

Response To Pre-Bid Queries (Pre-Bid date: 18.04.2022)				
Bid Number: GEM/2022/B/2072257 Dated: 28-03-2022				
Item Name: Hemodialysis machine with facility for hemodiafiltration in pediatric patients (Qty:02) along with Reverse Osmosis water treatment Plant (Qty:01)				
Sr. No.	Buyer Specification Document Page & Para	TENDER SPECIFICATION	REPRESENTATION RECEIVED FROM THE FIRM	COMMITTEE RECOMMENDATION
1	Pg 1 Item Name	Hemodialysis machine with facility for hemodiafiltration in pediatric patients (Qty:02) along with Reverse Osmosis water treatment Plant (Qty:01)	As per prebid discussion	<b>Amended as:</b> Hemodialysis Machine (Qty:02) along with Reverse Osmosis Water Treatment Plant (Qty:01)
2	Pg 1 Para 1	Provision for hemodialysis, sustained low efficiency dialysis, hemofiltration, hemodiafiltration and sequential dialysis (isolated ultrafiltration)	As per prebid discussion	<b>Amended as:</b> Provision for hemodialysis and isolated ultrafiltration
3	Pg 1 Para 2	Option of pediatric mode that allows accurate therapy for children weighing less than 20 kg	As per prebid discussion	<b>Deleted</b>
4	Pg 1 Para 5	Two bacterial filters (pyrogen or dialysate filters), one at the water inlet and another before the dialysate is supplied to the dialyser, to remove endotoxin and bacteria and prepare ultrapure dialysate	As per prebid discussion	<b>Amended as:</b> One bacterial filter (pyrogen or dialysate filter), at the water inlet to remove endotoxin and bacteria and prepare ultrapure dialysate
5	Pg 1 Para 7	Dialysate flow rate that can be varied from $\leq 100$ ml/min to $\geq 1000$ ml/minute, allowing increment of $\leq 100$ ml/min, with an accuracy of $\leq \pm 10\%$	As per prebid discussion	<b>Amended as:</b> Dialysate flow rate that can be varied among <b>300 ml/min, 500 ml/min and 800 ml/min</b> , with an accuracy of $\leq \pm 10\%$
6	Pg 1 Para 9	Blood pump flow rate that can be varied from $\leq 30$ ml/min to $\geq 600$ ml/min, allowing increments of $\leq 10$ ml/minute, with an accuracy of $\leq \pm 10\%$	As per prebid discussion	<b>Amended as:</b> Blood pump flow rate that can be varied from <b><math>\leq 10</math> ml/min</b> to $\geq 600$ ml/min, allowing increments of $\leq 10$ ml/minute, with an accuracy of $\leq \pm 10\%$ <b>Added Para: Blood pump that is adaptable to standard AV lines and can run without water or dialysate flow.</b>
7	Pg 1 Para 10	Facility to produce substitution fluid online that is delivered at a rate that can be varied from $\leq 20$ ml/minute to $\geq 350$ ml/minute	As per prebid discussion	<b>Deleted</b>
8	Pg 1 Para 13	Heparin pump that is automatic or manual, has start/stop function and allows infusion at rate of $\leq 0.5$ ml/hour in $\leq 0.1$ ml/hour increments, with $\pm 5\%$ accuracy, and allows user to stop heparinization during dialysis at a time chosen by the user	As per prebid discussion	<b>Amended as:</b> Heparin pump that is automatic or manual, <b>with pump syringe size of 20 ml</b> , has start/stop function and allows infusion at rate of $\leq 0.5$ ml/hour in $\leq 0.1$ ml/hour increments, with $\pm 5\%$ accuracy, and allows user to stop heparinization during dialysis at a time chosen by the user
9	Pg 1 Para 22	Touch screen and multicolor graphic display on TFT screen of $\geq 10"$ , viewable from all angles	As per prebid discussion	<b>Amended as:</b> Multicolor graphic display on TFT screen of $\geq 10"$ , viewable from all angles

