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Design Qualification Report for the 48-hour One-way Refrigerated Shipper

Intended for 1-10°C transport of refrigerated blood products



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1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the components and thermal performance of the 48-hour One-way Refrigerated Shipper (SKU#1RBC4X48). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the 1RBC4X48 to transport refrigerated blood products at 1-10°C for a minimum of 48 hours.

2. Requirements Summary:

Payload type	Refrigerated blood products such as Red Blood Cells (RBCs), Whole Blood (WB) etc.
Payload form factor	Standard blood bag
Payload volume	300-350mL per unit
Payload capacity	1 - 4 x units
Payload temperature	1-10°C
Validation	48 hours against ISTA-7D standards

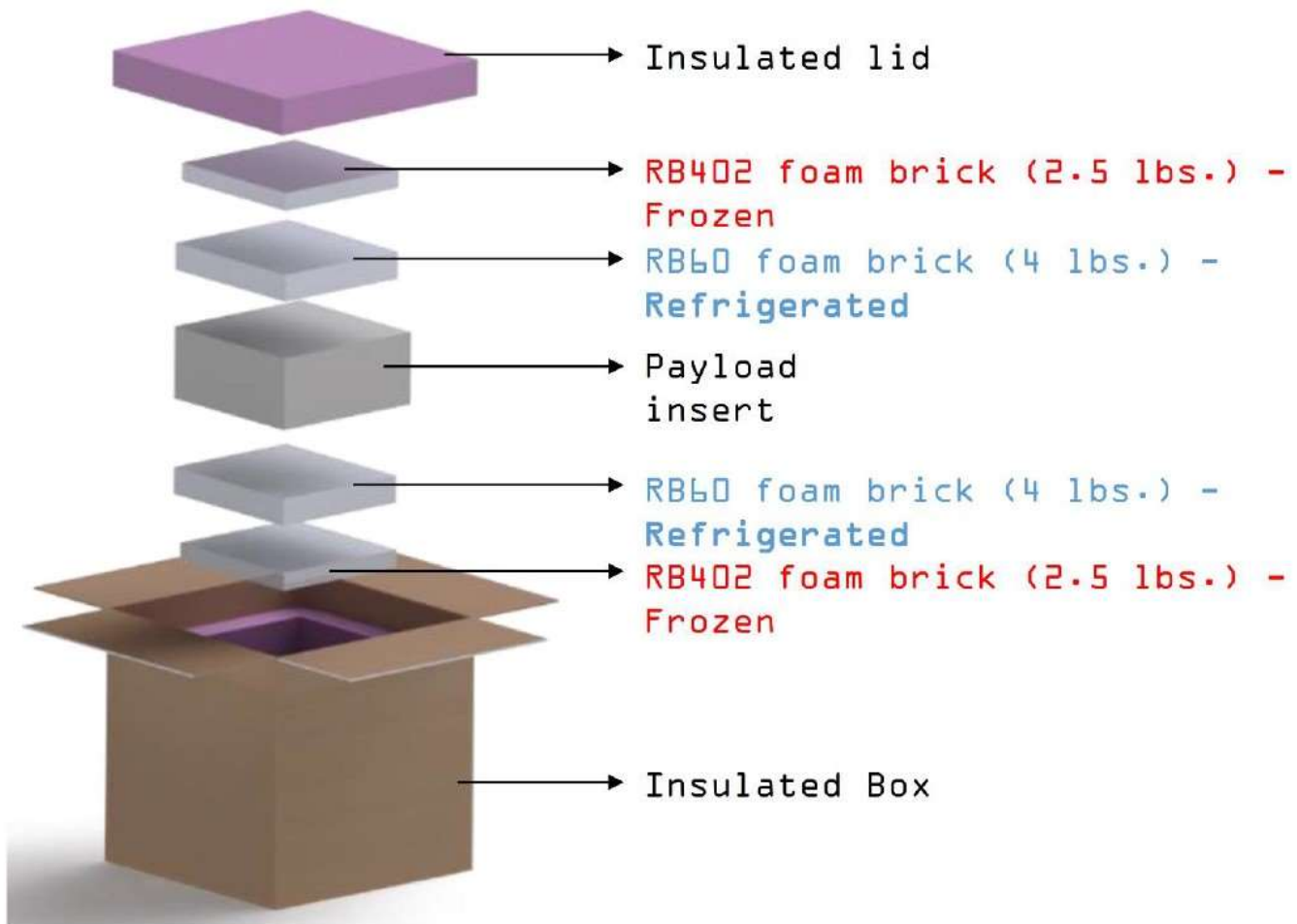
3. Product Summary and Components:

- Outer Shell Material: Corrugated cardboard, single-use
- Outer Dimensions: 14" x 14" x 14" (LWH)
- Payload Insert Dimensions: 9"x9"x5" (LWH)
- System Weight (excluding payload): 13 lbs
- Phase Change Coolant: RB402 bricks (x2), RB60 bricks (x2), Payload Insert



4. Packing Methods

4.1 1RBC4X48 System Packout Schematic:



4.2 1RBC4X48 Coolant Conditioning Procedure:

- Charge two (x2) RB60 bricks in a refrigerator at $(1-6^{\circ}\text{C} \pm 1^{\circ}\text{C})$ for a minimum of 24 hours.
- Charge two (x2) RB402 bricks in a freezer at $(< -20^{\circ}\text{C})$ for a minimum of 24 hours.

4.3 1RBC4X48 Packing Instructions:

- 1) Place one frozen RB402 in the bottom of the container.
- 2) Place a refrigerated RB60 into the container.
- 3) Load blood products (max 4 of units) into the payload insert provided.

- 4) Close the payload insert and tape shut with packaging tape and set on top of the bottom RB60 brick.
- 5) Place a refrigerated RB402 brick on top of the payload insert.
- 6) Set a frozen RB402 brick directly on top of the refrigerated RB60 brick.
- 7) Lastly, seat the lid on top of the fully packed 48-hour system, close the flaps and secure with packaging tape. The shipper is now ready for transport.

Note: If packing less than the maximum number of blood products (x4 units), use a bubble wrap dunnage material to fill any empty space inside of the payload insert to mitigate product movement during transit.

5. Design Qualification Test Methods and Results:

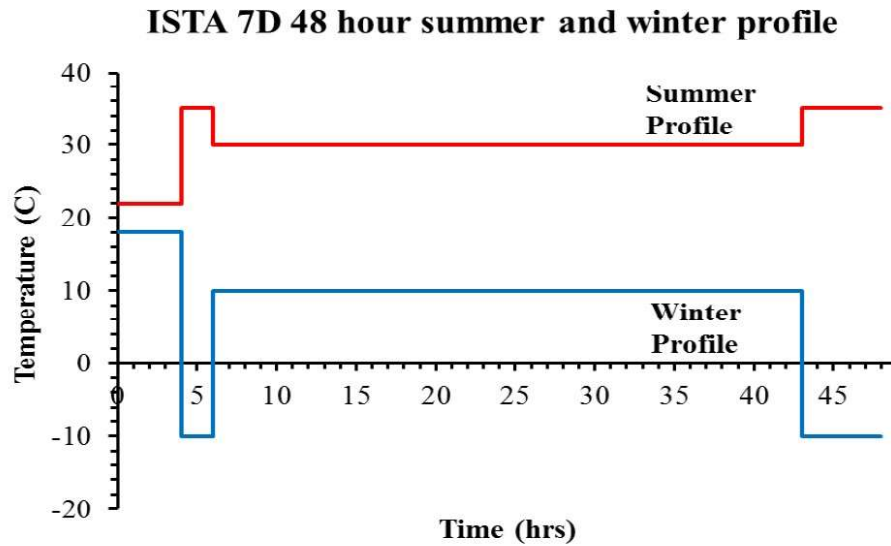
5.1 Test Methods:

