

Section II: Schedule of Requirements

eSourcing reference: ITB/2023/47723

Supply, Delivery and installation of haemodialysis (Plug & Play) generators for the Simao Mendes Hospital Haemodialysis Centre (HNSM) - FCA, CPT (Incoterm 2020) HNSM Bissau, Guinea Bissau: **Lot 1 & Lot 2**

A. Technical specifications for goods and comparative data table

Lot 1: Haemodialysis Machine & Water treatment equipment (Water filtration, water softener and reverse osmosis)

No	UNOPS minimum technical requirements		Qty
1.1	Haemodialysis Machine	<p>Hemodialysis Machine <i>Each machine must be delivered with 250 Hemodialysis sessions kits and consumables.</i></p> <p>Description of Function Haemodialysis is a method for removing waste products as well as free water from the blood when the Kidneys are incapable of this.</p> <p>Operational Requirement 1- Bicarbonate/Acetate Haemodialysis. The blood pump should run even in the absence of water or dialysate flow. Single needle dialysis using one blood pump. Isolated ultrafiltration/Sequential dialysis should be possible. Technical Specification. 2- Should have a facility for conventional & high flux dialysis. The Machine should have a color monitor display. 3- Blood flow rate minimum range should be 50 – 600ml/minute (Accuracy: $\pm 10\%$ or better; Resolution: 10 mL/min or better) & adaptable to standard AV blood lines. 4- Dialysate flow rate ranges from 300 – 800 ml/minute (minimum range). 5- Heparin pump: Delivery range 0.5 ml/min – 10 ml/min, Bolus function: 1.0 to 10.0 mL (minimum range) 6- Syringe size: At least 20 mL and 30 mL. 7- Automatic set up and priming is preferred. 8- Positive and negative extracorporeal circuit pressure shall not affect the infusion rate. 9- Optical Detector should be there to sense light and dark (blood and saline) and should not be affected by ambient light. 10- Self-check test. 11- Built in NIBP monitoring (Systole: 60 mmHg to 240 mmHg, Diastole: 40 mmHg to 200 mmHg, MAP: 45 mmHg to 235 mmHg, Pulse: 40 to 200 1/min, Accuracy: $\leq \pm 5$ mmHg, Resolution: 1 mmHg). 12- Should have built in facilities of hot & chemical disinfection with both short & long disinfection and 2 nos of 5 liters pack of hot disinfectant competent with quoted model with each machine should be supplied (or better technology). 13- Should have Arterial Monitoring (Display range: -300 mmHg to +300 mmHg, Accuracy: ± 7 mmHg, Resolution: 5 mmHg) 14- Should have Venous pressure monitoring (Display range: -100 mmHg to +500 mmHg, Accuracy: ± 7 mmHg, Resolution: 5 mmHg)</p>	10