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10	Pg 2 Para 27	Option for online clearance monitor for inbuilt measurement and monitoring of effective urea clearance, dialysis dose, Kt/v and plasma sodium during dialysis, without need for additional cost and consumables	As per prebid discussion	<b>Amended as:</b> Option for online clearance monitor for inbuilt measurement and monitoring of effective urea clearance <b>and</b> dialysis dose (Kt/v) and plasma sodium during dialysis, without need for additional cost and consumables
11	Pg 2 Para 28	Option for blood volume or hematocrit monitoring	As per prebid discussion	<b>Deleted</b>
12	Pg 2 Para 34	Blood volume monitoring to allow adaptation of ultrafiltration rate based on blood volume changes	Kindly amend it as deleted.  Justification: BVM is a module that help to prevent IDH (intradialytic hypotension) by using specially designed qubit-based blood tubing). Uses Of same module as well as blood tubing is very rare by physicians. Keeping this in mind we wish to offer our latest 5008s machine. Request to authorities to remove BVM module	<b>Deleted</b>
13	Pg 2 Para 36	The unit should have BIS or US FDA or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted. OR should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-16 standards and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer	As per prebid discussion	<b>Amended as:</b> The unit should have BIS or US FDA or European CE with four digit notified body number certificate for the quoted model and certificate to be submitted. OR should meet IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-16 standards <b>and IS 13450</b> and should submit valid test report for the quoted model from NABL accredited laboratory/ from labs in their country of origin in case of foreign manufacturer
14	Pg 2 Para 37	The system should be able to operate in ambient temperature of 20-35°C and relative humidity 0-70%	As per prebid discussion	<b>Amended as:</b> The system should be able to operate in ambient temperature of 20- <b>30°C</b> and relative humidity 0-70%
15	Pg 3 Para 45	Accessories, spare parts and consumables to be supplied with the equipment; all with at least one year between supply and expiry:	As per prebid discussion	<b>Amended as:</b> Accessories, spare parts and consumables to be supplied with the <b>two hemodialysis equipments</b> ; all with at least one year between supply and expiry:

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16	Pg 3 Para 45 Point 2	One additional pair of bacterial filters(total 4)	As per prebid discussion	<b>Amended as: Eight bacterial filters</b>
17	Pg 3 Para 45 Point 3	Compatible high fluxdisposable dialyzers in sizes 0.2-0.4 m2and 0.7-0.8 m2 (50 each in each of three years from installation of unit; total 300)	As per prebid discussion	<b>Amended as:</b> Compatible high flux disposable dialyzers in sizes 0.2-0.4 m2 and 0.7-0.8 m2 ( <b>25</b> each in each of three years from installation of unit; total <b>150</b> )
18	Pg 3 Para 45 Point 4	Pediatric tubings with facility for blood volume monitoring (100 per year for three years; total 300)	As per prebid discussion	<b>Amended as:</b> Pediatric tubings with facility for blood volume monitoring ( <b>50</b> per year for three years; total <b>150</b> )
19	Pg 3 Para 45 Point 5	Transducers for use with these tubings (100 per year for three years; total 300)	As per prebid discussion	<b>Deleted</b>
20	Pg 3 Para 45 Point 6	Disposable bicarbonate powder bags (100 per year for three years; total 300)	As per prebid discussion	<b>Amended as:</b> Disposable bicarbonate powder bags ( <b>50</b> per year for three years; total <b>150</b> )
21	Pg 3 Para 45 Point 7	Disposable cans of part A solution (100 per year for three years; total 300)	As per prebid discussion	<b>Amended as:</b> Disposable cans of part A solution ( <b>50</b> per year for three years; total <b>150</b> )
22	Pg 3 Para 45 Point 10	Blood pressure cuffs for use with inbuilt non-invasive blood pressure monitoring system, in two different sizes, 9 x18 cm and 12x22cm, two pieces each for each hemodialysis unit	As per prebid discussion	<b>Amended as:</b> Blood pressure cuffs for use with inbuilt non-invasive blood pressure monitoring system, in two different sizes, 9 x18 cm and 12x22cm, two pieces each for each hemodialysis unit; <b>total 4</b>
23	Pg 3 RO Plant 500 LPH	Includes supply, erection, commission, testing, operation and maintenance of reverse osmosis (RO)-based water treatment plant suitable for supplying water for 8 hemodialysis machines, along with the supportive arrangements, including pre- treatment unit, RO unit, post-treatment unit, electrical panel, RO panel, tubings and measuring devices, that are necessary for the proper functioning of the plant, in order to supply treated water that meets Association for the Advancement of Medical Instrumentation (AAMI) standards for hemodialysis units.	Kindly clarify the word Operation.  Justification: If Operation is the responsibility of Bidder, then bidder needs to employee operator staff. If operators are required, then how much operators are required.	<b>Amended as:</b> Includes supply, erection, commission, testing and maintenance of reverse osmosis (RO)-based water treatment plant suitable for supplying water for 8 hemodialysis machines, along with the supportive arrangements, including pre- treatment unit, RO unit, post-treatment unit, electrical panel, RO panel, tubings and measuring devices, that are necessary for the proper functioning of the plant, in order to supply treated water that meets Association for the Advancement of Medical Instrumentation (AAMI) standards for hemodialysis units.

