



November 13, 2024

**LIMITED INVITATION TO BID
 No. UNFPA/MNG/LIB/24/020**

AMENDMENT NO. 1

Please review the amendments applicable to UNFPA/MNG/LIB/24/020. Thank you for your attention to these updates.

- I. Please note that UNFPA is enlarging the list of items under LOT 1 with the additional four (4) items as follows:

Item No (or internal number)	Item short description	Qty
LOT 1		
Item 2 (OR 2)	Portable Blood Gas Analyzer	2
Item 10 (OR 16)	Electrosurgical system	1
Item 13 (OR 20)	Monitor for cerebral oximetry	1
Item 24 (OR 37)	Sternal, oscillating saw	2

The Technical Specifications of the new items are as follows:

Item No	Item name	Requirement	Quantity
LOT 1			
Item 2 (OR 2)	Portable Blood Gas Analyzer	<p>Product Description:</p> <p>The device is intended for in vitro diagnostic in point-of-care for quick testing of various analytes in whole blood or plasma.</p> <p>Electrical Requirements:</p> <ul style="list-style-type: none"> ● Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E. 	2

- Rechargeable batteries with autonomy of at least 30 minutes of continuous use.

Technical specifications:

- Handheld portable system for point-of-care use.
- Test available, at least: blood gases, electrolytes, chemistries, coagulation, cardiac markers (cTnl), Hematology.
- One cartridge for all the available tests or combinations of tests.
- Sample Type: arterial or venous whole blood.
- Sample Volume: < 100 µl.
- Time to Result: approx. 5 minutes or less.
- Self-test. Autocalibration.
- Integrated bar code scanning.
- Internal memory for at least 50 patient results and 1000 quality control results.
- LCD display
- Low battery indication.
- Keypad for manual entry information and operation.
- All materials resistant to hospital-use disinfectants.

Accessories:

- One (1) Pack of rechargeable batteries
- One (1) Battery charger
- One (1) Simulator
- One (1) Portable printer compatible with the system offered. Including data and power cables.
- Set of start-up consumables as coagulation cartridges.

NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.

Accessories should be reusable when an option is available.

Documentation requirement:

- User manuals must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, and safe disposal). In English, French and preferably also in Mongolian.
- A service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.
- A list of common spares and accessories with part numbers must be provided.

		<ul style="list-style-type: none"> ● Manufacturer authorization. ● Commitment Manufacturer letter, including: <ul style="list-style-type: none"> ○ at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty"). ○ at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services"). ○ training on use, cleaning, and disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training"). <p>Regulatory approvals required:</p> <ul style="list-style-type: none"> ● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia. ● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> ○ European Certificate of Conformity (CE) with Regulation 2017/746 or Directive 98/78 EC and Agreement Letter signed with the NB demonstrating the ongoing IVDR application, for IVD devices, or ○ FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or ○ Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. <p>Safety & Product Standards:</p> <ul style="list-style-type: none"> ● Bidder shall furnish the documentary evidence to demonstrate that the goods it offers meet the international safety & regulatory standards, providing, in addition, a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the following standards: <ul style="list-style-type: none"> ○ ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes. ○ IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements ○ IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment 	
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<p>Item 10 (OR 16)</p>	<p>Electrosurgical system</p>	<p>Product Description</p> <p>A device that uses high-frequency electrical energy in a radiofrequency (RF) band to develop heat directly within soft-tissue cells (thermodynamic) for cutting and coagulating tissue typically during general surgical procedures.</p> <p>Electrical Requirements:</p> <p>Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E</p> <p>Technical specifications:</p> <ul style="list-style-type: none"> ● Application Monopolar and bipolar ● Monopolar and bipolar modes: cut, coagulation, including forced and spray coagulation mode. ● Power activation is controlled by the foot switch, and by hand switch at the handpiece. ● Self-test ● Power output: <ul style="list-style-type: none"> ○ Bipolar: Max. 400 Watt ○ Monopolar: Max. 400 Watt ○ RF generator output: 350 kHz. ● Instruments socket connection: at least two monopolar and one bipolar. ● User interface: Power control and modes selection by touch high-resolution display. ● Neutral electrode isolated from ground. ● Neutral electrode contact monitoring system. ● Automatic power limitation. ● Power output blocking in case of active electrode or neutral electrode contact failure. ● Visual and audible activation indicators. ● Visual and audible alarms. <p>Accessories:</p> <ul style="list-style-type: none"> ● Double-pedal footswitch for monopolar and bipolar modes, with connecting cable. ● Two (2) neutral electrodes, reusable, sterilizable, monopolar with connecting cable. ● One (1) monopolar electrode handle (pencils), finger switch controlled, reusable, sterilizable, with connecting cable. 	<p>1</p>

