



## UNFPA/DNK/RFQ/25/002 Cardiac surgery equipment

### CLARIFICATION TO BIDDERS No: 01

2025.2.11

No	Questions from suppliers	Answer of UNFPA
1	<p>We are a team from China and are very interested in participating in your tender process. However, due to the Chinese New Year holiday, we have only recently resumed work, and some of our factories are still in the process of returning to full operation. This has affected our ability to prepare the tender documents within the current timeline. Therefore, we kindly request an extension for the tender submission deadline. We believe that with a little more time, we can provide a comprehensive and well-prepared proposal that meets your requirements.</p>	<p>Considering the fact that the bid announcement day coincides with the Chinese New Year holidays as well as posting the answer to bidder's questions were delayed, UNFPA is extending the bid submission deadline until February 24, 2025, at 23:00 (Central European Time).</p>
2	<p><b>Ref: Item 1 (Activated Clotting Time Measuring Device)</b> Test Chamber (Dual-Well vs. Single). The RFQ specifies a single test chamber, while the proposed product features a dual-well test chamber. This design provides enhanced quality control by enabling simultaneous reference and sample testing, ensuring greater accuracy in high-risk procedures like cardiovascular surgeries. Would a dual-well test chamber design, which improves quality control and reliability, be considered compliant with the tender requirements?</p>	<p>Yes, a dual-well test chamber will be accepted.</p>
3	<p><b>Ref: Item 1 (Activated Clotting Time Measuring Device)</b> Testing System (Cartridges vs. Single-Use Cuvettes) The RFQ specifies the use of disposable single-use cuvettes, while the proposed product employs a cartridge-based system. This system reduces</p>	<p>Yes, a cartridge-based system will be accepted.</p>

	<p>waste, improves workflow efficiency, and minimizes handling errors during testing.</p> <p>Can a cartridge-based testing system be accepted, considering its operational benefits and alignment with modern laboratory practices?</p>	
4	<p><b>Ref: Item 1 (Activated Clotting Time Measuring Device)</b></p> <p>Precision (2.6–5.1% C.V. vs. ≤10% C.V.) The RFQ specifies a precision of ≤10% C.V. for whole blood. The proposed product exceeds this requirement with a precision range of 2.6–5.1% C.V., offering more accurate and reliable results.</p> <p>Would the higher precision of the proposed product, which exceeds the RFQ's requirements, be deemed acceptable?</p>	<p>Yes, higher-precision equipment will be accepted.</p>
5	<p><b>Ref: Item 5 (Autotransfusion System)</b></p> <p>Bowl Sizes (One Standard Bowl Size vs. Four Bowl Sizes) The tender specifies the availability of four bowl sizes. The proposed system is equipped with a single standard bowl size (135 mL) designed to accommodate a wide range of procedures, simplifying operation and reducing the risk of errors during setup.</p> <p>Would the use of a single bowl size, optimized for most patient needs and enhancing operational simplicity, be acceptable under the tender specifications?</p>	<p>We suggest maintaining the specification of four bowl sizes. This is an important feature to face all operational situations.</p> <p>Sizes examples of use:</p> <ul style="list-style-type: none"> <li>- Bowl 55 The smallest bowl for minimal bleeding – Small size patients.</li> <li>- Bowl 125 The standard bowl for low bleeding - Obstetric Surgery</li> <li>- Bowl 175 The intermediate bowl for medium bleeding - Cardiovascular Surgery</li> <li>- Bowl 225 The largest bowl for high bleeding - Emergency &amp; Trauma</li> </ul>
6	<p><b>Ref: Item 5 (Autotransfusion System)</b></p> <p>Cleaning Speed (2.25–3.4 Minutes vs. Not Specified in the tender requirement)</p> <p>The tender does not specify cleaning speed. The proposed system offers a fast cleaning cycle of 2.25–3.4 minutes, ensuring minimal downtime during surgical procedures.</p> <p>Can the proposed cleaning speed, which enhances procedural efficiency, be considered compliant with the tender requirements?</p>	<p>Yes, this feature is not specified in the tender, so the offered cleaning speed complies but it is not mandatory.</p> <p>The offered fast cleaning cycle could be beneficial as it reduces downtime in surgical procedures, enhancing workflow efficiency.</p>
7	<p><b>Ref: Item 5 (Autotransfusion System)</b></p> <p>Hematocrit Levels (59–65% vs. Hematocrit Indicator Only) The tender specifies the presence of a hematocrit indicator. The proposed system not only includes a hematocrit indicator but also ensures consistently high hematocrit levels of 59–65%, providing high-quality blood for reinfusion.</p>	<p>It is not a specified requirement – Since the tender does not establish a required hematocrit range, the offered enhanced feature will comply with the requirement.</p> <p>The ability to consistently achieve high hematocrit levels could be considered a performance advantage, improving transfusion efficiency.</p>