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24	Pg 4 Para 4	The RO unit should be operated by either the manufacturer, supplier or an authorized dealer, and maintained by skilled staff.	Kindly clarify the requirement of operator.  Justification: If Operation is the responsibility of Bidder, then bidder needs to employee operator staff. If operators are required, then how much operators are required.	<b>Amended as:</b> The RO unit should be <b>installed and commissioned</b> by either the manufacturer, supplier or an authorized dealer, and <b>trained by the above</b> .
25	Pg 4 Para 5	The cost of testing of water quality (including chemical and bacterial testing, according to AAMI requirements) should be included in maintenance charges, and should be done every six months.	Kindly amend the standards Kindly amend the desired standards of Water Quality to ISO 23500-3:2019.	<b>Amended as:</b> The cost of testing of water quality, including chemical and bacterial testing <b>every 3 months for five years (total 20 times)</b> , according to <b>ISO 23500-3:2019 standards</b> , should be included in maintenance charges.
26	Pg 4 Para 12	Less than 24-hr of downtime shall be allowed at a stretch, otherwise a penalty of Rs 2000 per hour will be imposed. The bidder should guarantee to maintain an overall uptime of >95% throughout the calendar year, failing which the same penalty will be imposed.	Requesting to remove penalty clause of 2000. As a promising service provider, we commit to maintain overall uptime of 95%.	No change; essential to ensure uninterrupted provision of hemodialysis services to sick children
27	Pg 4 Components of the unit	The water treatment plant should have the following components: mesh filter; raw water tank; booster pump; sand filter; particle filters; dual column softener; charcoal filter; two 5 micron filters; the two stage RO units; treated water storage tank; bacterial filter; booster pump; hot disinfection or feed unit; tubing loops/circuits for manual feed; tubing loops/circuits for recycling of water; and tubing loops for supply to the individual hemodialysis machines.	Kindly make amendment as same component is asked with different specifications  Justification: Recommended Particle Filter pore size is 20 micron and 5 micron.	<b>Amended as:</b> The water treatment plant should have the following components: mesh filter; raw water tank; booster pump; sand filter; <b>one particle filter of 20 microns</b> ; dual column softener; charcoal filter; <b>one 5 micron filter</b> ; the two stage RO units; hot disinfection or feed unit; tubing loops/circuits for manual feed; tubing loops/circuits for recycling of water; and tubing loops for supply to the individual hemodialysis machines.
28	Pg 4 Pre-treatment system Para 3	The raw water tank should be of food grade quality and have capacity to store approximately 1000 liters water.	Amendment requested in tank capacity  Justification: 750 L or more	<b>Amended as:</b> The raw water tank should be of food grade quality and have capacity to store <b>at least 750</b> liters water.

