Notice Inviting e-Tender

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Supply and Commissioning of CRRT Machine with consumables for Department of Paediatrics, Medical College & Hospital, Kolkata
(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-259/2023	Dated-19.05.2023

2nd call of Bid Reference No.: WBMSCL/NIT-166/2023 ,Dated 10.04.2023
AMENDMENT-I

Revised Technical Specification

Specification of CRRT (Continuous Renal Replacement Therapy) Machine
Product Name Continuous Renal Replacement Therapy Machine Clinical purposeTo provided at least 24-hour continuous (nonstop) dialysis therapy used to support patients with kidney failure Patient Category Pediatrics and adults
Product Functional Features

1. The Machine should be of least technology with microprocessor controlled user interactive menu with operating and malfunction removal instructions on display screen
2. System should be user friendly
3. All materials used for the construction of the system shall be rust proof
4. System should be able to perform Slow Continuous Ultrafiltration (SCUF)
5. System should be able to perform Continuous Venous to Venous Hemofiltration (CVVHF)
6. System should be able to perform Continuous Venous to Venous Hemodialysis (CVVHD)
7. System should be able to perform Continuous Venous to Venous Hemodiafiltration (CVVHDF)
8. System should be able to perform Therapeutic Plasma Exchange (TPE)
9. System should be able to perform Hemoperfusion (HP)
10. System should have four pumps, one each for Blood, Dialysate, Replacement fluid and Effluent/filtrate

11. Provision of separate pump for pre-blood infusion

12. Should have close blood circuit to prevent air to blood interface
13. System should have short preparation and priming program and should be ready to start treatment within 10-20 minutes
14. System should have 3 weighing scales with weighing capacity of atleast 5kg for monitoring of the volumes of the total filtrate, replacement fluid and dialysate

15. Provision of separate weighing scale for pre blood pump

16. Equipped with independent pre filter pressure sensor
17. Equipped with independent Effluent pressure sensor
18. Equipped with independent Blood access pressure sensor
19. Equipped with independent Blood return pressure sensor

20. Provision of independent Pressure sensor port for future therapy eg couple filtration

21. System should have fluid/blood warmer for blood/dialysate warming
22. Machine should be able to increase or decrease the temperature in increments of 0 point 5 degree C with temp range to be
23. System should have capability of changing therapies without interrupting the treatment
24. Provision for Regional Citrate Anticoagulation for all CRRT therapies
25. Provision for simultaneous delivery of pre and post filter replacement solution in
26. Provision for recirculation mode
27. Provision to enable for sepsis treatment with compatible filter
28. Provision to enable low weight compatible set for CRRT treatment of babies
29. Provision of changing syringe size
30. Provision to upgrade software
31. System should operate with a low extracorporeal blood volume which is equal or less
32. Built in dosage calculator
33. Equioment should provided pre and post dilution capability using the same treatment set
34. Provision to use lactate based dialysate solution and bicarbonate solution simultaneously for CVVHDF therapy
35. Emergency hand crank to be provided for returning blood to patient in case of power
36. The system shall be easy to clean, disinfect and sterilize
37. The system should have integrated infusion pump for continuous or bolus anticoagulation with flow rate of

Flow Rate

Minimum Blood pump flow rate range with +/- 10% accuracy (ml/min) 10 – 450 mL/min
Minimum Replacement Solution flow rate range (ml/hr) – Approximate 0-4500 mL/Hr
Minimum Dialysate pump flow rate range (ml/hr) – Approximate 0-4500 mL/Hr
Minimum Effluent pump flow Rate Range (ml/hr) – Approximate 0-10000 mL/Hr

Pressure Monitoring Range

Minimum Access line pressure monitoring range – Approximate (-) 250 mmHg to (+) 300 mg
Minimum Return line pressure monitoring range – Approximate (-) 50 mmHg to (+) 300 mmHg
Minimum Pre Filter line pressure monitoring range – Approximate (-) 50 mmHg to (+) 400 mmHg
Minimum Effluent line pressure monitoring range – Approximate (-) 300 mmHg to (+) 300mmHg

Safety Features

Built in Blood leak detector
Built in air detector
System should have Alarms (Audio and Visual) in case of power failure, equipment malfunction, air in line, blood leak, arterial/venous pressure out of limits, emty dialysate/replacement bag, full effluent bag, TMP out of limit and filter clotting.
The system shall incorporate a self diagnostic program which upon start up, detect and clearly indicate any defects or malfunction
The system should be able to perform a self testing during treatment automatically in a fix period of time not less than one hour to ensure all the components are working properly

User Interface

Should have touch screen/touch pad TFT/LCD Monitor with adjustable brightness
Type of monitor – Color
Panel display size (inch) – At least 12 inch
The equipment should be able to monitor and display the parameters – Arterial pressure, Venous Pressure, TMP, Replacement flow rate, dialysate flow rate, ultrafiltration rate, temperature, Treatment therapy's set time, elapsed time and remaining time, continuous anticoagulation rate and anticoagulation by bolus
The machine should display continuous information of all parameters on one screen including graphical display of pressure monitoring
Recording of Patients treatment history up to 80-90 hours and storage of atleast 500 events Equipped with RS232/USB output for PC connectivity and Data acquisition

Electrical Features

LED indicator on front panel for status of machine
Power input – 220-240 VAC, 50Hz fitted with Indian plug
Machine should have automatic battery backup for blood pump without interruption for at least 10 minutes during power failure

Environmental Considerations

The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%

The unit shall be capable of operating continuously in ambient temperature of 10-45 deg C and relative humidity of 15-90%

Packing Mode

The product should be packed with all its accessories in such a way that there will be no transit damage takes place

Certification & Reports

Availability of test report/quality assurance report from parent manufacturer Product certification – EU-CE/US-FDA Product Certificate No Confirmity to Manufacturer's Certification (copy of the same should be submitted to buyer). System shall comply with IEC EN 60601-1-Type CF (Cardiac Float) for electrical safety. Submission of all the certifications and test reports to the buyer along with supplies on demand

Installation & Training

Supplied to perform installation, safety and operation checks before handover
Training of users in machine operation, trouble shooting aspects and basic maintenance shall be provided Contact details of manufacturer, supplier and local service agent to be provided

Documentation

User/technical/Maintenance manuals to be supplied in English
Certificate of calibration to be provided

Sl. No.	Accessories should be supplied with the machine	Quantity
1	Single use CRRT set that COMBINES adsorption of inflammatory mediators (e.g. cytokines) andendotoxins along with all functionalities of CRRT (uremic toxin)	3 units
2	CRRT circuits including dialyser (8 to 12 Kg.)	3 units
3	CRRT circuits including dialyser (12 to 50 Kg.)	3 units
4	All other standard accessories required to run the machine(With Calcium 25 bags, Without Calcium 5 bags)	30 units