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Design Qualification Report for the 72-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 72-hour One-way Refrigerated Shipper (SKU#1RBC10X72). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the 1RBC10X72 to transport refrigerated blood products at 2-8°C for a minimum of 72 hours.

2. Requirements Summary:

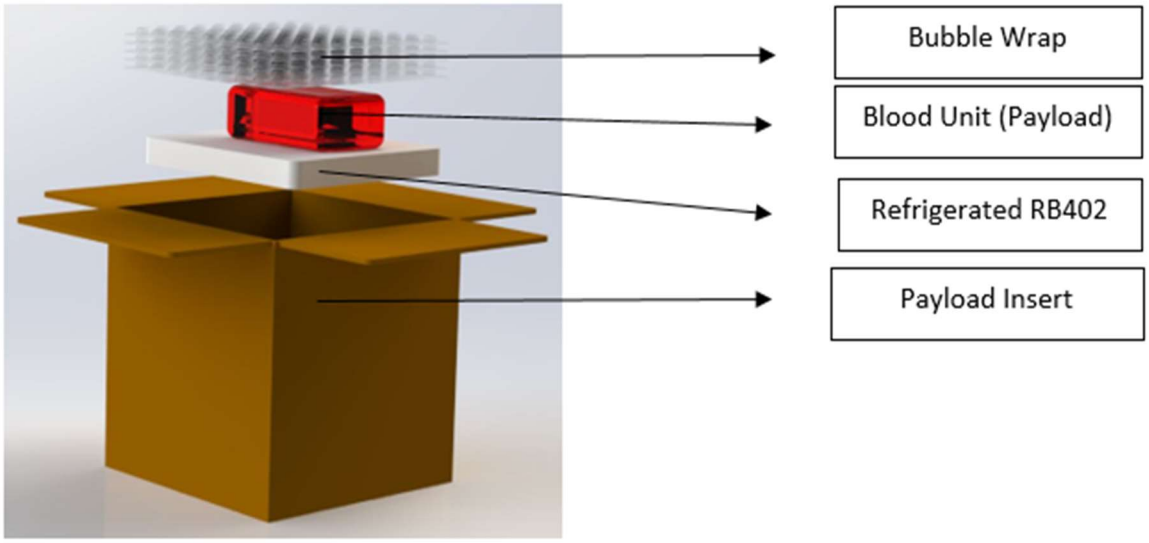
Payload type	Refrigerated blood products such as Red Blood Cells (RBCs), Whole Blood (WB) etc.
Payload form factor	Standard blood bag
Payload volume	300-350mL per unit
Payload capacity	1 -10 x units
Payload temperature	1-10°C
Validation	72 hours against extended ISTA 7D standards

3. Product Summary and Components:

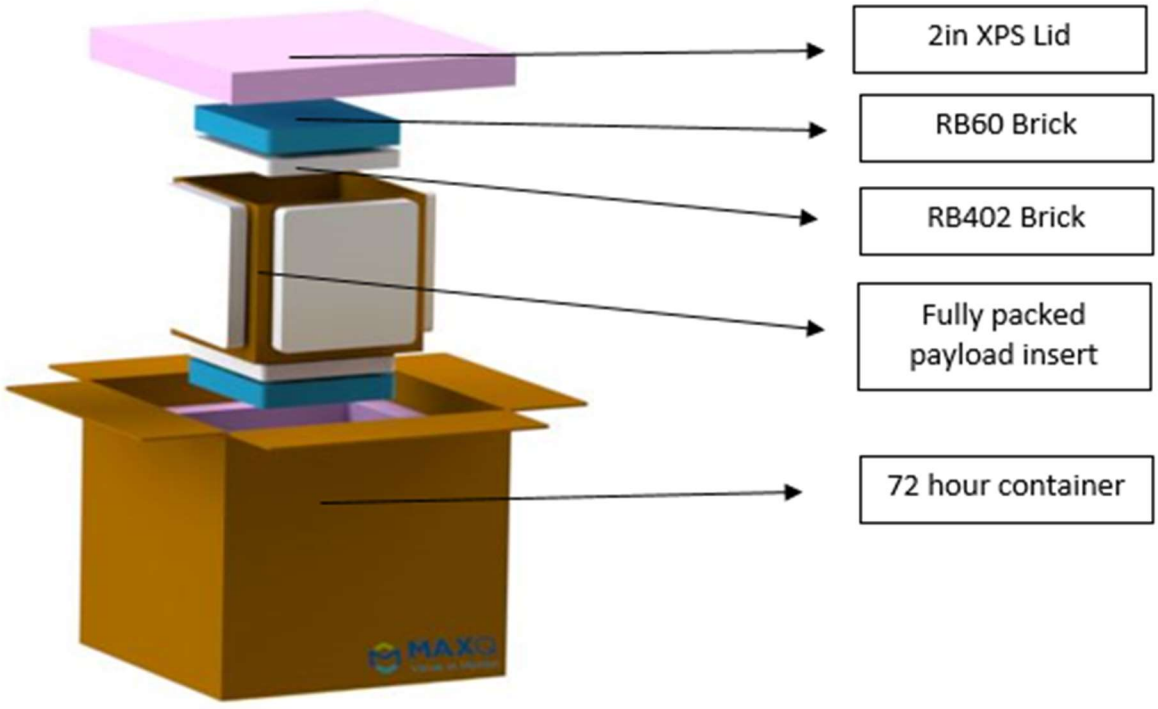
- Outer Shell Material: Corrugated cardboard, single-use
- Outer Dimensions: 17” x 17” x 17” (LWH)
- Payload Insert Dimensions: 10”x10”x6” (LWH)
- System Weight (excluding payload): 29.5 lbs
- Phase Change Coolant: RB402 bricks (x7), RB60 bricks (x2), Payload Insert

