Annexure-A

Tender Notice No.:-RIMS/MED/EQUIP-13

Imphal, the 19th July 2013
Due date 22nd Aug. 2013

A) Specification for portable R.O system for Haemodialysis Machines

1) Portable R.O system suitable for one machine with pure water capacity of 50 liters/hour.
2) Compact Microprocessor controlled reverse osmosis with facility for online monitoring of reject flow, feed water and pure water conductivity.
3) Should have following rejection ration:
   a) Hardness- 95%
   b) Bacteria & Endotoxins -99%
   c) Pure water efficiency- 75%. Ultra water sterilizer
   d) TDS – less than 50 ppm
4) Purity of treated water should be as per AAMI standard of water for hemdialysis.
5) Stainless Booster pump.
6) Should have adequate pre-treatment stage such as:-
   a) Sediment filter
   b) Carbon filter
   c) Water soft view for use with tap water
   d) Ultra violet system/ sterilizations.
7) The whole assembly should be housed in rust proof compact and sleek cabinet movable on four castors
8) Should be from reputed manufactures with experience in hemo- dialysis treatment.
9) Should be supplied with power cord, operating manual & water hoses with quick connectors for machine.
10) Power supply 220/230 volts, 50 Hz
11) Manufacturer should be ISO 9002 and ISO 14001 certified.
12) Should offer warranty for 2 years and should quote AMC Charge for 3 years after warranty and should have assured supply of spare parts for next five years.

B) Equipment Specifications for Haemodialysis Machine

1) Operational Requirements

1.1) Machine should have facility for Acetate, Bicarbonate, Sequential dialysis (Isolated UF)

1.2) Upgradable to future software development and linkable with Patient Data Management System.

1.3) The blood pump should be able to run from 50 to 600 ml/ min and adaptable to standard A –v blood lines and should run even in the absence of water or dialysis flow.

2) Technical Specifications.

2.1) Should have facility for conventional and high flux dialysis.

2.2) Machine should have two bacterial filter (Pyrogen filters) one at water inlet and one before water going to dialyser.

2.3) Battery back –up for 20-30 minutes to run complete machine with heater supply.

2.4) Should have Na, Bicarbonate and UF profiling

2.5) Dialysate temperatures selectable between 35 degrees C to 39 degrees C.

2.6) Variable conductivity setting between 12 to 15.

2.7) Should have variable dialysate flow 350- 800 ml/ mt and should have increasing facility to step up by 20 ml.

2.8) Should have facility to show trends curve of all parameter for 15 to 20 minutes.

2.9) Heparin pump with syringes sizes up to 50 ml with pump flow rate from 1 -10 ml/hr (0.1 ml increments).

2.10) Stroke pressure operated short term single needle dialysis.

2.11) 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.

2.12) Treatment parameter should be displayed by graph and digitally both.

2.13) Should have integrated heat and chemical disinfection facility with both short and long disinfection programme with day knight week schedule.

2.14) Should have accurate feedback control conductivity mixing technique.

2.15) Should have drain facility.

2.16) Should have accurate UF control by flow by volume control measurement technique.

2.17) Extra facilities like Blood volume sensor, Bicart select technique and online clearance kt/V.

2.18) Presettable important data so that machine can be used anytime without feeding data every time.

2.19) Should have automatic self test facility.

2.20) Should have auto on/ off facility.

2.21) Should have touch button screen and large colour TFT screen.

2.22) Automatic diagnosis of malfunctioning with on line ability to show the faults with trouble shooting (technical service mode).

2.23) Machine can be connected to computer to feed all data and trouble shoot whenever any problem arises.

2.24) Blood pump rate from 20 -500 ml/ min adaptable to standard A-V bloodlines.

2.25) Ability to monitor pulse rate and NIBP with graphic and tabulated trends.

2.26) Audio visual alarms on limit violation of conductivity, blood leak, air leak, transmembrane pressure alarms, Dialysis temperature alarm, dialysis can empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm.

2.27) Alarm for reverse Ultrafiltration and also be able to do sequential dialysis
On line in built NIBP recording.

2.28) On line creatinine clearance monitoring –build in device for measurement and monitoring of effective urea clearance and dialysis dose (KT/V).

3. System configuration Accessories, spare and consumables.
   3.1) System as specified.
   3.2) All consumables required for installation and standardization of system to be given free of cost.
   3.3) To be supplied free of cost
   Bacterial filters- 2sets extra, 100 polysulfone 1m2 dialyzers and tubings.

4. Power Supply

   4.1) Power input to be 220-240 VAC , 50 Hz fitted with Indian Plug
   4.2) UPS of suitable rating with voltage regulation and spike pretection for 60 minutes back up.

5. Standard, safety and training

   5.1) Should be FDA, CE, UL or BIS approved product.
   5.2) Manufacturer/supplier should have ISO certification for quality standards.
   5.3) Shall comply with IEC 60601-2-16 SAFETY requirements of medial electric equipment part 2 particular requirements for the safety of Haemodialysis equipment.
   5.4) Should carry warranty of 2 (two) years.
   Rate of AMC for next 3 (three) years to be quoted and should have spare parts for next 10 years. Supplier should have adequate experience and maintenance of similar equipment in at least 3 to 4 major hospitals.
   5.5) Comprehensive training for lab staff and support service till familiarity with the system.
   5.6) The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/ maintenance manual.

6. Documentation.

   6.1) User/Technical/Maintenance manuals in English to be supplied.
   6.2) Certificate of calibration and inspection
   6.3) List of equipments available for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service/technical manual.
   6.4) List of import spare parts and accessories with their part number and costing.
   6.5) Log book with instruction for daily, weekly and quarterly maintenance checklist. The responsibility of the hospital technician and company service engineer should be clearly spelt out.

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