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29	Pg 4 Pre-treatment system Para 5	Particle filters should be of cartridge filter type, of 50 microns and 10 microns.	Kindly make amendment as same component is asked with different specifications  Justification: Recommended Particle Filter pore size is 20 micron and 5 micron.	<b>Amended as:</b> Particle filters should be of cartridge filter type, of 5 microns and 20 microns.
30	Pg 4 Pre-treatment system Para 6	The built-in dual column softener should have a fully automated digital display, brine fill and clean cycles, and a brine tank incorporated in the system.	Amendment Requested – Type of regeneration. Dual Softener configuration with Parallel or alternate regeneration mode.	<b>Amended as:</b> The built-in dual column softener should be configured to allow both parallel and alternate regeneration mode, and have a fully automated digital display, brine fill and clean cycles, and a brine tank incorporated in the system.
31	Pg 4 Pre-treatment system Para 8	The fine filters should be of cartridge type, of 5 microns and 1 micron.	Kindly make amendment as same component is asked with different specifications  Justification: Recommended Particle Filter pore size is 20 micron and 5 micron.	Deleted
32	Pg 4 RO Unit Para 1	The RO unit should be microprocessor based dual stage RO system which produces water as per AAMI standard for hemodialysis water quality.	Kindly amend the standards Kindly amend the desired standards of Water Quality to ISO 23500-2 & 3:2019.	<b>Amended as:</b> The RO unit should be microprocessor based dual stage RO system which produces water as per ISO 23500-2 & 3:2019 standard for hemodialysis water quality.
33	Pg 4 RO Unit Para 6	There should be facility to upgrade the system by adding more membranes to increase the capacity.	Amend to delete Any upgradation in RO plant with increase in capacity of RO system cancels the certificate of equipment.	Deleted
34	Pg 4 RO Unit Para 7	The yield setting should be variable between 50% and 70%.	Amendment The dynamic yield setting should be variable between 50% and 75%.	<b>Amended as:</b> The yield setting should be variable between 50% and 75%.
35	Pg 5 Para 12	There should be a provision of OFFLINE as well as ONLINE mode of permeate supply.	Kindly amend it as deleted.	Deleted (all four statements)

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36	Pg 5 Post-treatment system Para 1	The system should have appropriate material and shape, with a permeate storage tank of at least 500 liters capacity and with level control system.	Justification: Since Online Hot disinfection is demanded in first point of other Specifications and in point 13 of RO Unit Specifications it is demanded that is a great that RO should operate in online mode so points related to offline should be removed. ONLINE RO system has better management of microbial contaminants then OFFLINE RO system. Online Hotdisinfection of permeate water storage tank is not possible.	
37	Pg 5 Post-treatment system Para 2	The system should have a bacterial filter of 0.2 microns that can be back-washed manually.		
38	Pg 5 Post-treatment system Para 4	The system should have one additional booster pump.		
39	Pg 6 After Certification Para	NA	As per prebid discussion	<p><b>Added Para: All equipment and consumables required for maintenance of the unit, including spare parts (electronic, mechanical, plastic, etc.) and all consumables and testing including the following, should be included in the bid and be covered in the warranty period of five years:</b></p> <p>(i) All types of filters, to be replaced every 3 months (20 number of each filter)</p> <p>(ii) Two cans of disinfectant to be provided every 3 months (total 40 cans of disinfectant)</p> <p>(iii) Fifteen bags of salt every month (total 900 bags of salt)</p>
40	Pg 6 BOQ Para 2	Bacterial filters - 4 Nos	As per prebid discussion	<b>Amended as: Bacterial filters - 8 Nos.</b>
41	Pg 6 BOQ Para 3	Compatible high fluxdisposable dialyzers in sizes 0.2-0.4 m2and 0.7-0.8 m2 (50 each in each of three years from installation of unit; total 300) - 300 Nos	As per prebid discussion	<b>Amended as: Compatible high fluxdisposable dialyzers in sizes 0.2-0.4 m2and 0.7-0.8 m2 (25 each in each of three years from installation of unit; total 150) - 150 Nos</b>

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42	Pg 6 BOQ Para 4	Pediatric tubings with facility for blood volume monitoring (100 per year for three years; total 300) - 300 Nos	As per prebid discussion	<b>Amended as:</b> Pediatric tubings with facility for blood volume monitoring (50 per year for three years; total 150) - 150 Nos
43	Pg 6 BOQ Para 5	Transducers for use with the tubings (100 per year for three years; total 300) - 300 Nos	As per prebid discussion	<b>Deleted</b>
44	Pg 6 BOQ Para 6	Disposable bicarbonate powder bags (100 per year for three years; total 300) - 300 Nos	As per prebid discussion	<b>Amended as:</b> Disposable bicarbonate powder bags (50 per year for three years; total 150) - 150 Nos
45	Pg 6 BOQ Para 7	Disposable cans of part A solution (100 per year for three years; total 300) - 300 Nos	As per prebid discussion	<b>Amended as:</b> Disposable cans of part A solution (50 per year for three years; total 150) - 150 Nos
46	Pg 6 BOQ Para 8	Blood pressure cuffs : 9 x18 cm and 12x22cm - 2 Nos each	As per prebid discussion	<b>Amended as:</b> Blood pressure cuffs : 9 x18 cm and 12x22cm - 4 Nos