

SPECIFICATION FOR APHAERESIS MACHINE

1. The cell separator should have a facility for all blood components (platelets, plasma, and red cell collection including peripheral blood stem cell with both single and double access, and also therapeutic plasma aphaeresis and red cell exchange)
2. Should be fully automatic microprocessor controlled and should have continuous flow separator/ intermittent flow during both single and double access to minimize the procedure duration
3. Should have a help screen, troubleshooting menu, alphanumeric display, and extended memory for special procedures and research protocols
4. Should be able to perform priming with normal saline or with a mixture of anticoagulant and self-test as part of donor safety.
5. Should have in-build cuff pressure and prompt grip for donor comfort and better flow
6. Should have auto cuff mechanism for inflation and deflation
7. In case of inlet line occlusion, the cell separator should be able to rectify it automatically
8. Should have fluid leak detector for donor safety
9. Should have provision for saline reinfusion to donor/ patients
10. Extra-corporeal volume should not be more than 250 ml
11. The system should have an online leukocyte reduction system
12. Should be able to regulate anticoagulant delivery
13. Should not have bolus return of blood to ensure reduced citrate reactions for donor safety and comfort
14. Should have a data port to enable the equipment to be connected to the printer
15. Should be equipped with UPS compatible to complete one cycle in case of power failure
16. Should have automatic door lock for centrifuge during the procedure
17. Interface detector should be able to continuously monitor the collection line to avoid any contamination during each protocol
18. Should have a totally closed system
19. Lockable caster and wheels for mobility
20. Protocols for blood components separation and peripheral stem cell collection should be provided
21. Should have a semi-automated kit loading facility

22. System Configuration Accessories, spares, and consumables:

- a. 10 disposable kits should be provided with equipment for training and standardization

23. Standards and Safety

- a. DCGI approval is mandatory

Refrigerated Transport Box

- a. Blood carriage trolley with temperature display and refrigeration maintaining temperature from 2-8 C
- b. 45-50 Litre capacity to transport 40 or more blood bags
- c. Thermal insulated high-quality polyurethane & virgin plastic
- d. Suitable for movement over rough and uneven terrain.

Conditions for tenderer:

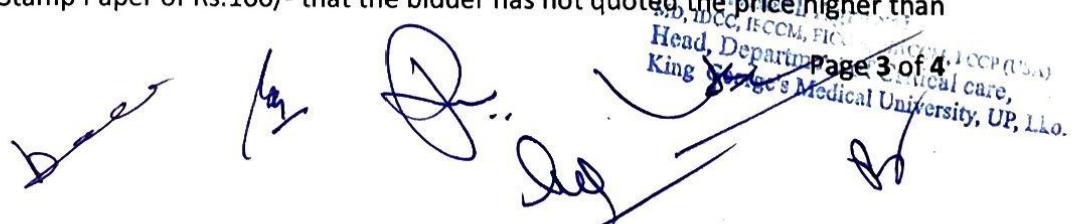
1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting 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.

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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.
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

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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., 6th, 7th, 8th, 9th and 10th 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 6th to 10th 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.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

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