



Terms of Reference /Technical Specification Clauses

Item Name: Platelet Agitator and Incubator

I- Specifications:

1. Purpose of Equipment	<p>To continuously agitate platelet concentrate in an even suspension in a temperature controlled environment $+22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ in standard platelet bags (random unit or apheresis).</p> <p>Must be designed specifically for blood bank use. Commercial or modified commercial incubators for other purpose are not acceptable.</p>
2. Type of Equipment	Flatbed agitator fitted inside a temperature controlled incubator that uses CFC-free refrigerant and CFC free insulation material.
3. Quality Standard	<p>Manufacturing should be compliant with ISO 13485, and/or ISO 9001:2008.</p> <p>Should be compliant with European CE Class IIA and/or US FDA</p> <p>Equipment must meet electrical safety specifications of IEC 61010-1</p>
4. Capacity	At least 96 standard random platelet unit bags.
5. Construction	<p>Outside C. R. (Corrosion Resistant) sheet preferably coated with bacteria resistant material</p> <p>Inside stainless steel.</p> <p>Insulation foaming agent CFC free</p>
6. Drawers and agitator	<p>Nonslip corrosion resistant drawers coated with bacteria resistant material</p> <p>Drawers perforated to ensure good air circulation</p> <p>The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator.</p> <p>Gentle side to side agitation at 1.5 inch (3.6–4 cm) and 60– 70 strokes/min.</p> <p>Heavy duty ball bearing gear motor for noiseless and continuous operation for 24 hours a day 365 days a year</p> <p>Auto-pause of agitator on opening door</p> <p>Shelves cannot be pulled out in error.</p> <p>Push button switch to pause agitator.</p>
7. Door	<p>Glass door with full visibility of units without opening door.</p> <p>Manual door lock should be available.</p>
8. Electrical characteristics	<p>Compatible with Input 240V 50 Hz Single phase Ac</p> <p>Equipment meets electrical safety specifications such as that of the IEC</p> <p>Should have an integrated voltage stabilizer or external servo stabilizer of appropriate ratings</p>
9. Internal Temperature	<p>Platelet agitator should have inside temperature range of $20^{\circ}\text{C} - 24^{\circ}\text{C}$</p> <p>Whatever the load, setting accuracy less than or equal to 0.5°C (preferably 0.1°C).</p>



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	Should ensure frost free performance thereby avoiding either freezing or heating. If defrosting function used, temperature should not go outside range specified above.
10. Temperature monitoring, thermograph and related alarms	<p>At least 1 temperature sensor.</p> <p>Digital temperature (LED) display with 0.1 °C graduation.</p> <p>Integrated Visual AND Audible alarm systems for temperature, motion failure, sensor failure, agitator off, power failure</p> <ul style="list-style-type: none"> – Can be connected to a remote monitoring system and remote alarm. – The temperature record should be electronically logged (that can be retrieved eg by USB port) – Equipped with 7-day, graphic chart recorder with supply of free charts for full period of warranty. <p>Must have Battery backup for temperature recordings, which is especially needed during power failure/fluctuations.</p> <p>Additional Battery backup for alarm so that alarm will not fail in case of power failure, and should be able to sustain the alarm.</p>
11. Air circulation	The temperature inside should be kept uniform in all shelves by Forced air circulation through fans.

II- Training:

Demonstration and continued comprehensive training for lab staff and support services until familiarity with the system.

III- Documents to be delivered:

- Calibration certificates
- Warranty
- Installation Qualification (IQ) and Operational Qualification (OQ).
- Supplier Qualification documentation (to be completed using form provided by LRC Blood Transfusion Services “**QUAL-FOR-024 Supplier Qualification Questionnaire/QMS Compliance**”).
- Should provide electronic and hard copies of User Manual (English), Service manual (English) and Complete construction details with respect to material specification, thickness, finish etc....

IV- Accessories required:

- Seven day temperature recorder chart for continuous temperature re-cording
- Ink stylus pens

V – Transport, installation, and setup

Assured by the company.