ANX D TO
DGDP TENDER NUMBER 216.07.473.24
DATED: 13 JANUARY 2025

**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. | **General Specification:** General speaacifications 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. **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/ Equipments/ Accessories and Local supplied item to be mentioned specifically. | |
| 2. | **Function/Capability:** To be mentioned. | | |
| 3. | **Features/Faciloties:**<br>a. **Recording System** | | |

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| (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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| | b. **Stimulator**<br>(1) Must be preferably separate Digital Stimulator Integrated to the Amplifier<br>(2) Should have a facility of 4 pacing channels with up to 6 extra stimulation options<br>(3) Should have 9 preprogrammed protocol and 10 programmable protocol<br>(4) Should have an option of Stimulator Touch screen.<br>(5) Stimulation protocols can be controlled through touch screen, keyboard and mouse.<br>c. **Radio Frequency Ablator System**<br>(1) RF Ablator should be of 100 watt<br>(2) Must be companies.compatible with Thermistor or Thermocouple catheters of all leading<br>(3) Should have a memory features for ablation parameter storage & recall<br>(4) Must have auto cut-off intelligence feature in RF ablator<br>(5) Must have Temperature and Power Control Mode available | | |
| 4. | **Advance 3D Cardiac Electro-Anatomical Mapping System**<br>a. **Specification**<br>(1) Capable of 3D non-fluoroscopic mapping of arrhythmia facilitates radio frequency ablation.<br>(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.<br>(3) Platform based on PC computer<br>(4) The system should be State of Art with capability to create 3D map of multiple Arrhythmias.<br>(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 & Ablation.<br>(6) System should have Intuitive Graphical representation of catheters up to 256 Shadows to identify previous position.<br>(7) System should offer both Contact & Advanced Non-Contact Mapping for multiple arrhythmias.<br>(8) System should have the capability of Single Beat Non-Contact Mapping to treat Non- sustained arrhythmias & create Voltage Map from a single PVC beat.<br>(9) System should offer uninterrupted view of unlimited number of EP catheters and minimum 128 Catheter Electrodes in a three-Dimensional Map.<br>(10) System should have the capability to record simultaneously up to 3000 Virtual Unipolar Electro grams & display them as selected by user.<br>(11) System should store permanently at least 10 beats of patient data & have the facility to make a Map from stored ECG in the Review mode<br>(12) System should have Respiration compensation facility by measuring actual change by impedance & modest patient movement should not affect the procedure.<br>(13) System should have the capability of creating Real time geometry from up to 20 electrodes on the catheter.<br>(14) Should be 900 GB or more hard drive storage for data with full disk encryption for patient data.<br>(15) System should be capable of doing pediatric cases as well with pediatric consumables required for pediatric patients<br>(16) System should offer feature of simultaneous Real time and Review Options. | |

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

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

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<tr><th>Ser</th><th>Description</th><th colspan="2">Technical specification</th><th>To be filled up by the Principal/ Manufacturer</th></tr>
<tr><td></td><td></td><td colspan="2"></td><td rowspan="2"></td></tr>
<tr><td>9.</td><td colspan="3"><u>Complete BOQ/BOM.</u> All Foreign & Local supplied items to be listed separately for full range of operation of the equipment as per following table:
<table>
<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>
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<tr><td>10.</td><td colspan="2"><u>Foreign Training</u></td><td></td></tr>
<tr><td></td><td>a. Operational Training</td><td>Not required</td><td></td></tr>
<tr><td></td><td>b. Repair/Maintenance Training</td><td>Not required</td><td></td></tr>
<tr><td>11.</td><td colspan="2"><u>Local Training</u></td><td></td></tr>
<tr><td></td><td>a. Operational Training</td><td>04x Cardiologist for 01 week.</td><td></td></tr>
<tr><td></td><td>b. Repair/Maintenance Training</td><td>02x EM Tech for 01 week.</td><td></td></tr>
<tr><td>12.</td><td>Warranty</td><td>07 (Seven) years from the date of issuance of Inspection Note (I/Note).</td><td></td></tr>
<tr><td>13.</td><td>After sales service</td><td>12 (Twelve) years from the date of installation</td><td></td></tr>
<tr><td>14.</td><td>Certificate of quality</td><td>FDA/CE/JIS Certificate must be submitted with offer.</td><td></td></tr>
<tr><td>15.</td><td rowspan="5">Books and Publication</td><td>Following books and publication will be supplied in English along with the stores free of cost (As per requirement of EME Dte).</td><td></td></tr>
<tr><td>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</td><td></td></tr>
<tr><td>b. Workshop/ Repair Manual in English (Book type):<br>(1) 06 x Hard copies original (Book type) and 01x CD/DVD (Soft copy) to be provided with supply of the equipment.<br>(2) Online workshop/repair software to be mentioned.<br>(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.</td><td></td></tr>
<tr><td>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.</td><td></td></tr>
<tr><td>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.</td><td></td></tr>
<tr><td>16.</td><td colspan="2">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.</td><td></td></tr>
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