Electrolyte Analyser

S.N.	Purchaser's Specifications	Bidder's Offer
	Electrolyte Analyser	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	ISE electrolyte analyser (Na+, K+, Cl-) for analysis of serum, urine.	
2	**Operational Requirements**	
2.1	It shall be open system and based on ISE technology.	
3	**System Configuration**	
3.1	Electrolyte analyser with integrated printer and with complete accessories.	
4	**Technical Specifications**	
4.1	Microprocessor controlled electrolyte analyser with the measured parameter of at least Na+, K+, and Cl^-.	
4.2	Sample volume shall be less than or equal to 100ul.	
4.3	Analysing time-less than 60 seconds/test, sample throughout at least 50 samples/hour.	
4.4	Shall have fully automatic calibration of all parameters.	
4.5	Maintenance free electrodes with long warranty (1 year or at least 10000 tests).	
4.6	Shall have data display on built in LCD display screen.	
4.7	Both manual and automatic 'Standby Mode' facilities for economical operations.	
4.8	QC data, memory storage and calibration results.	
4.9	Shall have automatic flagging of abnormal result.	
4.10	The system shall utilize and easy to replace reagent system with safe fluidic waste management.	
4.11	It shall have cleaning reagents for electrodes and daily maintenance.	
4.12	Inbuilt thermal printer for printing patient data and facility to interface with computer an external printer.	
4.13	It shall have a memory of at least 200 samples.	
4.14	Shall supply reagent pack for 1000 tests with cleaning solution and 3 level quality control solution and 3 set of printer paper roll.	
5	**Accessories, spares and consumables**	
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
6	**Operating Environment**	
6.1	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, Altitude, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
6.3	Shall provide pure sine wave online UPS of suitable rating with voltage regulation and spike protection for 30 minutes back-up.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO13485:2016 for Medical Devices **AND**	

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7.2	The bidder shall submit a valid CE certificate demonstrating compliance with the In Vitro Diagnostic Regulation (IVDR) 2017/746 (or previously under In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC) or USFDA approved product certificate. Self-declaration of CE conformity shall not be accepted	
7.3	Shall meet IEC 61010-2-081safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.	
8	**User Training**	
8.1	Must provide onsite user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure planned preventive maintenance (PPM) and corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	The bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.	
12	**Documentation**	
12.1	User (Operating) manual in English	
12.2	Service (Technical / Maintenance) manual in English	
12.3	Certificate of calibration and inspection as per manufacturer guideline.	
12.4	Manufacturer shall provide commitment letter for availability of spare parts for 5 years after warranty period.	