The presented 48-hour One-way Refrigerated Shipper (SKU#1RBC4X48) with (x2) RB402 bricks and (x2) RB60 bricks is designed to maintain refrigerated blood products between 1-10°C for a minimum of 48 hours. Two different test cases were conducted to demonstrate the shipper's ability to meet the extreme ambient requirements. Thermal chambers with NIST traceable calibration were programmed with a 48-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 4 and placed inside a chamber for 48 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

5.2 Ambient profiles used for testing:

For design qualification testing, the MaxPlus One-way Refrigerated Shipper was exposed to the following summer and winter ambient profiles (based on ISTA 7D standards) inside a precision temperature regulated thermal chamber for performance validation testing.

- **Summer 48-hour profile:** 22°C for 4 hours → 35°C for 2 hours → 30°C for 36 hours → 35°C for 6 hours
- **Winter 48-hour profile:** 18°C for 4 hours → -10°C for 2 hours → 10°C for 36 hours → -10°C for 6 hours



5.3 Pass and Fail Criteria

Pass Criteria: Payload temperature stayed within 1-10°C ($\pm 0.5^\circ\text{C}$) during the 48 hours of test duration

Fail Criteria: Payload temperature did not stay within 1-10°C ($\pm 0.5^\circ\text{C}$) during the 48 hours of test duration

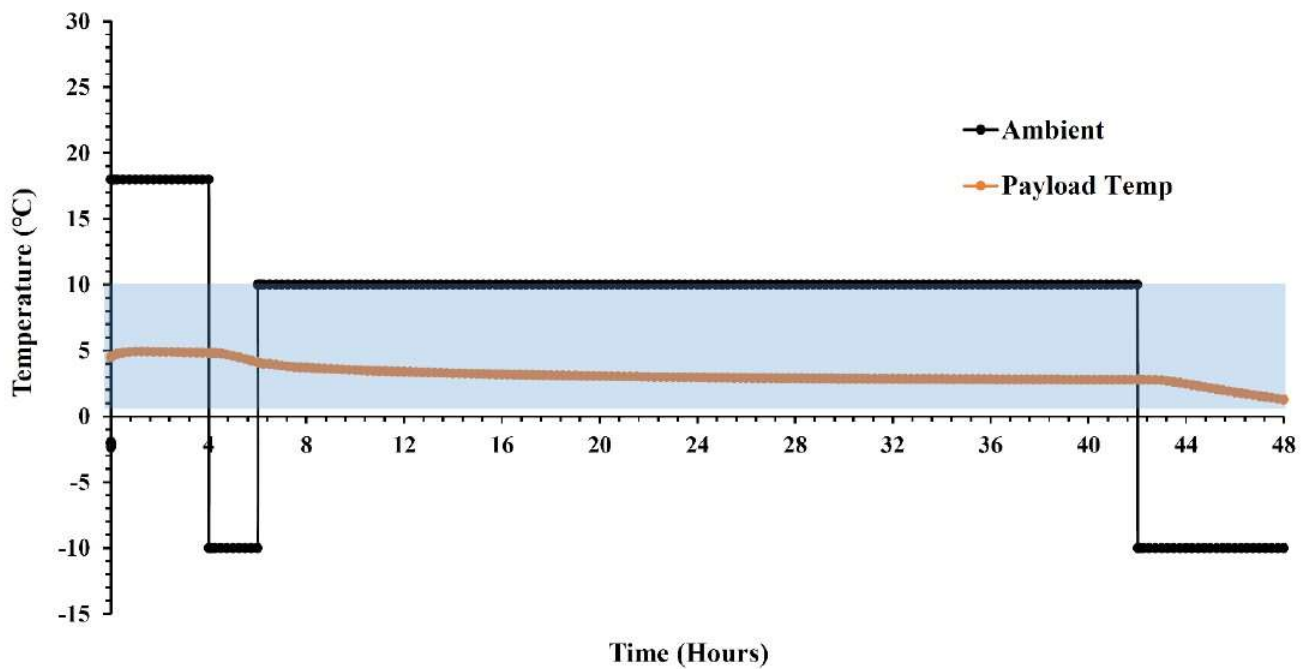
5.4 Test Results:

