Technical Specification for Electrosurgical Unit (Diathermy Machine)

S N.	Purchaser's Specifications	Bidder's Offer
	Electrosurgical unit (Diathermy Machine)	
	Manufacturer	
	Brand	
	Type/Model	
	Country of Origin	
1	**Description of Functions**	
1.1	A 300W diathermy machine (electrosurgical unit)	
2	**Operational Requirements**	
2.1	It shall operate on AC power supply in the operating theatre.	
3	**System Configurations**	
3.1	Diathermy Machine (Electrosurgical) 300W with complete accessories.	
4	**Technical Specifications**	
4.1	Nominal HF output: 300W at ~400Ω	
4.2	At least 2 modes of operation: mono-polar cutting and mono-polar/bipolar coagulation.	
4.3	Mono-polar cutting modes shall have different level of effects from pure cutting to blend cutting (cutting with haemostasis).	
4.4	Come with 3 mono-polar coagulation modes: soft, forced and spray.	
4.5	Desiccate mode for low voltage contact coagulation suitable in delicate tissue work	
4.6	Fulgurate mode for efficient non-contact coagulation in most applications.	
4.7	Spray mode for coagulation large tissue areas with minimum depth of necrosis.	
4.8	Come with 3 bipolar modes: precise, standard and macro or equivalent.	
4.9	Precise mode to have fine control of desiccation in delicate tissue.	
4.10	Standard mode for applications at low voltage to prevent sparking.	
4.11	Macro mode for applications on tissue with high resistance.	
4.12	Control panel with digital setting and display of power of modes used.	
4.13	All mono-polar and bipolar modes shall be controllable by hand switch and footswitch.	
4.14	Bipolar mode can be activated by either foot pedal and / or auto coagulate by using forceps.	
4.15	Footswitches shall be splash-proof, resistant to commonly encountered operating room fluid spills, and easy to clean. They shall incorporate suitable mechanical protection against accidental pedal depression and shall be designed to prevent the switch from sticking in the ON position.	
4.16	Unit must have automatic power regulating feature to always keep minimum current to the patient throughout the procedures.	
4.17	Shall come with Return Electrode Contact Quality Monitors (RECQMs) or equivalent to monitor the quality of electrode-skin contact to eliminate the risk of patient's burn. It shall give audio-visual alarm and deactivate output if contact between patient and electrode is loosened or disconnected.	
4.18	Come with output Leakage controller.	
4.19	Shall have over current protection.	
4.20	Shall be able to be activated from only one output at a time.	
4.21	Shall have an undefeatable audible activation-tone indicator/alarm.	
4.22	The unit must have RF activation port to tell other equipment like ECG or EEG that RF current is being generated.	
5	**Accessories, Spare Parts and Consumables**	

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5.1	All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Forms.	
5.2	The unit shall be supplied with a dedicated trolley/cart from the same manufacturer, specifically designed to accommodate the generator, with suitable drawers for safe and organized storage of accessories.	
5.3	One unit/ set of explosion-protected foot pedal for mono-polar and bipolar operation	
5.4	Reusable standard mono-polar pencil/ handle with 2 button switch **- 1 unit**	
5.5	Reusable mono-polar cord **- 1 set**	
5.6	Reusable standard mono-polar coagulation forceps. **– 1 pc**	
5.7	Reusable standard bipolar forceps with hand switch. **– 1 pc**	
5.8	Reusable bipolar cord **-1 set**	
5.9	Reusable connecting cable for patient electrode **- 1 set**	
5.10	Patient return electrode for Adult & Child **- 10 pieces each**	
5.11	Patient return electrode disposable reusable silicon **– 1 pc**	
6	**Operating Environment**	
6.1	Power supply: 220-240V AC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.	
7	**Standards & Safety Requirements**	
7.1	Submit product's valid ISO 13485 for Medical Devices	
7.2	Submit product's valid CE (MDD Directive 93/42/EEC) certificate **or** official extension notice issued directly by the notified body, clearly listing the offered model **or** MDR (2017/745) for offered medical device **or** USFDA (510K) approved product	
8	**User Training:**	
8.1	The Supplier shall 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	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
9.2	Submit commitment letter from the manufacturer for availability of spare parts for 5 years after completion of warranty period	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	Supplier must accomplish proper installation & commissioning of equipment onsite.	
12	**Documentation**	
12.1	User (Operating) manual in English.	
12.2	Service (Technical / Maintenance) manual in English.	