		<ul style="list-style-type: none"> ● One (1) monopolar electrode handle (pencils), foot switch controlled, reusable, sterilizable, with connecting cable. ● One (1) set of different monopolar reusable electrodes: blade/knife, needle, ball, loop, spatula, and coagulation electrodes. ● Two (2) bipolar forceps, foot switch controlled, reusable, sterilizable, with connecting cable. ● Two (2) reusable connection cables for disposable split neutral electrodes. ● Reusable adapters and connecting cables for monopolar and bipolar handpieces, as necessary. ● Trolley with basket, made of steel with anti-corrosive epoxy coating, aluminum, AISI 304 stainless steel or higher quality material. With 4 antistatic castors, and 2 with brakes. ● Set of start-up consumables. <p><i>NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.</i></p> <p><i>Accessories should be reusable when an option is available.</i></p> <p>Documentation requirement:</p> <ul style="list-style-type: none"> ● User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, and safe disposal). In English, French and preferably also in Mongolian. ● A service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian. ● A list of common spares and accessories with part numbers must be provided. ● Manufacturer authorization. ● Commitment Manufacturer letter, including: <ul style="list-style-type: none"> ○ at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty"). ○ at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services"). ○ training on use, cleaning, and disinfecting for healthcare staff and basic maintenance technical staff, in English and 	
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		<p>Mongolian. (according to the general requirements in the bid document under the clause "Training").</p> <p>Regulatory approvals required:</p> <ul style="list-style-type: none"> ● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia. ● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> ○ European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the ongoing MDR application, for Class IIb devices, or ○ FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or ○ Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. <p>Safety & Product Standards:</p> <p>Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the following standards:</p> <ul style="list-style-type: none"> ● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes. ● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ● IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests ● IEC 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and high-frequency surgical accessories. ● ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process. 	
<p>Item 13 (OR 20)</p>	<p>Monitor for cerebral oximetry</p>	<p>Product Description</p> <p>The device is intended for use in hospitals, providing continuous non-invasive measurement of cerebral oxygen saturation and changes in regional oxygen saturation of blood in the brain or other body tissues beneath the sensor.</p>	<p>1</p>

		<p>Electrical Requirements:</p> <ul style="list-style-type: none"> ● Power requirements according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E. ● Battery Type Lithium-ion ● Operating time 1 hour under normal monitoring conditions. <p>Technical specifications:</p> <ul style="list-style-type: none"> ● Sensor Application: Noninvasive monitoring of regional haemoglobin oxygen saturation in up to four site-specific areas. ● Screen type TFT LCD: screen size - At least 25 cm (diagonally) ● Technology: Real-time data on oxygen supply and demand balance, reflecting venous oxygen reserve. ● Patient Monitoring: Intended for single-patient use in monitoring regional oxygen saturation in neonatal, pediatric, and adult patients. ● Two- or Four-Channel Monitoring: Capability to monitor either two or four channels simultaneously. ● Signal Strength Indicator (SSI): Indicator showing the strength of the signal being received. ● Alarms and Status Messages: Information on alarms and status messages displayed by the system. <p>Accessories:</p> <p>Two (2) Reusable sensor cables (RSC)</p>	
<p>Item 24 (OR 37)</p>	<p>Sternal, oscillating saw</p>	<p>Product Description</p> <p>A device designed for sternotomy during a cardiovascular surgical intervention. Battery-operated system. For pediatric and precision procedures.</p> <p>Electrical Requirements:</p> <ul style="list-style-type: none"> ● Operation: Rechargeable battery-powered. ● Charger power requirements: according to Mongolia standards: 220 VAC, 50 Hz. Power cord with plug type E <p>Technical specifications:</p> <ul style="list-style-type: none"> ● Type: Sternum saw, battery-operated ● Use: Must be able to be used for pediatric surgery. ● Progressive Velocity: from 0 to at least 13.000 cpm. ● Detachable and steam sterilizable saw system. ● Single handpiece for multiple saw head. ● Saw head included: ● Oscillating pediatric saw 	<p>2</p>

- Sternum saw with a saw guide.
- Cordless with removable battery for sterilization
- Aseptic battery (no sterilization needed)
- Trigger function with safety lock mode.

