

## SPECIFICATION FOR HEART-LUNG MACHINE

Sr. No.	Technical Specification Heart-Lung Machine
1	Only the high-end/sophisticated model will be considered.
2	The heart-lung machine should have flexible pump mounting capability on masts so that the perfusionist can minimize a substantial amount of tubing and also reduce priming volume.
3	Should have a compact base with a mast system where monitors, pumps, and all other equipment can be mounted on height adjustable swivel arms of various lengths, adjustable to individual requirements.
4	Should have a battery backup of a minimum of 30 mins with all systems running and 90 mins in power-saving mode.
5	The pump should be operated on medically safe low voltage, 24 DC.
6	The pump head raceway should be horseshoe/U shaped so that blood damage (Haemolysis) is minimized by reducing the pressure spikes.
7	The system should have the following configuration- 3 large single roller pumps and 2 small single roller pumps. The Pumps should be detachable.
8	The system should be provided with a data management system with software for automatic online storage and display, including trends of all parameters before, during, and after CPB.
9	Should have a master-slave feature to set two pumps as a master-slave during blood cardioplegia delivery.
10	Touch screen monitors should be able to show all pressures, flows, volumes, levels, temperature, timing, patient data, gas flow, and concentration in real-time along with adjustable alarm limits for all parameters.
11	Selected Pump speed should be regulated automatically in level control and pressure control modes to keep the blood level or line pressure within the set limit.
12	Should be provided with a level sensor with a holder (One level sensor, one holder )

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13	Should have at least two channels for measurements and display of pressures.
14	should have a bubble detector and sensor. (Two bubble detectors and two sensors to be provided)
15	Roller Pumps should be able to deliver pulsatile flow according to the operator's selected parameter.
16	Cardioplegia control module with full monitoring of pressure, time of delivery, elapsed time, volume delivered per dose and cumulative volume delivered.
17	Temperature probes a minimum of four nasal, rectal, cardioplegia, and arterial.
18	An electronic / Mechanical Gas blender is compulsory. Gas blender for pipeline Oxygen and air to allow delivering selected FiO <sub>2</sub>
19	Should be provided BCAPTA with Continuous measurement of online parameters like PCO <sub>2</sub> , hCT, and Venous temperature can be provided.
20	Should have EVO (Electrical Venous Occluder). No manual venous occlude will be accepted.
21	Should have integrated Centrifugal Pump System.
22	Self-adjusting tubing clamps/tubing clamps adjustable with inserts should be provided for all pumps.
23	Systems should have the ability to measure two pressures through a double pressure sensor module to allow the operator to control two pumps independently of one another. The control and display module of the system panel is used for setting parameters and adjusting the zero points.
24	Systems should have compatible temperature control module/heater-cooler module
25	Cuvettes for O <sub>2</sub> saturation and haematocrit monitor: -
a)	1/2" Qty-100
b)	3/8" Qty-50

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c)	1/4" Qty-50
25	Should be FDA and/or CE approved.
<b>Sr. No.</b>	<b>Technical Specification 3T Heater Cooler</b>
1	The unit is capable of operating continuously at an ambient temperature of 2 - 40.5 degrees Celsius.
2	The unit has 3 independent tanks and 3 separate circuits and these circuits can control the temperature oxygenator, patient blanket, and cardioplegia simultaneously.
3	The accuracy is up to 0.1 C.
4	Settings should be adjustable to 0.1
5	The heater-cooler has an automatic De-airing facility
6	The heater-cooler unit is also compatible to get integration into the heart-lung machine.
7	One adult cooling blanket and one pediatric cooling blanket along with the compatible blanket connection kit should be supplied along with the machine.
8	Should be capable of providing hot and cold water for heat exchanger and cardioplegia.
9	Should have a separate port for supplying water to the blankets.
10	The System should operate on 220V/50HZ single-phase supply.
11	Should have a separate port for draining water from cold and hot tanks.

**Conditions for tender:**

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.

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2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ or European CE be approved by 4 digits notified body?
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.

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14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6<sup>th</sup> to 10<sup>th</sup> year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC

contract without assigning any reason for the same, which shall be binding upon the bid.



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