

## SPECIFICATIONS FOR FULLY AUTOMATED COMPONENT EXTRACTOR

1. An automated blood component extractor equipment, is used to provide the means for the controlled transfer of one or more blood component(s) from the centrifuged blood bag into one or more transfer pack(s).
2. Able to provide pure components with optimum leukoreduction levels
3. Compatible and able to maximise the extraction performances for Top and Bottom blood bags, apart from other conventional types such as double, triple, and quadruple (optional) blood bags.
4. Able to automatically seal the blood bag tubing at the end of the separation Process, with the help of clamps integrated with sealers.
5. Option to store various programs (in total 7 programs with 9 protocols each) based on Buffy coat volume, Seal options and Optical sensitivity, hence optimising the volume & yield of the component for standard dosages.
6. Microprocessor-controlled & electrically driven pressure plate mechanism with 15 pairs of Optical sensors, to provide better control and separation of buffy coat from the primary bag.
7. Alphanumeric LCD Display and Keyboard, allows the operator to handle very easily for the separation process. Available with Pack Hanger & Cannula breaker on the front side allows the operator for easy separation technique. Has top & bottom Clamps with two Integrated Sealers, controlling the flow of components from the primary bag to different transfer packs and also being able to seal the tubes automatically at the end of each process.
8. Option for using different types of profile backplates (9 backplates can be used), to optimise the separation as per the different protocols of PRP, Buffy coat, Buffy coat Pooling, etc. Electromagnet mechanics should open the clamps in case of power failure, allowing the operator to safeguard the blood components being separated. Has an Upper Optical sensor to detect the presence of Red cells in tubing, during the second separation protocol of platelet removal, hence optimizing the platelet yield and leukoreduction. Capable of volume reduction of Cord Blood Units and separated into Buffy coat containing stem/progenitor cells. The adjustment of the Buffy coat volume parameter shall provide flexibility to the blood centre, to go for future protocols such as buffy coat pooling. Option available to upgrade with a data management system-Optilink, allowing measurement of each component being prepared and acquisition of

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separation process data including blood components volume, time, blood bag type used, operator ID, etc.

9. Operated with an input voltage within the range of 100-240VAC at 50/60 Hz.

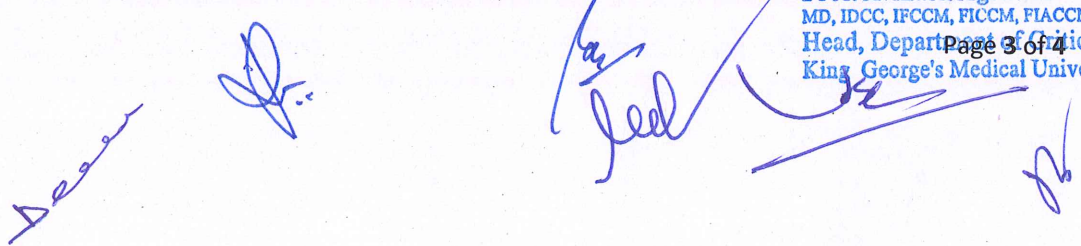
**Conditions for tender:**

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. WHO-GMP;ISTM;CE;SGS UKAS; ISO 13845.
5. Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) IEC-60601-1-2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.
6. In compliance with EN 60601-1 Standards (1988), Moisture protection: IPX 1, EN 60601-2 Standards (1993), Class A for emission.
7. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
8. 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.
9. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
10. 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.

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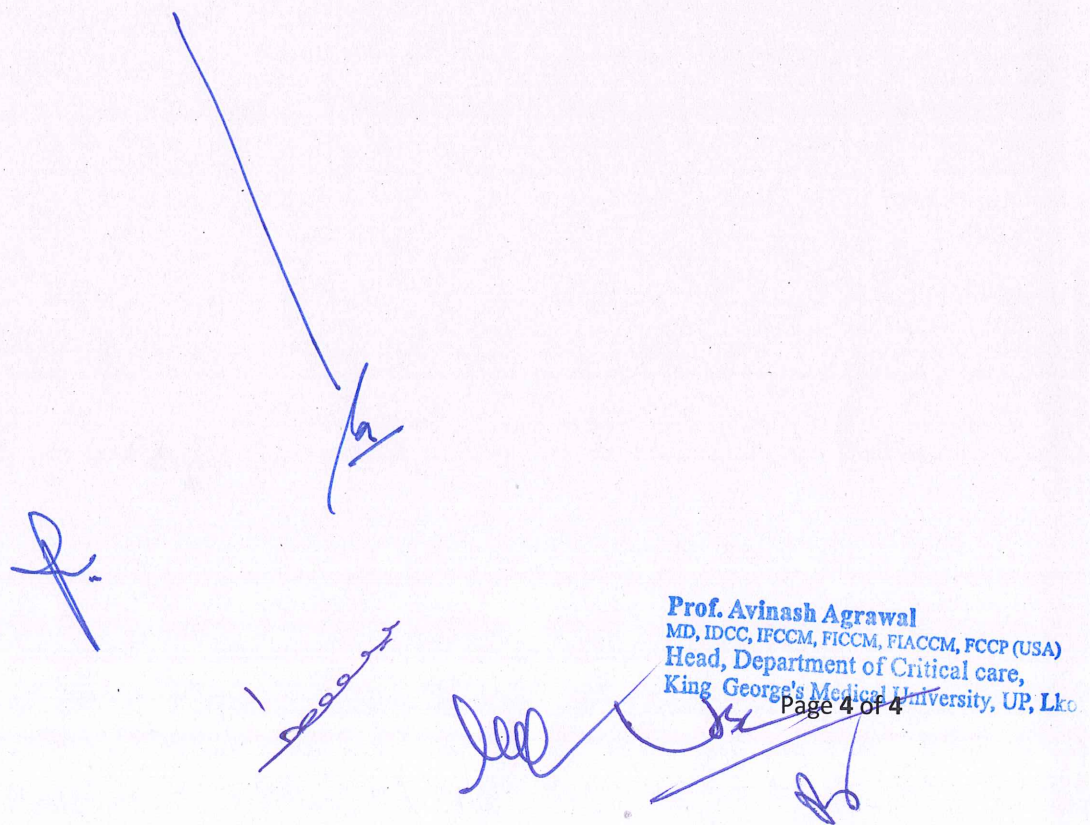
11. Offered Equipment should have a strong Government Installation base.
12. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
13. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
14. 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.
15. 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.
16. Company should quote their latest model and need to provide an affidavit for the same.
17. 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.
18. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
19. 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.
20. 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.
21. 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).

22. 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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