4. Packing Methods

4.1 1RBC10X72 Payload Insert Packout Schematic:



4.2 1RBC10X72 System Packout Schematic:



4.3 1RBC10X72 Coolant Conditioning Procedure:

- Charge seven (x7) RB402 bricks in a refrigerator at (1-6°C ± 1°C) for a minimum of 24 hours.
- Charge two (x2) RB60 bricks in a freezer at (< -20°C) for a minimum of 24 hours.
- Refrigerated bubble wrap dunnage material on standby (not supplied by MaxQ) kept between (1-6°C ± 1°C).

4.4 1RBC10X72 Payload Insert Packing Instructions:

1) Place one refrigerated RB402 in the bottom of the payload insert.
2) Load blood product (max 10 of units) directly on top of the bottom RB402 brick.
3) Fill any remaining space in the payload insert with refrigerated bubble wrap.
4) Close the payload insert and tape shut with packaging tape and move to the steps below.

4.5 1RBC10X72 System Packing Instructions:

5) Place a frozen RB60 brick into the bottom of the 72-hour container.
6) Set a refrigerated RB402 brick directly on top of the frozen RB60 brick.
7) Load the packed payload insert into the 72-hour container.
8) Position the remaining five (x5) refrigerated RB402 bricks along the left, right, front, rear and top faces of the payload insert as shown in the schematic on page 4 above.
9) Remove the last RB60 brick from the freezer and place on the top refrigerated RB402 brick.
10) Lastly, seat the lid on top of the fully packed 72-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 (x10 units), use a refrigerated bubble wrap material to fill any empty space inside of the payload insert to mitigate product movement during transit.

5. Design Qualification Test Methods and Results:

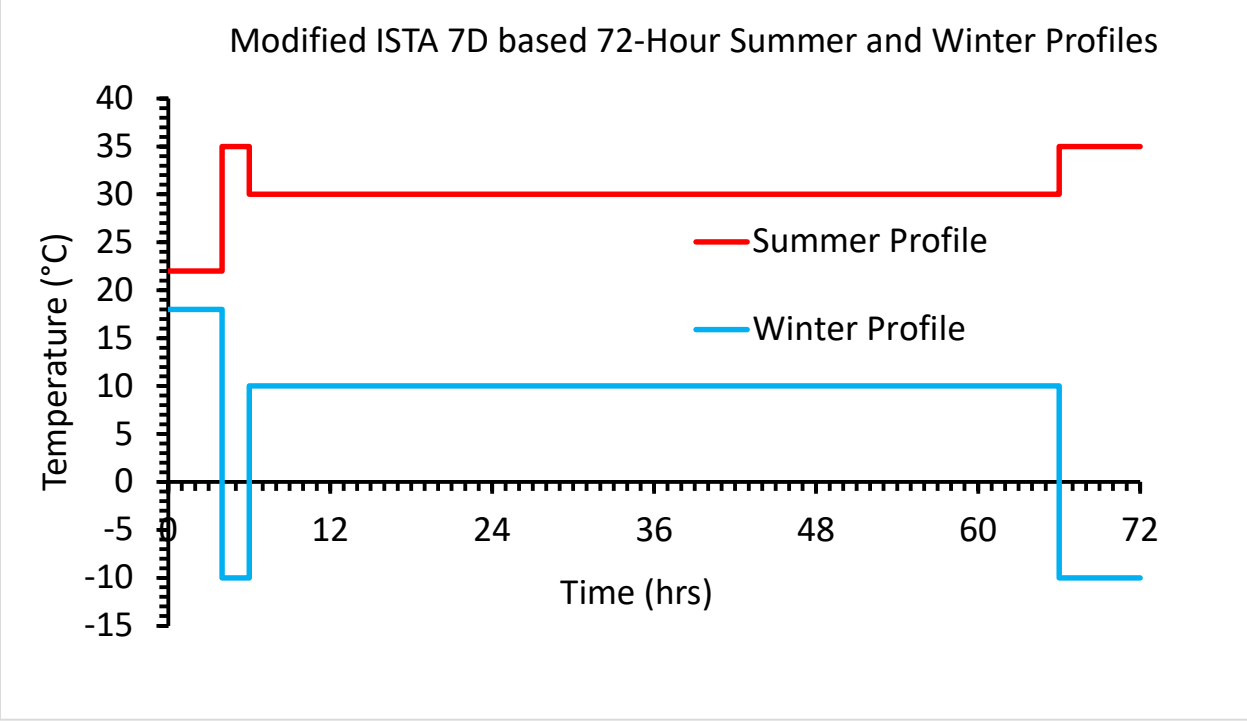
5.1 Test Methods:

