TECHNICAL SPECIFICATIONS FOR HAEMODIALYSIS MACHINE

I. Description of Function

Haemodialysis, is a method for removing waste products such as potassium and urea, as well as free water from the blood when the kidneys are incapable of this (i.e. in renal failure). It is a form of renal dialysis and is therefore a renal replacement therapy.

II. Operational Requirements

. Machine should have facility for Acetate, Bicarbonate, sequential dialysis (isolated UF) upgradable to future software developments.

. The blood pump should run even in the absence of water or dialysate flow.

III. Technical specifications

1. Should have facility for conventional and High Flux dialysis.
2. Machine should have two bacterial filters (pyrogen filters) one at water inlet and one at before water going to dialyser.
3. Battery back-up for at least 20-30 minutes to run complete machine with heater supply.
4. Should have Na, Bicarbonate and UF profiling.
5. Dialysate temperatures selectable between 35 degrees C to 39 deg. C.
6. Variable conductivity setting between 12 to 15 ms/cm.
7. Should have variable dialysate flow 300-800 ml/min.
8. Should have facility to show trends curve of all parameter for 15-20 minutes.
9. Heparin pump with syringe sizes up to 50ml with pump flow rate from 1-10 ml/hr (0.1 ml increments)
10. Ultrafiltration 0.1 to 2.5 litres/hr. The in and out fluid circuit must be separated so that there is no chance of contamination in the event of membrane rupture.
11. Treatment parameter should be displayed by graph and digitally both.
12. Should have integrated heat and chemical disinfection programme with day night week schedule.
13. Should have accurate feedback control conductivity mixing technique.
14. Should have drain facility.
15. Should have accurate UF control by flow by volume measurement technique.
16. Extra facilities like Blood Volume sensor, Bicarb select technique.
17. All important data should be presented so that machine can be used anytime without feeding data every time.
18. Should have automatic self-test facility.
19. Should have auto ON/OFF facility.
20. Should have touch button screen and large colour TFT screen.
21. Automatic diagnosis of malfunctioning with on line ability to show the faults with trouble (Technical service mode).
22. Machine can be connected to computer to feed all data and trouble shoot whenever any problem.
24. Ability to monitor pulse rate and NIBP.
25. Audio visual alarms on limit violation of conductivity, blood leak, air leak, transmembrane pressure alarms, Dialysis pressure alarms, Dialysis temperature alarms, dialysis can empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm.
27. Built-in device for measurement and monitoring of effective urea clearance and dialysis dose (KT/V).

IV. System as specified
   . All consumables required for installation and standardization of system to be given free of cost.

V. Environmental factors
   . The unit shall be capable of being stored continuously in ambient temperature of 0-50 deg C and relative humidity of 15-90%.
   . The unit shall be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity of 15-90%.

V. POWER SUPPLY
   . Pore input of to be 220-240 V AC, 50 Hz fitted with Indian plug.
   . UPS of suitable rating with voltage regulation and spike protection for 30 minutes back up.

VI. Standards, safety and training.
   . US-FDA OR European CE approved product.
   . Manufacturer/supplier should have ISO certification for quality standards.
   . Shall comply with IEC 60601-2-16 safety requirements of medical electric part 2-particular requirements for the safety of Haemodialysis equipment.
   . Should carries warranty for 2 years.
   . Comprehensive training lab staff and support services till familiarity with the system.
   . Should have local service facility. The service provider should have necessary equipments recommended by the manufacturers carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.

VII) Documentation
   . User/Technical/Maintenance manuals to be supplied in English.
   . Certificate of calibration and inspection.
   . List of equipment available for providing calibration and routine preventive maintenance, support, as per technical manual.
   . List of important spare parts and accessories with their part number and costing.