United Nations Population Fund (UNFPA)
Country Office in Ukraine
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Website: www.unfpa.org
Date: 12/06/2024

Yerkezhan Tabyldiyeva, International Operations Manager

Invitation to Bid (ITB) No.UNFPA/UKR/ITB/24/03

Dear Sir/Madam,

We hereby solicit your Bid for the supply of the following items with the following technical specifications:

Item	Technical requirements	Quantity, pcs
Infant ventilator with HFOV	**Product Description** Device designed to provide temporary ventilation for premature born, infant and pediatric patients who require assistance maintaining adequate ventilation. Equipment to be used in critical care areas, stationary. **Electrical Requirements:** ● Power requirements according to Ukraine standards: 220 VAC ± 10%, 50 Hz. ● Power cord with "F" type plug for medical devices. ● Built-in rechargeable battery, allowing at least 2.5 hours of continuous operation. **Technical specifications:** ● Premature born, infant and pediatric patients up to 30 Kg. ● Mounted on a trolley with four (4) antistatic castors, at least two of the castors with brakes. Structure made at least of steel tube with anticorrosive finish in epoxy/electrostatic paint or higher quality. ● Gas inlet connections for supply from wall outlets: O_2 and Air. Connections compliant with DIN (according to the requirements of the destination country). With security systems to avoid errors in the gas connection. ● Display LCD, at least 12". ● Hot-wire flow sensor, proximal to patient. ● Flow sensor removable and autoclavable, included. Cable for flow sensor included. ● Automatic compliance and leakage compensation. ● Expiratory valve or expiratory block autoclavable ● Self-test ● Leak test. ● Preoxygenation function. 23% – 100% O2, up to 2 min ● PEEP/CPAP range at least: 0 – 30 cmH_2O ● Ventilation rate 2-200 bpm	**24**

	● Tidal volume 2–300 ml ● Adjustable I/E ratio or adjustable inspiration time. ● Peak inspiratory pressure: at least 4 to 60 cm H2O. ● Inspiration rise time adjustable. ● Inspiratory flow: at least 1 - 32 l/min ● Expiratory flow: at least 2 - 10 l/min ● Constant / Bias Flow adjustable at least: 5 to 20 Lpm ● Manual breath in all modes. Maximum time manual breath adjustable: at least 2 – 30s ● Inspiration time in the range of at least 0.1 -2 seconds ● FiO_2 adjustable: 21 - 100%. Oxygen cell included. ● High-frequency oscillation ventilation. Pressure amplitude range: 5 - 90 mbar. Frequency range: at least between 5 and 20 Hz Mean airway pressure: at least 5 - 40 mbar VTG in HFOV at least 0,2 ml - 30 ml I:E HFO: 1:1, 1:2, 1:3 Recruitment Maneuver: Frequency, inspiratory Time, and Pmean, adjustable. ● Volume, flow, and pressure adjustable trigger ● Termination criteria for PSV must be modifiable by the user. ● Ventilation modes, at least: o Intermittent Positive Pressure Ventilation (IPPV), with Volume-limited ventilation. o Volume guarantee ventilation o Volume-limited o Positive Pressure Ventilation (IPPV) o Positive Pressure Ventilation (IPPV) with Volume-limited ventilation and Volume guaranteed. o Synchronized Intermittent Positive Pressure Ventilation (S-IPPV), with Volume-limited ventilation and Volume guaranteed. o Synchronized Intermittent Mandatory Ventilation (SIMV) o Synchronized Intermittent Mandatory Ventilation (SIMV), with pressure support (PSV), Volume-guarantee and Volume-limited. o Continuous Positive Airway Pressure mode (CPAP), with Backup Frequency o Pressure supports ventilation with Synchronized Intermittent Positive Pressure Ventilation (PSV + S-IPPV), with Volume guaranteed and Volume-limited. o Pressure support ventilation with Synchronized Intermittent Positive Pressure Ventilation (PSV + SIMV), with Volume guaranteed and Volume-limited. o Biphasic positive airway pressure mode (BiLevel Airway Pressure Ventilation, BiPAP, DuoPAP, PDUO or similar) o Backup ventilation o High frequency oscillatory ventilation (HFOV) with volume guarantee o Non-invasive ventilation: o Nasal intermittent positive pressure ventilation (nIPPV) o Nasal continuous positive airway pressure (nCPAP) o Biphasic positive airway pressure mode o O2 Therapy High and Low Flow Oxygen Therapy (Optional) o nHFO ● Monitored and Displayed parameters, at least: o Capnography (sensor included)	