	Would this advanced capability for delivering superior hematocrit levels, along with the indicator, meet the tender's requirements?	
8	<p><b>Ref: Item 5 (Autotransfusion System)</b>            Fat Removal Protocol (99% Efficiency vs. Specific Protocol) The tender specifies a specific protocol for fat removal. The proposed system achieves fat removal with an efficiency of 99% through its integrated washing technology.            Would this superior fat removal efficiency be considered compliant with the tender requirements?</p>	Achieving 99% fat removal is a strong performance advantage that could improve the quality of reinfused blood. We recommend using an alternative method in the specification as an inclusion criteria for alternative brands.
9	<p><b>Ref: Item 5 (Autotransfusion System)</b>            Touchscreen Display (7-inch vs. 8-inch or Larger) The tender requires a touchscreen display of 8 inches or larger. The proposed system features a 7-inch high-resolution touchscreen, providing an intuitive and user-friendly interface with real-time data visualization.            Can the smaller, yet efficient, 7-inch display meet the tender's requirements given its advanced functionality and ease of use?</p>	This size difference does not impact functionality or user experience. It specifies a minimum expected technical characteristic for the display. Eg. a 3-inch non-touchscreen display would be a lower characteristic.
10	<p><b>Ref: Item 5 (Autotransfusion System)</b>            Data Storage (100 Patient Records vs. Not Specified in the tender requirement)            The tender does not specify requirements for data storage. The proposed system can store up to 100 patient records and includes USB ports for data export, ensuring traceability and compliance with modern data management practices.            Question: Would these additional data management features be accepted as beneficial enhancements to the tender requirements?</p>	Yes, the extra data storage and export features are beneficial enhancements, but the specifications are not mandatory.
11	<p><b>Ref: Item 5 (Autotransfusion System)</b>            Compact Dimensions and Weight (50 kg vs. Not Specified in the tender requirement)            The tender does not specify size or weight requirements. The proposed system is compact and lightweight, facilitating easy mobility in operating rooms with limited space.            Can the proposed system's ergonomic design and portability be accepted under the tender's specifications?</p>	Yes, ergonomic design and portability are beneficial characteristics, but the specifications are not mandatory.
12	<p><b>Ref: Item 5 (Autotransfusion System)</b>            Vacuum Range (-10 to -370 mmHg vs. -50 to -300 mmHg)</p>	Yes, an extended vacuum range may be acceptable.