	<p> 15- Alarm should be activated for air bubbles and microbubbles over the entire blood flow. 16- Should have facility to change sodium range 130 – 150 mmol/l 17- Temperature control range should be 35.0 degree C to 39.0 degree C. The dialysate conductivity shall be adjusted by setting the sodium concentration. 18- Machine should have inbuilt sodium & ultrafiltration profiling. 19- Machine should have a blood leak detector alarm with a Sensitivity of : ≤ 0.35 mL blood/min (or better). 20- Ultrafiltration rate should be 0 to 4L/ hr given by the set values of UF volume and treatment time. 21- Treatment Time adjustable up to 9 hr 59 min. in 1 min increment. 22- TMP Monitoring should be displayed. 23- Built-in device for measurement and monitor of effective urea clearance (K) dialysis dose (Kt/V), and plasma sodium (Na) automatically during treatment. 24- The measurement of effective urea clearance (K), dialysis dose (kt/V and plasma sodium (Na) shall be performed in noninvasive, real-time mode without additional disposable required during treatment. 25- Facility for heat, chemical disinfection and auto-switch off. 26- Should have inbuilt Dry Bicarbonate powder module to provide hygiene online mixing to avoid precipitation and it should be supplied with each machine (10 nos) and should be competent with quoted model. 27- Machine should have a built-in facility of endotoxin retention filter and should have an automatic programme and guidance message for changing the filter. </p> <p> System Configuration Accessories, Spares and consumables 28- System application software to be in at least French and English while in Portuguese (if possible) 29- All consumables required for installation and standardization of the system to be given free of cost. </p> <p> 30- Company must supply Bacterial filters-6 sets extra and 100 dialyzers with tubings free of cost. 31- Environmental Factors Machine should operate & being stored under extreme temperature conditions of lowest 2 degrees C and highest 48 degree C and humidity of > 80%. Power supply: Power input to be 200-240VAC, 50Hz fitted with Guinee- Bissau plug. Machine should have battery backup for at least 15 min in case of AC power failure. One online UPS (minimum 3KVA) with at least 30 min power backup must be supplied with each machine. </p> <p> 32- Standard, Safety and Training The machine should be: - ISO13485, -ISO 9001 or Manufacturer's QMS certificate, -US FDA/European CE certified. -Shall comply with IEC 60601-2-16 SAFETY requirements of medical electric equipment Part-2 All certificate copies should be provided. </p> <p> 33- Comprehensive users' and service training and support services till familiarity with the system must be included in the offer. 34- Documentation User/Technical/Maintenance manuals to be supplied in French and English (Portuguese if possible). Certificate of calibration and inspection. </p>	
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1.2	Water treatment equipment	<p><i>Water treatment equipment (Water filtration, water softener and reverse osmosis) must be sized, delivered, installed, commissioned along with the hemodialysis delivered and have capacity to supply treated water to at least 20 Hemodialysis units.</i></p> <p><i>45- Incorporated monitoring instruments to the water treatment plant for continuous water quality control monitoring.</i></p> <p><i>46- Must be ISO9001 certified or Manufacturer's QMS certificate</i></p> <p><i>47- Must be ISO 23500-2:2019 certified.</i></p> <p><i>48- All certificate copies must be provided.</i></p> <p><i>49- The below reference list must be used to provide a water quality control report during system installation with the maximum concentration expected.</i></p> <table border="1"><thead><tr><th><i>Contaminant</i></th><th><i>Max Concentration (mg/L)</i></th></tr></thead><tbody><tr><td>Selenium</td><td>0.091-<u>Contaminants with documented toxicity to haemodialysis</u></td></tr><tr><td>Aluminum</td><td>0.01</td></tr><tr><td>Total chlorine</td><td>0.1</td></tr><tr><td>Copper</td><td>0.1</td></tr><tr><td>Fluoride</td><td>0.2</td></tr><tr><td>Lead</td><td>0.005</td></tr><tr><td>Nitrate (as N)</td><td>2</td></tr><tr><td>Sulfate</td><td>100</td></tr><tr><td>Zinc</td><td>0.1</td></tr></tbody></table> <p><i>2-Electrolytes normally included in dialysis fluid</i></p>	<i>Contaminant</i>	<i>Max Concentration (mg/L)</i>	Selenium	0.091- <u>Contaminants with documented toxicity to haemodialysis</u>	Aluminum	0.01	Total chlorine	0.1	Copper	0.1	Fluoride	0.2	Lead	0.005	Nitrate (as N)	2	Sulfate	100	Zinc	0.1	01
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		<i>Calcium</i> <i>Magnesium</i> <i>Potassium</i> <i>Sodium</i>	<i>2 (0.05 mmol/L)</i> <i>4 (0.15 mmol/L)</i> <i>8 (0.2 mmol/L)</i> <i>70 (3.0 mmol/L)</i>	
		<u>3-race elements</u> <i>Antimony</i> <i>Arsenic</i> <i>Barium</i> <i>Beryllium</i> <i>Cadmium</i> <i>Chromium</i> <i>Mercury</i>	 <i>0.006</i> <i>0.005</i> <i>0.1</i> <i>0.0004</i> <i>0.001</i> <i>0.014</i> <i>0.0002</i>	
		<i>Silver</i> <i>Thallium</i>	 <i>0.005</i> <i>0.002</i>	

Lot 2: External Quality control monitoring instruments for hemodialysis water

No	UNOPS minimum technical requirements		Qty
2.1	Handheld Digital conductivity & Resistivity meter	Handheld Digital conductivity & Resistivity meter <ul style="list-style-type: none"> • Meter Type : Portable • Display type : LCD • Min Conductivity : 0 - 2000 uS (minimum range) • Max Conductivity 0 - 200 mS (minimum range) • Conductivity Resolution: 0.01 , 0.1, or 1 µS; 0.01, or 0.1 mS (or better) • Cell Constant K = 0.1, 1.0, or 10 (or better) • Temperature : 10 (° C) to 110 (° C) (minimum range) • Temperature compensation : both Automatic and manual • Resistivity: 2 to 20 MΩ•cm (minimum range) • Total Dissolved Solids (TDS) : 0 to 35.0 g/L (minimum range) • Salinity: 0 to 25.0 ppt (minimum range) • Waterproof • ISO 9001 certified or Manufacturer's QMS certificate, or Equivalent 	02
2.2	Digital Handheld PH meter	Handheld PH meter specifications <ul style="list-style-type: none"> • Measuring Range: 0 to 14.0 • pH Resolution: 0.01 (or better) • pH Accuracy: +/-0.01 (or better) • pH Operation Temperature: 0 to 60°C • Waterproof • ISO 9001 certified or Manufacturer's QMS certificate, or Equivalent 	02