Accessories:

- Two (2) Rechargeable batteries (preferably Li-ion battery)
- Two (2) Autoclavable battery case or house
- One (1) Autoclavable aseptic transfer shield for battery loading (if applicable)
- One (1) Battery charger for 1 battery
- One (1) Pediatric sternum saw guide or guard.
- Two (2) Pediatric sternum saw blades.
- One (1) Oscillating sternum saw blade.
- One (1) Sterilization tray with fixations according to the offered system.
- Set of start-up consumables, if necessary.

NOTE: All the necessary accessories for the correct operation of the product, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included.

Accessories should be reusable when an option is available.

The accessories will be used for both neonates and pediatric patients.

Documentation requirement:

- User manual must be provided (including operation instructions, maintenance and/or procedures for decontamination, storage conditions, and safe disposal). In English, French and preferably also in Mongolian.
- A service manual must be provided (including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits). In English, French and preferably also in Mongolian.
- A list of common spares and accessories with part numbers must be provided.
- Manufacturer authorization.
- Commitment Manufacturer letter, including:
 - at least two (2) years of full onsite warranty (according to the general requirements in the bid document under the clause "Warranty").
 - at least five (5) years of Spare Parts availability (according to the general requirements in the bid document under the clause "Post-sale Services").

		<ul style="list-style-type: none"> ○ training on use, cleaning, and disinfecting for healthcare staff and basic maintenance technical staff, in English and Mongolian. (according to the general requirements in the bid document under the clause "Training"). <p>Regulatory approvals required:</p> <ul style="list-style-type: none"> ● Valid Mongolian official Import license from the main manufacturer for receiving, installing, and maintaining medical equipment in Mongolia. ● And at least one of the following regulatory approvals and certificates: <ul style="list-style-type: none"> ○ European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the ongoing MDR application, for Class IIa devices, or ○ FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or ○ Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan. <p>Safety & Product Standards:</p> <p>Bidder shall furnish the documentary evidence to demonstrate that the good it offers meet the international safety & regulatory standards, providing in addition a signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the following standards:</p> <ul style="list-style-type: none"> ● ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes. ● IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ● IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests ● ISO 7153-1: Surgical instruments — Materials — Part 1: Metals ● ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process. 	
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Hence, the complete list of the items under LOT 1 is as follows (the new items are marked in bold):

Item No (or internal number)	Item short description	Qty
LOT 1		
Item 1 (OR 1)	Activated Clotting Time (ACT) Measuring device	2
Item 2 (OR 2)	Portable Blood Gas Analyzer	2
Item 3 (OR 3)	Extra Corporeal Circulation (ECC) Machine	1
Item 4 (OR 4)	Hypo-hyperthermia Machine	1
Item 5 (OR 33)	Patient Auto-Transfusion System	1
Item 10 (OR 16)	Electrosurgical system	1
Item 12 (OR 19)	Brain Monitoring System	1
Item 13 (OR 20)	Monitor for cerebral oximetry	1
Item 22 (OR 32)	Portable external pacemaker	3
Item 23 (OR 34)	Patient drainage system	1
Item 24 (OR 37)	Sternal, oscillating saw	2
Item 25 (OR 38)	Surgeon's headlamp	1
Item 26 (ICU 3)	Dialysis Equipment for Neonate - Peritoneal dialysis system	1

For “List of Goods and Delivery Schedule”, “Consignee Address and Consignee-wise Quantity Distribution” including “List of Related Services and Completion Schedule” please refer to Section “2.2. Schedule of Requirements for LOT 1” of the LIB Document.

The list of the items included under LOT 2 remains unchanged.

- II. The deadline for submission of questions is now extended until Friday, November 15, 2024, 11:00 CET Time.

Please refer to the revised estimated timeline for the LIB:

Date	CET Time Zone*	Solicitation stage
07/11/2024	15:00	Bid Release Date
15/11/2024	11:00	Deadline for submission of Questions and Queries
18/11/2024	15:00	Answers and clarifications shared by UNFPA
19/11/2024	15:00	Submission of completed Bid Confirmation Form
28/11/2024	23:00	Deadline for Bid Submission
29/11/2024	10:00	Bid Opening
29/11/2024	10:00	Preliminary Examination
03/12/2024	10:00	Commercial Evaluation
06/12/2024	10:00	Technical Evaluation
20/12/2024	10:00	Final Evaluation
07/01/2025	10:00	UNFPA Internal Review and Approval
14/01/2025	10:00	Contract Award

* Reference: <https://www.timeanddate.com/worldclock/denmark/copenhagen>

Thank you for your attention and commitment.

Sincerely,

Ms. Natalia Giortz-Behrens

Pronouns: she, her, hers

Development Supplies Procurement Analyst, Team Lead

Supply Chain Management Unit

UNFPA, the United Nations Population Fund

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