	<p>The tender specifies a vacuum range of -50 to -300 mmHg with adjustments in steps of 10 mmHg. The proposed system offers an extended range of -10 to -370 mmHg, providing greater flexibility for a variety of surgical scenarios.</p> <p>Question: Would the enhanced vacuum range, which exceeds the specified requirements, be considered compliant?</p>	
13	<p><b>Ref: Item 5 (Autotransfusion System)</b> We believe the proposed system's advanced features enhance operational efficiency, patient safety, and clinical outcomes. We kindly request clarification on whether these deviations, which offer significant benefits, would be deemed acceptable under the tender requirements.</p>	<p>Yes, enhanced features may be considered acceptable. The minimum specifications are mandatory; if any of these are not compliant, deviations are reported. If you have a deviation to comment, we kindly review it; otherwise, any enhanced feature is acceptable.</p>
14	<p><b>Ref to: Item 6 (Electrosurgical System)</b> RF Generator Output (434 kHz vs. 350 kHz) The tender specifies an RF generator output of 350 kHz. However, our proposed product features an RF output of 434 kHz. This higher frequency allows for more precise energy delivery, reducing collateral thermal damage and enhancing surgical outcomes. Would this superior frequency be considered compliant with the tender, as it enhances precision and patient safety?</p>	<p>Yes, any justification for the improved feature can be considered (if applicable). Please provide support documentation within the bid documentation to review and consider as an acceptable deviation.</p>
15	<p><b>Ref to: Item 6 (Electrosurgical System)</b> Power Output (Bipolar: 70–530 W vs. Max 400 W) The tender specifies a maximum bipolar power output of 400 W. The proposed product offers a range of 70–530 W, allowing for greater flexibility across surgical applications. Question: Can a broader power range that exceeds the specified maximum but ensures greater adaptability and precision be accepted?</p>	<p>Yes, an extended power output range may be acceptable.</p>
16	<p><b>Ref to: Item 6 (Electrosurgical System)</b> Power Output (Monopolar: 120–300 W vs. Max 400 W) The tender specifies a maximum monopolar power output of 400 W. The proposed product provides a range of 120–300 W, optimized for precision without compromising safety. Question: Is a product with a more refined monopolar power output range, ensuring safety and accuracy, acceptable for compliance?</p>	<p>Monopolar power output: Max 400W is required but Max 300W could be eventually accepted. Please provide support documentation within the bid documentation to review and consider as an acceptable deviation.</p>
17	<p><b>Ref: Item 14 (OR 34): Patient Drainage System.</b></p>	<p>The intention was to indicate a performance standard rather than a specific brand, the bidder should provide technical</p>

	<p>The specifications indicate that “The offered item should be equivalent to ‘<b>Dräger</b>’ or exceed its performance standards.” However, after communicating with Dräger, we learned that they do not have this solution in their portfolio.</p> <p>Could you please clarify if this was an oversight and whether you meant to refer to a different supplier?</p>	<p>justifications on how their system meets or exceeds recognized performance benchmarks in the industry.</p> <p>The offered device must fulfill the specs and be used for continuous wound and chest drainage.</p>
18	<p>Could you provide details on the evaluation and award criteria? Will priority be given to the specified brand over equivalent alternatives? What other factors might be decisive in the evaluation process, such as price or technical compliance?</p>	<p>Please refer to the Section IV, V, VI, VII and VIII.</p> <p>A preliminary examination will be conducted before the technical evaluation to assess the bidder’s eligibility (Section IV) and the completeness of the documentation (Section V). Bids that pass the preliminary examination will have their technical offers evaluated against the specifications outlined in the RFQ document and a bid comparison will be made on the total cost, delivered to the final destination (Section VII).</p>
19	<p>It is understood that this request for quotation is a request for re-quotation of the equipment that was announced in the UNFPA.DNK.ITB.24.014 tender or the equipment that does not have a selected supplier, is it correct?</p> <p>If so, have you been notified that some devices that were offered in previous bids were not selected? Please clarify this</p>	<p>The evaluation process for UNFPA/DNK/ITB/24/014 is still ongoing, hence UNFPA cannot yet disclose any information regarding the outcome of this ITB.</p>
20	<p><b>Ref: Item 3 (Extra Corporeal Circulation (ECC) Machine)</b></p> <p>The proposed Terumo Advanced Perfusion System 1 offers alternative or advanced features that may not fully align with the tender requirements. Below are specific questions regarding these aspects, along with justifications on how the proposed system meets or exceeds the tender requirements.</p> <p>1. UPS Autonomy (20 Minutes vs. 60 Minutes)</p> <ul style="list-style-type: none"> <li>Clarification: The tender specifies a UPS with at least 20 minutes of autonomy under maximum power. The proposed Terumo Advanced Perfusion System 1 provides a robust UPS solution with a runtime of 60 minutes on a fully loaded system, which exceeds the requirement and ensures prolonged backup during critical operations.</li> </ul>	<p>The acceptance or rejection of any offer is not possible at this time. All offers will undergo evaluation by a technical assessment panel before a final decision is made. We recommend that bidders ensure their offers meet or exceed the minimum technical requirements outlined in the RFQ.</p>

