

West Bengal Medical Services Corporation Limited Swasthya Sathi GN-29, Salt Lake, Sector-V Kolkata-700091

Phone No (033) 40340307/320 E mail: procurement@wbmsc.gov.in

Supply and commissioning of 1(one) unit of Coagulator with Solid State Microprocessor Controlled Unit to offer Bipolar Output with Controlled Irrigation System for Department of Neurosurgery OT at Calcutta National Medical College & Hospital (Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-088/2025

Dated-31.01.2025

Amendment-I

REVISED TECHNICAL SPECIFICATION

Technical Specification

<u>Schedule-I</u>

Coagulator with solid state microprocessor-controlled unit to offer bipolar output with controlled irrigation system

Bipolar Generator for coagulation

- The generator should be a Microprocessor Controlled Electrosurgical Unit specially designed to deliver output power dedicated for Neurosurgeries
- Unit should have Over-Current protection with indicator in the generator (preferably with bright display)
- Unit should be a bipolar output generator with both "Cut-Bipolar" and "Coag-Bipolar" features.

- The generator should not be connected to any sort of patient return electrode (A true Bipolar generator does not require Patient plate)
- Unit should generate isolated Bipolar Output to avoid any sort of leakage current to flow through patient
- Bipolar Cut and Coagulation should be activated via "Yellow" and "Blue" coloured dual pedal footswitches for activating "Cut" and "Coagulation Respectively.
- Microprocessor should monitor the output current real time basis and decrease the current in case the output-current is higher or Cut-off output in case it is beyond the desired range.
- Auto adjust feature in terms of Output should be available.
- Output duty cycle should be 33.33% at maximum output power.
- Sealing performance should be satisfactory.
- The Generator should have a specialized waveform capable of reducing charring.
- Error Alarms for the following must be available Sound Controller, Relay Monitoring & malfunction & Over Current in Output
- Coagulation Output must be higher than or equal to 1MHz damped Aperiodic for smooth coagulation with minimum charring
- Cut output Should be higher than or equal to 1MHz Sinusoidal
- Maximum available Bipolar Cut power should be at least 100 watt or more.
- Maximum available bipolar Coagulation power should be at least 75 watts or more
- Generator should have no or least Radiofrequency emission so that no other equipment present in operation room suffers from interference.
- The generator should meet all product safety compliances like
 - ANSI/AAMI ES 60601-1: 2005, EN 60601-1: 2006, CAN/CSA-C22.2 No. 601-1-08
 - Medical Electrical Equipment General Requirement for Safety and Essential Performance
 - IEC 60601-2-2: 2009, Particular Standards for the Safety of High Frequency Surgical Equipment
 - EN 60601-1-2: 2009, Electromagnetic Compatibility-Requirements and Tests
- The System should come with bipolar irrigator (pump) that should be fitted to the cart provided. It should come with Bipolar irrigator integrated tubing, bipolar cord set & unitized/un-unitized plug.
- The bipolar irrigator should display the following:
- Irrigation Rate Display This LED indicator numerically shows the irrigation rate setting for the chosen irrigation mode

- Cut Irrigation Mode Indicator When this indicator is illuminated, the irrigation rate display indicates the cut rate of irrigation
- Coagulation Irrigation Mode Indicator When this indicator is illuminated, the irrigation rate display indicates the coagulation rate of irrigation
- Caution Indicator If the caution indicator is illuminated or flashing, an error condition has been detected by the irrigator
- Irrigation Rate Knob to choose between the coagulation irrigation mode setting and cut irrigation mode setting
- Irrigator Door Allows access to the pump hood and pump rollers for installation of the irrigation tubing set
- Pump Rollers Rotate to push fluid through the irrigation tubing
- Equipotential Connector to connect all neutral & grounding wires
- The system should be Electromagnetic Compatible authentic documentation to be submitted
- The irrigator should be capable to have variable irrigation rates.
- The generator should have touch screen to display the actual power being delivered and fully operable from the same touch screen
- It should be programmable as per surgeon's preference.
- It should have a function for controlling brightness, alarms and Tone volume.
- Easy output power adjustment should be available
- Should work with Main voltage 220-240 V AC, 50-60 Hz
- CE European marked & CDSCO approved
- Should meet the following safety standards: IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-11
- Should have auto bipolar mode with auto start/stop capability
- Non-stick Bipolar Forceps to be supplied with following descriptions.
 - i. Tip Metal should be a heavy-duty metal to avoid damage to the quality of tip due to regular usage.
 - ii. Hollow tine design for irrigating forceps
 - iii. To be supplied with reusable bipolar cord 5 nos
 - iv. Non-Stick Silver tip Bipolar non-irrigating bayonet forceps with guide stop to prevent scissoring effect, 22/24 cm 45 degree tip up with a tip diameter of 0.7mm 1 No
 - v. Non-Stick Silver tip Bipolar non-irrigating bayonet forceps with guide stop to prevent scissoring effect, 24/25 cm with a tip diameter of 0.7mm 1 No

- vi. Non-Stick Silver/Gold tip Bipolar non-irrigating bayonet forceps with guide stop to prevent scissoring effect, 19/22 cm with a tip diameter of 0.7 mm-1 No
- vii. Non-Stick Silver/Gold tip Bipolar irrigating bayonet forceps with guide stop to prevent scissoring effect, 19/20 cm with a tip diameter of 0.7 mm 1 No
- viii. Non-Stick Silver/Gold tip Bipolar non-irrigating bayonet forceps with guide stop to prevent scissoring effect, 19/22 cm with a tip diameter of 0.4 mm 1 No

The system should be supplied with a cart from the same manufacturer. The cart should have the following:

- 1. Hanger, IV pole, Mounting bracket to mount the irrigation system, Shelf (minimum 3), Equipment strap (minimum 3 nos), cord wrap (2 nos), cond strap (2 nos), Hanger bracket, drawer, drawer lock & wheel lock (4 nos)
- 2. Overall height should be minimum 180 cm to ensure proper irrigation flow
- 3. IV pole should have a load strength of 2000 ml of saline
- 4. The cart should be easily movable & should have minimum weight of 34 kgs to ensure stability
- 5. The longevity of the system should be at least 10 years with availability of spare parts for that period of time
- 6. The manufacturing company gives assurance for coverage of the machine under CMC for total period of 10 years including warranty period.