Technical Specificatiions of Elecrtrosurgical Unit

S.N.	Technical Specification		Bidder's Proposed Specifications	Deviation (If Any)	Page no. in technical datasheet
	Manufacturer				
	Brand				
	Type / Model				
	Country of Origin				
1.0	**Description of Function**				
1.1	Electrosurgical Units are used for cutting and coagulating electrically during surgery. Sometimes called Surgical Diathermy or Cautery machine, Suitable for all Laparoscopic & open surgeries				
2.0	**Operational Requirements**				
2.1	Microcontroller-based isolated Electro Surgical Generator				
3	**System Configuration**				
3.1	300Watt Elecrtosurgery Unit with complete accessories.				
4.0	**Technical Specification**				
4.1	Ergonomic Operator interface (Quick Step Control).				
4.2	It shall be able to maintain set power over wider range of tissue				
4.3	It shall have built-in patient plate contact quality monitoring system for patient's safety.				
4.4	There shall be two Simultaneous coagulation facility in Monopolar.				
4.5	It shall ensure high frequency leakage monitoring and controlling system along with self test during Power ON				
4.6	There shall be atleast 5 modes in monopolar & 2 modes in bipolar.				
4.7	There shall be audio and visual indication for easy interpretation, different audible tones for activation and warnings, light indication for split or non-split patient plate connection.				
4.8	The unit shall have 3 pedal footswitch.				
4.9	Monopolar Cut: Pure - Continues output, 300 W at 300 Ω, CF 1.5 Lowcut - Current for laparoscopic & general procedure, 200 W at 300 Ω, CF 1.5 Blend - 100 W at 300 Ω, CF 2.5				
4.10	Monopolar Coag : Fulgurate - Nominal Frequency 550 kHz, 100 W at 500 Ω, CF 7 Desicate- Nominal Frequency 660 kHz, 100 W at 500 Ω, CF 5.5				
4.11	Bipolar : Force - Medium output voltage, 80 W at 100 Ω, CF 1.5 Cut - Nominal frequency 660 kHz, 80 W at 100 Ω, CF 1.5				
5.0	**Accessories, spares and consumables**				
5.1	· Footswitch Standard (Three Pedal) : 1 nos.				
5.2	· Handswitch pencil with cable - Disposable : 2 nos.				
5.3	· Handswitch pencil with electrode set - Reusable : 1 nos.				
5.4	· Bipolar forceps : 1 nos. Reusable				
5.5	· Bipolar cord for forecep: 1 nos. Reusable				
5.6	· Dual/Split Pad patient plate : 2 nos Disposable				
6.0	**Operating Environment**				
6.1	The product 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 Single Phase fitted with appropriate plug. The power cable must be at least 3 metre in length.				
7.0	**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 60601-2-2 Medical Electrical Equipment - PART 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment.				
8.0	**User Training**				
8.1	The bidder must conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.				
9.0	**Warranty**				
9.1	Comprehensive warranty for 1 year after acceptance.				

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10.0	**Maintenance Service during Warranty Period**			
10.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.			
10.2	The bidder must submit the letter of commitment regarding the availability of spare parts and accessories for next 10 years at the time of bidding.			
11.0	**Installation and Commissioning**			
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.			
12.0	**Documentation**			
12.1	Bidder should provide user (Operating) manual in English(Hardcopy and CD)			
12.2	Bidder should provide Service (Technical / Maintenance) manual in English(Hardcopy and CD).			
12.3	List of important spare parts and accessories with their part number and costing.			
12.4	Bidder should be provide certificate of calibration and inspection from the manufacturer during installation.			

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