<ul style="list-style-type: none"><li>● Justification: This extended runtime offers enhanced reliability and safety during procedures, surpassing the minimum autonomy requirement.</li><li>● Clarification Request: Would exceeding the minimum UPS autonomy requirement with a 60-minute runtime be acceptable?</li></ul> <p>2. Panel Display Exchange During HLM Function</p> <ul style="list-style-type: none"><li>● Clarification: The proposed system has modular touchscreen displays, but documentation does not explicitly confirm replacement during operation.</li><li>● Justification: The Terumo Advanced Perfusion System 1 design allows for hot-swappable display modules, ensuring continued operation.</li><li>● Clarification Request: Can this feature be evaluated for your consideration?</li></ul> <p>3. Timer Range (0–999 min 59 sec)</p> <ul style="list-style-type: none"><li>● Clarification: The proposed system's timer operates with a different format (HHH:MM:SS).</li><li>● Justification: The Terumo Advanced Perfusion System 1 provides an extended timekeeping range (990:59 HH:MM format), exceeding the required 999 min 59 sec.</li><li>● Clarification Request: Would a functionally equivalent or superior timer format be accepted?</li></ul> <p>4. Double Roller Pump Dimensions</p> <ul style="list-style-type: none"><li>● Clarification: The proposed system does not include a double roller pump with a pump raceway of Ø 85 mm and occlusion roller Ø 15 mm.</li><li>● Justification: The Terumo Advanced Perfusion System 1 utilizes advanced single-roller pumps with exceptional flow precision and control mechanisms. Specifically, the Terumo roller pump achieves a maximum flow rate of 10 L/min with precise flow adjustments, ensuring superior control over blood flow. This design minimizes fluctuations, providing consistency within 0.1 L/min for both pediatric and adult perfusion needs. Additionally, the system supports bi-directional operation and pulsatile flow capabilities, enhancing its adaptability for</li></ul>	
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<p>complex surgical procedures. Furthermore, the roller pump's occlusion mechanism with audible feedback allows for setting adjustments while the pump is running, eliminating the need to stop the roller pump during critical operations.</p> <ul style="list-style-type: none"><li>• Clarification Request: Would a high-precision single roller pump be acceptable instead of a double roller pump?</li></ul> <p>5. Sensors (Not Fully Specified for All Parameters)</p> <ul style="list-style-type: none"><li>• Clarification: The system includes pressure, temperature, level, and bubble detection sensors, but does not explicitly list all the required ranges (e.g., bubble sizes of 4 mm, 5 mm, and 6.5 mm Ø).</li><li>• Justification: The bubble detector in the Terumo Advanced Perfusion System 1 is highly sensitive, detecting air bubbles as small as 0.3 cc, exceeding standard safety requirements.</li><li>• Clarification Request: Would submission of exact sensor specifications be sufficient for compliance confirmation?</li></ul> <p>Summary of Superior Features</p> <p>Despite minor technical deviations, the Terumo Advanced Perfusion System 1 meets or exceeds performance expectations due to:</p> <ul style="list-style-type: none"><li>• High-precision roller pumps ensuring accurate blood flow regulation.</li><li>• Advanced safety features such as a pushbutton microprocessor-controlled direction change and integrated bubble detection sensitivity.</li><li>• Modular and user-configurable controls, ensuring seamless operation and flexibility.</li><li>• Extended UPS backup time, reducing the risk of power failures during procedures.</li></ul> <p>We kindly request confirmation on whether these deviations or technological enhancements can be considered acceptable under the RFQ evaluation process. We look forward to your response and appreciate your guidance in ensuring compliance.</p>	
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