	○ Respiratory rate ○ Inspired and expired tidal volume ○ Minute volume. ○ I:E ratio ○ Inspiratory and expiratory times. ○ Airway pressure, peak and mean. ○ FiO2 ○ PEEP ○ Peak pressure ○ Waves vs time: pressure, volume, and flow ○ Pressure-Volume, Flow-Volume and Pressure-Flow loops. ○ Battery status. ○ Alarm settings. ○ Resistance, compliance C20/C ○ Ventilation gas leak ● Audio and visual alarms for at least: ○ High and low airway pressure. ○ Tidal volume ○ Minute Volume ○ FiO_2 ○ Apnea ○ Respiratory rate ○ Patient disconnection ○ Gas supply failure ○ Power failure ○ Low battery ○ System failures ● All materials resistant to disinfection with hospital-grade products. ● Indications and messages on the equipment must be in English language as mandatory, and preferably also in Ukrainian language. **Accessories:** ● Support arm for patient-circuit, adjustable. ● One (1) Air pressure regulator, compatible with the medical gas system of the health unit if it is necessary. ● One (1) O2 pressure regulator, compatible with the medical gas system of the health unit if it is necessary. ● Hoses for Air and O2, length: at least 2 meters (2-3 meters preferably), with their respective connections compatible with the gas inlet of the equipment and the supplied pressure regulators. ● One (1) expiratory valve or expiratory block autoclavable, in addition to that included in the device. ● One (1) test lung, neonatal size. ● Sixty (60) Neonatal disposable patient circuits for invasive ventilation, complete, including pressure line if applicable. ● Two hundred (200) complete disposable neonatal high-frequency ventilation circuits (including adapters, filters, pressure lines and any element necessary for their correct functioning). Only applies if they are different from conventional ventilation circuits. ● Nine (9) neonatal nasal masks, in three different sizes, for nCPAP and nIPPV, reusables. ● Nine (9) neonatal nasal prongs, in three different sizes, for nCPAP and nIPPV, reusables. ● Twenty (20) Neonatal disposable patient circuits for non-invasive ventilation, complete, including all necessary adapters. ● One (1) Oxygen cell, if applicable, in addition to that included in the device. ● One (1) cable for proximal flow sensor, in addition to that included	

	with the device. ● Two (2) distal flow sensors, reusable, if applicable, in addition to that included in the device. ● Three (3) Neonatal (proximal) flow sensors, reusable, in addition to that included in the device. ● One (1) capnography sensor, in addition to that provided with the device, and ten (10) reusable adapters for patient circuit (pediatric size). *NOTE: If applicable, all other necessary accessories and consumables for the correct operation of the product during the first 12 months, including all standard tools, cleaning, and lubrication materials, even if they are not included in these required technical specifications must be included and listed in the offer.*	
	Documentation required: Bidder shall furnish the following documents: ● Manufacturer brochure or data sheet including at least all technical specifications required. ● User manual must be provided including installation requirements, operation instructions, maintenance and procedures for decontamination, storage conditions, safe disposal. ● Service manuals must be provided including preventive maintenance and calibration procedures, equipment necessary for preventive maintenance and repair, diagrams, and circuits. ● List of all common spare parts and accessories with part numbers. ● Manufacturer authorization Letter. ● Commitment manufacturer letter including: o installation and commissioning on site would be performed by the manufacturer or his representative in the country. o at least two (2) years of full onsite warranty. o at least five (5) years of Spare Parts availability. o training on use, cleaning, and disinfecting for the healthcare staff, and basic maintenance for the technical staff, in Ukrainian and English language. **NOTE: All the documents must be submitted in English and Ukrainian language as mandatory. The Russian language could be accepted as an exception to the Ukrainian language.**	
	Regulatory approvals required: Bidder shall furnish **documentary evidence** to demonstrate that the good offered is approved according: ● Valid certificate or approval letter from national Ukrainian regulatory body, which confirms local registration of the product and permission to use it in medical practice. ● Valid manufacturing licenses. ● And at least one of the following regulatory approvals and certificates: o European Certificate of Conformity (CE) with Regulation 2017/745 or Directive 93/42 EC and Agreement Letter signed with the NB demonstrating the on-going MDR application, for Class IIb devices, or o FDA (Food and Drug Administration) of the USA that certifies marketing permission in the United States, or o Other regulatory bodies of an IMDRF founding member country such as Australia, Canada, or Japan.	

