p>l. System should be CE and US FDA approved.</p> <p>m 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.</p> <p>n. The Consumables, probes and the system quoted should be preferably from the same manufacturer or principal.</p> <p>p. ICE system should have capability to integrate with conventional EP Lab platform.</p>		
6.	<p><b><u>Standard Specification :</u></b></p> <p>a. All the components should have FDA &amp; CE certificate as the mark of quality Standard.</p> <p>b. All the interconnection between the spare parts should be through fiber optic cables.</p> <p>c. All the components of EP Lab, Recording System, Stimulator, RF Ablator 3D Mapping System and ICE System should be from Single Principle/manufacturer.</p>		
7	<p><b>Standard accessories:</b> To be mentioned</p>		
8.	<p>Power Supply</p>	<p>Input voltage 220 VAC ± 10%, 50 Hz</p>	



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9.	<b>Complete BOQ/BOM.</b> All Foreign & Local supplied items to be listed separately for full range of operation of the equipment as per following table:																	
	<table border="1"> <thead> <tr> <th>Ser</th> <th>Name of item</th> <th>Qty</th> <th>Brand</th> <th>Model</th> <th>Country of Origin</th> <th>Country of Manufacturer</th> <th>Remarks</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Ser	Name of item	Qty	Brand	Model	Country of Origin	Country of Manufacturer	Remarks									
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10.	<b>Foreign Training</b>																	
	a. Operational Training	Not required																
	b. Repair/Maintenance Training	Not required																
11.	<b>Local Training</b>																	
	a. Operational Training	04x Cardiologist for 01 week.																
	b. Repair/Maintenance Training	02x EM Tech for 01 week.																
12.	Warranty	07 (Seven) years from the date of issuance of Inspection Note (I/Note).																
13.	After sales service	12 (Twelve) years from the date of installation																
14.	Certificate of quality	FDA/CE/JIS Certificate must be submitted with offer.																
15.	Books and Publication	<p>Following books and publication will be supplied in English along with the stores free of cost (As per requirement of EME Dte).</p> <p>a. Owners/ Operators Manual in English (Book type): 01 x Hard copy original (Book type) for each equipment and 01x CD/DVD (Soft copy) to be provided with the supply of the</p> <p>b. Workshop/ Repair Manual in English (Book type):</p> <p>(1) 06 x Hard copies original (Book type) and 01x CD/DVD (Soft copy) to be provided with supply of the equipment.</p> <p>(2) Online workshop/repair software to be mentioned.</p> <p>(3) 03 copies (01 x Original and 02 x photocopies) operation and maintenance manual of all components and accessories to be supplied with main equipment.</p> <p>c. 100% Updated Master Spare Parts Catalogue in English (Book type): 06 x Hard copies original (Book type) and 01x CD/DVD (soft copy) to be provided with supply of the equipment.</p> <p>d. Complete and Updated Master Spare Parts Price Catalogue/ list in English (Book Type): 01 x Hard copy original (Book type) and 01x CD/DVD (soft copy) to be provided with the supply of the equipment.</p>																
16.	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.																	