The presented 72-hour One-way Refrigerated Shipper (SKU#1RBC10X72) with (x7) RB402 bricks and (x2) RB60 bricks is designed to maintain refrigerated blood products between 1-10°C for a minimum of 72 hours. Four 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 extended 72-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 72 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 modified ISTA 7D standards) inside a precision temperature regulated thermal chamber for performance validation testing.

- Summer 72-hour profile : 22°C for 4 hours → 35°C for 2 hours → 30°C for 60 hours → 35°C for 6 hours
- Winter 72-hour profile : 18°C for 4 hours → -10°C for 2 hours → 10°C for 60 hours → -10°C for 6 hours



5.3 Pass and Fail Criteria

Pass Criteria: Payload temperature stayed within 2-8°C (±0.5°C) during the 72 hours of test duration
Fail Criteria: Payload temperature did not stay within 2-8°C (±0,5°C) during the 72 hours of test duration

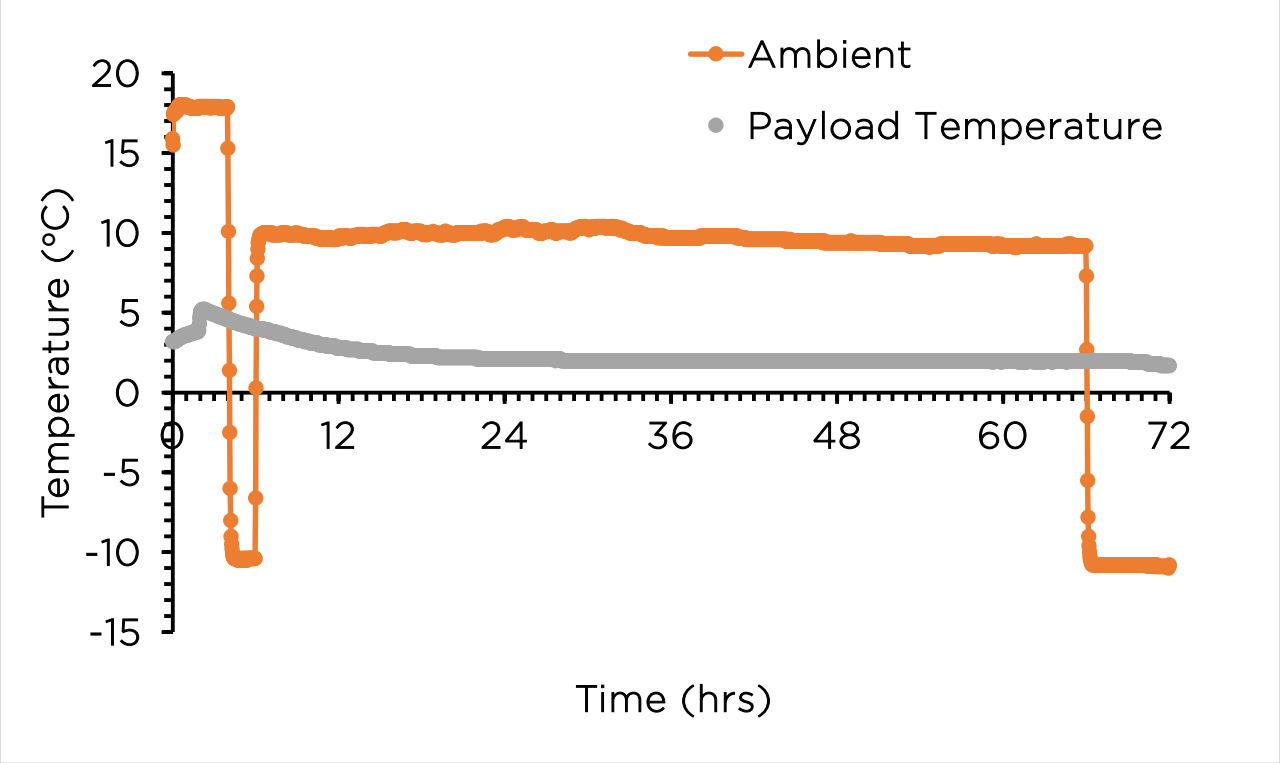
5.4 Test Results:

