

Supply, Installation & Commissioning of Heart Lung Machine with Heater Cooler Unit for Open Heart & Bypass Surgery

No.	Item Specifications	Fill your Specification
1	Description of function	
1.1	Heart Lung Machine is an apparatus, through which blood is temporarily diverted, during heart surgery, to oxygenate it and pump it throughout the body, thus maintaining circulation until the heart and lungs are able to return to normal functioning.	
2	Operational requirements	
2.1	Basic equipment will consist of the following unit	
	1. 5 Pump Console.	
	2. Temperature Control Module (Hypo-Hyper thermia unit) HEMOTHERM UNIT	
	3. Monitors:	
	A. Pressure monitor – arterial and cardioplegia with transducers	
	B. Time – at least three timers	
	C. Temperature Monitor with at least two probes	
	D. Cardioplegia pump should have display of total volume of each infusion along with delivery time.	
	4. Blender:	
	a) Air- Oxygen Blender with hoses and Flow meter	
	5. Safety Devices:	
	a) Level Sensor	
	b) Ultrasonic air sensor (optional)	
	Accessories will include:	
2.2	1. Stainless steel line clamps - 10 nos	
	2. Stainless steel intra cardiac suckers - 4 adult & 4 Pediatric	
3	Technical Specification	
3.1	1- Pump Console	
3.2	1. The unit should have 5 pump consoles compactly arranged with separate power supply and control modules. Should have easy access connectors for interchanging the pump.	
	2. Each individual roller pump should be capable of running independently at available voltage.	
	3. Should have a spill proof base.	
	4. The unit should be supplied with a Battery backup for at least two pumps, all safety systems and accessories for a minimum of 60 minutes. Switch over from main power to battery backup should be automatic and immediate. The battery unit should be built in to the pump base and it should be recharged automatically when the system is operating with main power supply.	
	5. Individual pump heads should have Harvey Roller pumps with facility for tubing to be used adjustable from 1/4" to 5/8" through 3/8" and 1/2" by easily changeable mechanism.	
	6. Individual pump heads should have display in digital –The total infusion volume in litres and delivery time, the flow rates in LPM and in RPM	
	7. Each Pump should have easy mechanism for occlusion setting for different thickness of tubes available in the market, 1/32" to 3/32".	
	8. Should have hand crank facility as a critical safety feature hand crank loading should be from top for faster access.	
	9. The Console should have a compact base mount for the entire pump heads together, with pole and handles.	
	10. Should have variable, changeable tubing holders in each pump head: 1/4", 3/8", 1/2" and 5/8"	
	11. Should have removable oxygenator holder.	
	12. Roller pump should have a self-diagnostic circuit with provision to detect and display critical alarm conditions. Optional Pulsatile module which can be mounted on any of the blood pump.	
	13. Should have a monitor mount with adjustable monitoring arm	
3.3	TEMPERATURE CONTROL MODULE:	
	1. Temperature Control and Monitor system with Cardioplegia Supply	
	2. Simultaneous delivery of water for arterial and cardioplegia heat exchangers and to thermal blankets to be available from suitable ports.	
	3. To work with power supply of 220± 20 V 50 Hz.	
	4. Pressure regulated blanket ports maintaining the temperature of the arterial port.	
	5. Temperature display range of 0- 50 ° Celsius	
	6. Microprocessor based unit to control, cool, rewarm and maintain temperature.	
	7. Water outlet temperature of heat exchanger and blanket range 0-40° C.	
	8. Maximum flow performance of oxygenator heat exchanger supply port 15 – 22 LPM for fast cooling; 480mmHg maximum pressure; Blanket 1.5 to 2.5 LPM at zero head.	
	9. Built in ice Maker to provide 50 lbs of ice in about 8 hours from 25° C water.	
	10. Should be capable of providing ice water for cardioplegia independently with variable cooling rate	
	11. Rewarming facility with venous difference mode settable at 6 to 10 ° C gradients to hold the water bath temperature at higher than the venous blood temperature.	
	12. Temperature probe module for the operating ranges of 0-40° C.	
	13. Temperature probes to fit in standard oxygenators (bubble / membrane)	
	14. Optional remote control unit should be capable of taking 3 Temp. Probes and display temperature in digital readouts. Alarm limits setting for at least three probes at crucial sites.	
3.4	Monitors:	
	1) PRESSURE MONITOR: Facility to monitor one arterial line pressure and one cardioplegia line pressures(total 2);along with necessary pressure transducers, cardioplegia line pressures (total 2); along with necessary pressure transducers, cables six (2 x 3 = 6) and domes reusable, with accurate digital display and alarm facilities audio and visual. Delivery, With stop, reset and start function.	
	TEMPERATURE: 4 temperature displays for patient monitoring and for cardioplegia monitoring with digital display in Celsius should be available	
3.5	Air-Oxygen Blender:	
	To work at 50-60 PSI for membrane oxygenator with water trap attached with necessary hoses and connections of minimum of 5 meters length.	
	Safety Devices: Safety monitor should have optional capability for computer interface to retrieve perfusion data	
3.6	ULTRASONIC AIR SENSOR: Ultra sonic air sensor to detect bubbles to work equally well with crystalloid and blood; should be possible to fit anywhere in the circuit easily.	
	LEVEL SENSOR SYSTEM: Ultrasonic transducers to work well with crystalloid and blood with adhesive pads, with alarm settings.	
4	Accessories:	
	1. STAINLESS STEEL LINE CLAMPS for cardio pulmonary bypass 12 Nos.	
	2. Should be capable of taking 3 Temp. Probes and display temperature in digital readouts. Alarm limits setting for at least three probes at crucial sites.	
	3. Instrument Tray with Mounting Arm	
	4. Two Thermal Blanket.	
5	System Configuration Accessories, spares and consumables	
5.1	Machine cover	
5.2	System should be provided with appropriate furniture like adjustable revolving chair for the perfusionist to operate the system. The system should contain all the above accessories in Integrated or as separate accessories.	
6	Power supply	
	Suitable online UPS of with voltage regulation and spike protection for 60 minutes back up	
7	Standards, safety and training	
	Should have European CE with 4 digit notifying body no/USFDA Approved; certificate to be provided.	
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1	Heart Lung machine as specified	1 No	
2	Stainless steel line clamps	12 Nos	
3	Stainless steel intra cardiac suckers (adult & Pead)	4 Nos Each	
4	Thermal Blanket.	2 Nos	
5	Heater cooler unit	01 nos	
8	Operating Environment		
	The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%		
	The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%		
9	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.		
	Suitable UPS with maintenance free batteries for minimum 30 min. back-up shall be supplied with the system.		
10	Standards and Safety Requirements		
	Must submit ISO13485:2003/AC:2007 for Medical Devices AND		
	Should be FDA/CE/BIS approved product.		
	Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1.		
	Certified to be compliant with IEC 61010-1, IEC 61010-2-281, 61010-2- 101 for safety.		
11	Warranty		
	Comprehensive warranty for 2 years from acceptance.		
12	Maintenance Service During Warranty Period		
	During the warranty period supplier must ensure planned preventive maintenance (PPM) and corrective/breakdown maintenance whenever required.		
13	Installation and Commissioning		
	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 user in advance, in detail.		
14	Documentation		
	User (Operating) manual in English Should provide 2 sets(hardcopy and soft-copy)		
	Service (Technical / Maintenance) manual in English Should provide 2 sets(hardcopy and soft-copy)		
	List of important spare parts and accessories with their part number and costing.		
	Certificate of calibration and inspection from factory.		