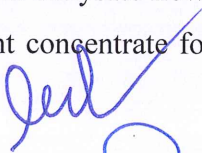

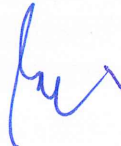




## SPECIFICATIONS FOR HEMODIALYSIS MACHINE

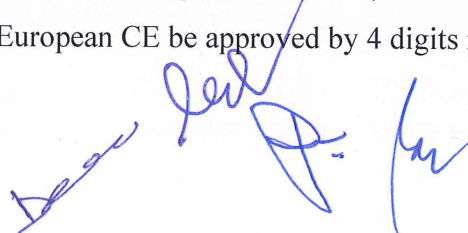
1. The Machine should be of the latest technology with microprocessor-controlled.
2. The Machine should have at least a 10" Colour TFT display operated by soft-touch buttons or a touch screen.
3. The Machine should have Acetate & Bicarbonate dialysis facilities.
4. The Machine should have a Sequential/ Isolation Ultra filtration facility.
5. It should have an Arterial, Venous & Transmembrane pressure monitoring facility.
  - Arterial Pressure Monitoring: -300mmHg to +300mmHg
  - Venous Pressure Monitoring: -60mmHg to +500mmHg
  - Transmembrane Pressure Monitoring: -60mmHg to +500mmHg
6. Treatment parameters should be displayed by trend curve and digital.
7. Blood pump flow rate should be from 20 ml/min. to 600 ml/min. The blood tubing pump segment should be operator changeable for use of different types of blood tubing sets (Blood Pump Tubing Pump segment 4mm to 10mm).
8. The Machine should have a Single Needle dialysis facility (Optional).
9. The Machine should have Volumetric Ultrafiltration System.
10. The Machine should have an inbuilt online Dialysate fluid filter system for ultrapure Dialysate delivery.
11. The Machine should have In-line Bicarbonate mixing and solution preparation facility with a sterile dry powder cartridge during dialysis.
12. The Machine should have an Air bubble detector facility with a level adjustment facility for the Venous chamber by up-down keys.
13. The Machine should have Optical Sensor to check the presence of blood/saline in the extracorporeal blood circuit system.
14. The Machine should have a Heparin Infusion Pump with a rate of 0 to 10 ml/min. and Bolus Infusion up to 5 ml/min.
15. The Machine should have a Blood leak Sensor. The alarm will be activated for a blood loss rate not greater than 0.5ml/min at max. dialysate flow of 800ml/min.
16. The Machine Should accept different concentrate formulations, different Dialyzers, and blood tubing sets.

  
  
  
  
  
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17. The Machine should have Variable Dialysate flow from 300 to 800 ml/min.
18. The Machine Should have a dialysate temperature setting range of 35°C to 39°C.
19. Ultrafiltration rate should be from 0 to 4.00 L/Hr.
20. The Machine should have an in house water filter assembly with a cartridge filter.
21. The Machine should have a facility for priming and rinsing of dialyzer and bloodline.
22. The Machine should have Hot Rinsing and Hot Chemical Disinfection facility (Temp. above 80 deg. Celsius) with a recirculation system.
23. The Machine should have Ultrafiltration and Sodium Profiling facility.
24. The machine should have an Automatic Battery backup of 15 to 20 minutes for a complete Extracorporeal blood system during power failure.
25. The machine should have Inbuilt online Non-Invasive patient blood pressure monitoring.
26. The machine should be upgradable to future software developments and can be linked with the Patient.
27. Power supply - 230VAC, 50Hz.
28. Should work on AC mains without batteries.
29. operating & service manual with a detailed circuit diagram should be provided.
30. The machine should have real-time clearance surveillance for urea & Kt/V to assess the adequacy of dialysis. It should display real-time Urea clearance, Plasma Sodium, Current Kt/V, and the Time required to achieve Target Kt/V.
31. Should have an in-built patient card reader for downloading therapy data.
32. Operating room Temp. 15°C up to 35°C.
33. Storage room temp 5°C up to 60°C.
34. Relative humidity 30% up to 75% non-condensing.