	Safety & product Standards: Bidder shall furnish the following documents: ● Valid ISO 13485 certificate. ● Signed and dated Declaration of Conformity (DoC) according to ISO 17050 to demonstrate that, the good offered, meet at least the follow international safety & regulatory standards: ○ 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 80601-2-12: This standard outlines the basic safety and essential performance requirements for a ventilator in critical care environments, ensuring compliance with ventilation accuracy, alarms, monitoring capabilities, electrical safety, mechanical	

Goods should be provided on **DAP (Kyiv, Ukraine) basis**.

If you are interested in submitting a bid for these items/services, kindly fill in the attached submission form and send to the secure email address indicated below/ not later than **June 26, 2024 at 10:00 AM (Kyiv time).**

Please ensure to mark your email with the ITB reference number and the words "Sealed bid. Do not open before **June 26, 2024 at 10:00 AM (Kyiv time).**".

Secure email address for bid submission ***ua-procurement@unfpa.org***

Note: Do not submit your bid/proposal to the contact person's email address!

Please submit your quotation in **USD currency**. Conversion of currency into the UNFPA preferred currency, if the offer is quoted differently from what is required, shall be based only on UN Operational Exchange Rate prevailing at the time of competition deadline.

Email address of Contact Person in case of technical questions: ***seredenko@unfpa.org*** - Andrii Seredenko, SRH Project Manager, with copying to: ***grechishnikov@unfpa.org*** - Maksym Grechishnikov, Procurement and Logistics Associate.

Bidding shall be conducted through ONE envelope. The technical bid containing the technical specifications and the financial bid containing the price information shall be submitted together.

Documents to be submitted with the bid:

a. Completed and signed Bid Submission Form (Annex - 1);
b. Bidders Identification Form (Annex - 2);
c. Product Item Overview Form (Annex - 3);
d. Technical bid, including brochures, pictures and product catalogue to demonstrate that specification and quality of the products are in line with the requirements listed in the bidding documents. Please note that brochures of the proposed model shall be provided in both English and Ukrainian language;
e. Financial bid including the price schedule (Annex - 4);
f. FTP Questionnaire for Medical Devices (Annex - 5);
g. Approval letter or certificate from national Ukrainian regulatory body (which confirms local registration of the product and permission to use in medical practice);
h. Authorization Letter from the Manufacturer to the Bidder which authorizes sales in Ukraine;
i. Authorization Letter from the bidder to a local representative to provide the after sales services, installation, commissioning and training for the staff in Ukraine (if different from the bidder);
j. Quality Assurance Certificates:

- EC certificate (referencing the name/number of the notifying body) with an additional copy of EC Design Examination certificate, and/or 510k/PMA FDA clearance;
- A signed and dated document according to ISO 17050 stating compliance to critical ISO standards (e.g. ISO 13485 QMS) and directives, and which has a reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted.

Partial bids are not allowed under this ITB.

INCOTERMS 2010:

- Price of goods should include the delivery on **DAP (Kyiv, Ukraine) basis**.

Validity of Bid:

The prices of the bid shall be valid for **90 days** after the closing date of bid submission as specified by UNFPA. A bid valid for a shorter period shall be rejected by UNFPA.

Delivery Time:

The maximum allowed delivery time is **90 days** upon issuing of purchase order.

All items are subject for pre-shipment inspection while requested by UNFPA CO Ukraine.

Evaluation of Bids:

UNFPA shall compare all substantially responsive bids to determine the lowest priced substantially responsive bid.

A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the bidding documents without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

a. affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or
b. limits in any substantial way, inconsistent with the bidding documents, UNFPA's rights or the bidder's obligations under the contract; or
c. if rectified would unfairly affect the competitive position of other bidders presenting substantially responsive bids.

Contract Award:

UNFPA shall award the contract to the lowest priced bidder(s) whose bid has been determined to be substantially responsive with the bidding documents, including the maximum allowable lead time, and full acceptance of the UNFPA General Terms and Conditions.

Note: Current UNFPA supplier policies apply to this solicitation and can be found at: http://www.unfpa.org/suppliers.

UNFPA reserves the right to increase or decrease the quantity of the order given in this request for proposals, without changing the price per unit of the product or other conditions.

Attachments:

- **Annex 1 - Bid Submission Form**
- **Annex 2 - Bidders Identification Form**
- **Annex 3 - Product Item Overview Form**
- **Annex 4 - Financial bid (Price Schedule Form)**
- **Annex 5 - FTP Questionnaire for Medical Devices**