



Republic of the Philippines
Department of Health
Regional Office No. XI
SOUTHERN PHILIPPINES MEDICAL CENTER
J.P. Laurel Avenue, Davao City



TECHNICAL SPECIFICATION

ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR

Name of Project

Instructions:

Bidders must state in the column under **Statement of Compliance** the word either “Comply” or “Not Comply” against each of the individual parameters of each Specification stating the corresponding performance parameter of the equipment offered. Statements of “Comply” must be supported by evidence in a Bidders Bid and cross-referenced to that evidence. Evidence shall be in the form of manufacturer’s un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate. A statement that is not supported by evidence or is subsequently found to be contradicted by the evidence presented will render the Bid under evaluation liable for rejection. A statement either in the Bidders statement of compliance or the supporting evidence that is found to be false either during Bid evaluation, post-qualification or the execution of the Contract may be regarded as fraudulent and render the Bidder or supplier liable for prosecution subject to the provisions of **ITB** Clause 3.1(a)(ii) and/or **GCC** Clause 2.1(a)(ii).

Bidder may submit offer which provides for superior specifications and /or better terms and conditions to the government at no extra cost. However, these shall not be given any bonus, credit or premium in the bid evaluation

Prepared by Technical Working Group

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<i>Item</i>	<i>Procuring Entity's Specification</i>	<i>Bidder's Specification as Technical Offer</i>	<i>Statement of Compliance</i>
ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR	<p>THREE (3) UNITS BRAND NEW PLASMA THAWER (DRY)</p> <p>1. Description of Function/Key Features</p> <ul style="list-style-type: none">▪ The Plasma Dry Thawing Bath achieves a uniform and quality standard of defrosted plasma without allowing the operators hand to get wet and plasma packs are protected from direct contact with water keeping the plasma bag dry.▪ Plasma Thawer should be able to thaw all types of plasma packs, either folded or flat in form, and apheresis packs. <p>2. Operational Requirements</p> <p>Digital, electronic bench top system is required with touch screen operation & LED display.</p> <p>3. Technical Specifications</p> <p>3.1 Should be able to thaw at least 6 plasma bags (FFP / Apheresis or plasma bags of any size).</p> <p>3.2 Should have separate compartment that could accommodate at least 2 units of FFP per individual compartment or 1 Apheresis component/per compartment.</p>		

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ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR (continuation)	<p>3.3 Equipped with the following safety and alarm features:</p> <ul style="list-style-type: none">a. an audio alarm system at the end of the thawing cycle.b. sensor to detect and alarm in case of plasma leaks and auto shut off thawing process on detection of the leak.c. audio and visual alarm for temperature rise of 1.0°C than the set 37°C temp.d. safety thermostat that would put off heaters & reset if temperature rise to 45°C.e. must be equipped with drainage tubing port. <p>4. Environmental safety factors</p> <p>4.1 The unit shall be capable of operating continuously in ambient temperature</p> <p>5. Power Supply</p> <p>5.1 Power input to be 220-240VAC, 60Hz as appropriate with Local plug.</p> <p>6. Standards and Safety</p> <p>6.1 Should be FDA, CE, or its equivalent approved product.</p> <p>6.2 Electrical safety conforms to standards for electrical safety IEC.</p>		

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ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR (continuation)	<p>7. Warning Systems:</p> <p>7.1 Digital temperature (LED) display with 0.1 °C graduation</p> <p>7.2 Visual and audible alarm system indicating temperature outside range</p> <p>7.3 Audio/visual alarm if water level drops.</p> <p>7.4 Audio/visual alarm if plasma pack leaks during thawing</p> <p>ONE (1) BRAND NEW UNIT PLATELET AGITATOR</p> <p>1. Description of Function/Key Features</p> <p>To continuously agitate platelet concentrates in a temperature controlled environment at 20-25 °C in an even suspension in a plasma bag.</p> <p>2. Technical Specifications</p> <p>Must meet the following WHO standards for blood cold chain equipment:</p> <ul style="list-style-type: none">▪ Flatbed agitator▪ Easy loading and withdrawal of platelet packs.▪ Agitation at side to side , 60–75 strokes/min.▪ Shelves material with sufficient clearance to minimize noise▪ Platform are made of stainless steel with spaces enough to allow oxygen exchange within and outside the blood pack.		

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ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR (continuation)	<p>3. Storage Requirement: Capable of storing at designed to hold random (300ml) platelet packs and apheresis (500ml)derived platelet packs at least 50-60 Equipped with stainless steel compartment.</p> <p>4. Environmental safety factors 4.1 The unit shall be capable of operating continuously in ambient temperature (ambient temperature 5 °C to 30°C).</p> <p>5. Power Supply 5.1 Power input to be 220-240VAC, 60Hz as appropriate with local plug.</p> <p>6. Standards and Safety 6.1 Should be FDA, CE, or its equivalent approved product. 6.2 Electrical safety conforms to standards for electrical safety IEC. 6.3 Fan cooling. Electronic temperature control to maintain even temperature at +22 °C (±0.5 °C) at all shelves.</p> <p>7. Warning Systems: 7.1 Audible motion failure alarm is critical for monitoring the agitator. 7.2 Audio/visual alarm power failure.</p>		

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ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR (continuation)	<p><i>Other terms and conditions for acceptability.</i></p> <ol style="list-style-type: none">1. The equipment must be a BRAND NEW unit and under warranty including spare parts for at least 2 years. The offered plasma thawer must be compatible with the existing thawer. Supplier must bind itself to conduct preventive maintenance on a quarterly basis at its own expense (including labor and cost of spare parts in compliance) with SPMC ISO and CQI Standards.2. All machines must be manufactured by a known and reputable company with Certificate of Good Manufacturing Practice (GMP), TUV or ISO or its equivalent for equipment.3. The equipment/machine must be able to comply with its Installation and Operational Qualification which would be conducted in the presence of a Biomedical Technician with the End-user and the Company Engineer.4. In line with ISO standard requirement the engineer must be capable of conducting annual calibration certification and provisions of the following data:<ol style="list-style-type: none">a. Reference Standards		

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ONE (1) LOT BRAND NEW PLASMA THAWERS (DRY) AND PLATELET AGITATOR	<p>8. The principal in coordination with the supplier must provide a comprehensive certification training program preferably onsite for the end-users and biomedical technician without additional cost to the procuring entity. Supplier must submit a comprehensive training module as part of the technical specification which covers product orientation, hands-on training and troubleshooting. The said training must be conducted by a certified product specialist.</p> <p>9. Cost of damages on the existing facility that will be incurred during delivery and installation of all equipment will be shouldered by the supplier.</p> <p>10. The Southern Philippines Medical Center has the right to terminate the contract for any violation in the terms and conditions stated in the technical specification and other reasons as stated in the GCC.</p>		

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