5.4.1 Blood Products 1-10°C | [Winter Ambient](#) | Maximum Payload Configuration

Test setup:

Test payload	4 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours

Thermal performance plot:



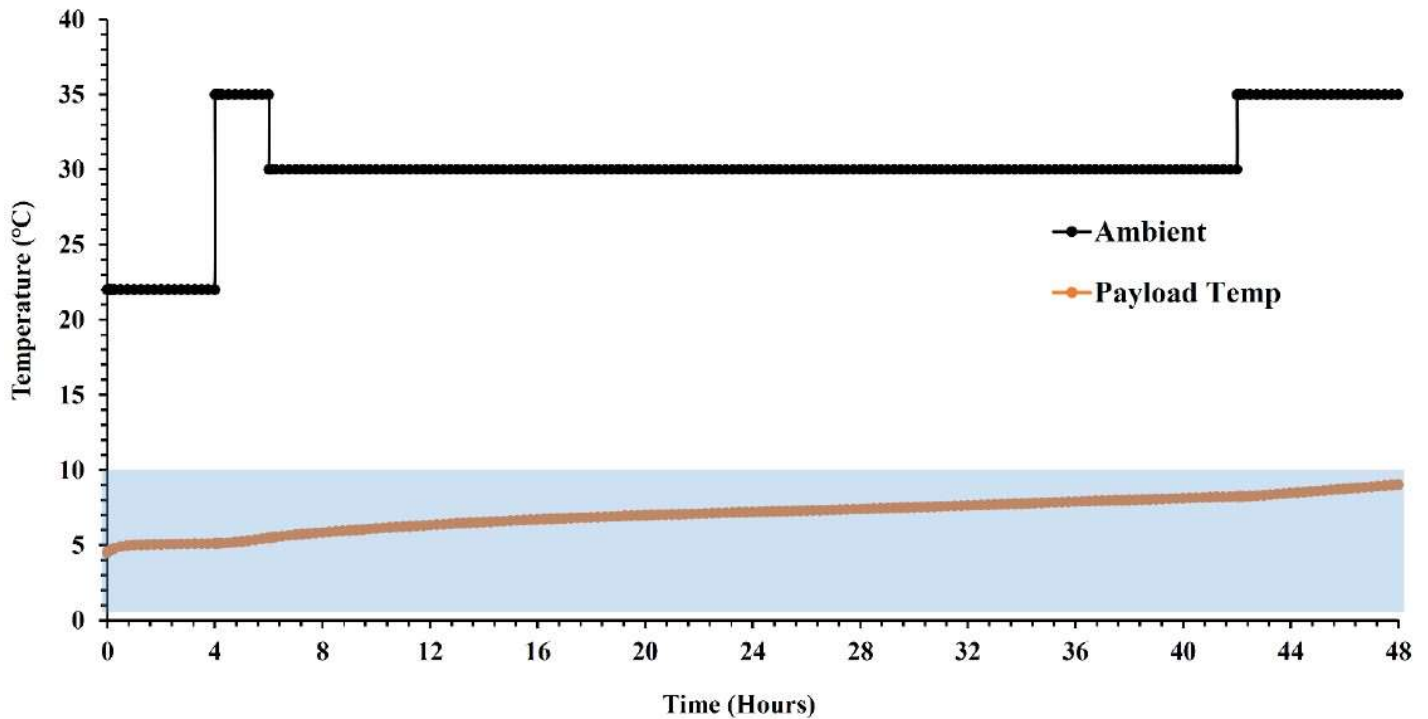
Test Result: Pass

5.4.2 Blood Products 1-10°C | Summer Ambient | Maximum Payload Configuration

Test setup:

Test payload	4 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Summer Ambient
Test duration	48 hours

Thermal performance plot:



Test Result: Pass