**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 European CE be approved by 4 digits notified body.


  
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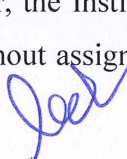


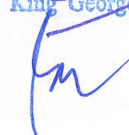



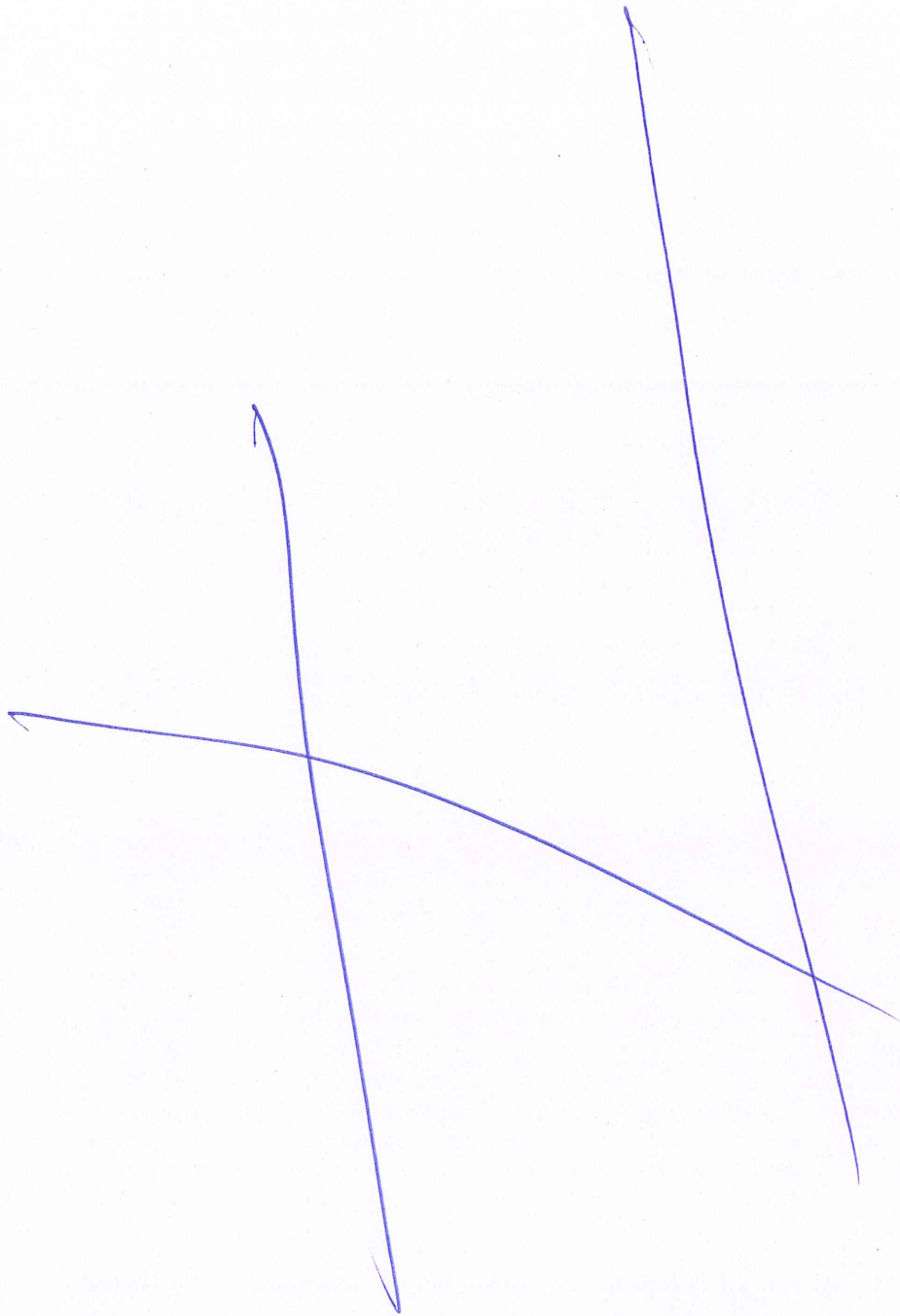
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory 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.
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.

  
  
  
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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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*[Handwritten signatures in blue ink]*