2.3	Handheld Digital Chlorine Meter specifications	Handheld Digital Chlorine Meter specifications <ul style="list-style-type: none"> • Total Chlorine minimum Range: 0.01 to 10 ppm (10 to 50 ppm using dilution method) • Accuracy : $\pm 10\%$ rdg. ± 0.01 ppm (or better) • Waterproof • ISO 9001 certified or Manufacturer's QMS certificate, or Equivalent 	02
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B. Sustainability and warranty requirements

N°	Minimum technical requirements of UNOPS
Environmental management system	Bidders must provide evidence that the manufacturer is in possession of ISO 13485 & ISO 9001, or equivalent certification. If not, a copy of the manufacturer's internal environmental management policy must be provided.
Quality Standards	Bidders must provide evidence of all quality standards certificates as listed in the technical requirements. <ul style="list-style-type: none"> ➤ If the tenderer is the manufacturer, it must provide a manufacturing approval for the equipment (valid license from the competent authority); or ➤ If the tenderer is not the manufacturer, it must provide the manufacturer's authorisation.
After sales services (technical support)	<p>Bidders shall provide after-sales services to ensure that the gluing machine is used in optimal conditions. The tenderer shall provide this technical support through a local representative or partner.</p> <ul style="list-style-type: none"> ➔ Previous experience in providing support services for this or similar equipment); ➔ Previous experience in providing support services for this or similar equipment; ➔ Commitment that the local partner/representative will have the necessary stock of spare parts, the required qualification to provide the required services within the given timeframe.
Warranty	<p><u>Period:</u> The minimum duration of the warranty shall be 12 months, starting from the start of the equipment.</p> <p><u>Service:</u> The warranty covers preventive maintenance services and repair/replacement of defective equipment during the warranty period. The tenderer must provide its preventive maintenance plan for at least 12 months from the start-up.</p>

User's and service manuals	Bidders shall provide the operation and/or user manual for the equipment in English, French and if possible Portuguese.
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C. Related service needed

Services	UNOPS minimum service requirements	Qty	Units	Place of performance of the services	End date(s) of the service provision
1	Installation and start-up: start-up of the equipment on site with sample production for all equipment of the Lot 1 (1.1 & 1.2)	1	EA	HNSM (Hospital Nacional Simão Mendes, Bissau) - Guinea Bissau	Upon receipt of the equipment on site, the supplier will be contacted for installation within 2 weeks.
2	Training on: - the water quality monitoring and control - the operation and the maintenance of all the equipment delivered and installed. The tenderer must submit a training plan* describing what will be covered during the training.	1	Package deal	HNSM (Hospital Nacional Simão Mendes, Bissau) - Guinea Bissau	From the 2nd day after start-up
3	Preventive maintenance of the equipment according to the manufacturer's maintenance plan** (technician, spare parts, etc) during the warranty period - at least one (1) year.	1	Year	HNSM (Hospital Nacional Simão Mendes, Bissau) - Guinea Bissau	As per the maintenance plan

D. Delivery requirements

UNOPS Requirements	
Delivery time	<p>Bidder shall deliver the goods 70 Days FCA after Contract signature.</p> <p>UNOPS plans to award contract/s based on FCA incoterm basis and arrange its own freight, but reserves the right to award on CPT (90 days) basis if it finds the proposed costs and delivery time more advantageous. The readiness of the goods should be 70 days after contract signature in case of FCA award.</p> <p>Bidders must quote FCA (Port to be defined), indicating both FCA and CPT prices.</p>
Delivery place and Incoterms rules	<p>Incoterms 2020:</p> <p>FCA - Port to define (70 days)</p> <p>CPT Bissau Port - Guinea Bissau (90 days)</p>
Consignee détails	Hospital Nacional Simão Mendes, Bissau - Guinea Bissau

UNOPS Right to vary requirements	At the time the Contract is awarded, UNOPS reserves the right to vary the quantity of the goods and associated services specified above, provided this does not exceed +/- 20% , without any change in the unit prices or other terms and conditions of the ITB.
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Inspections and tests

The following inspections and tests should be carried out:

- Inspection of the equipment at the manufacturer's site by a competent authority;
- Submission of the certificate of conformity;
- Start-up of the equipment;
- Complete testing of the equipment at start-up;
- Submission of the warranty certificate.

This inspection and approval of the equipment does not affect the right of the recipient (Hospital Nacional Simão Mendes, Bissau - Guinea Bissau) to carry out its own inspections and tests upon commissioning of the equipment.

If the equipment does not meet the established specifications, the supplier shall take immediate steps to remedy the defects or replace the defective equipment to the satisfaction of the purchaser.