5.4.1 Blood Products 2-8°C | Winter Ambient | Minimum Payload Configuration

Test setup:

Test payload	1 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Winter Ambient
Test duration	72 hours

Thermal performance plot:



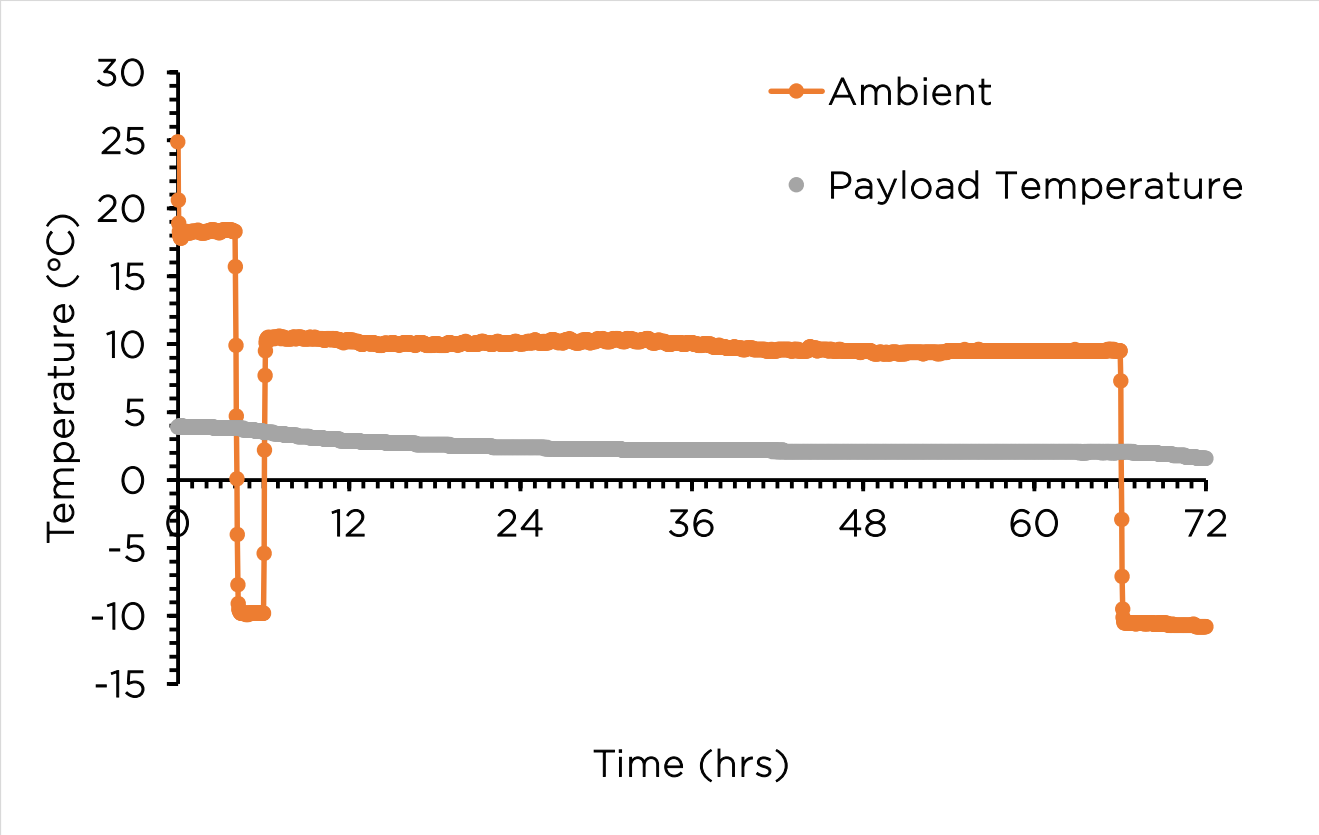
Average Payload Temperature: 2.55 °C | Test Result: Pass

5.4.2 Blood Products 2-8°C | Winter Ambient | Maximum Payload Configuration

Test setup:

Test payload	10 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Winter Ambient
Test duration	72 hours

Thermal performance plot:



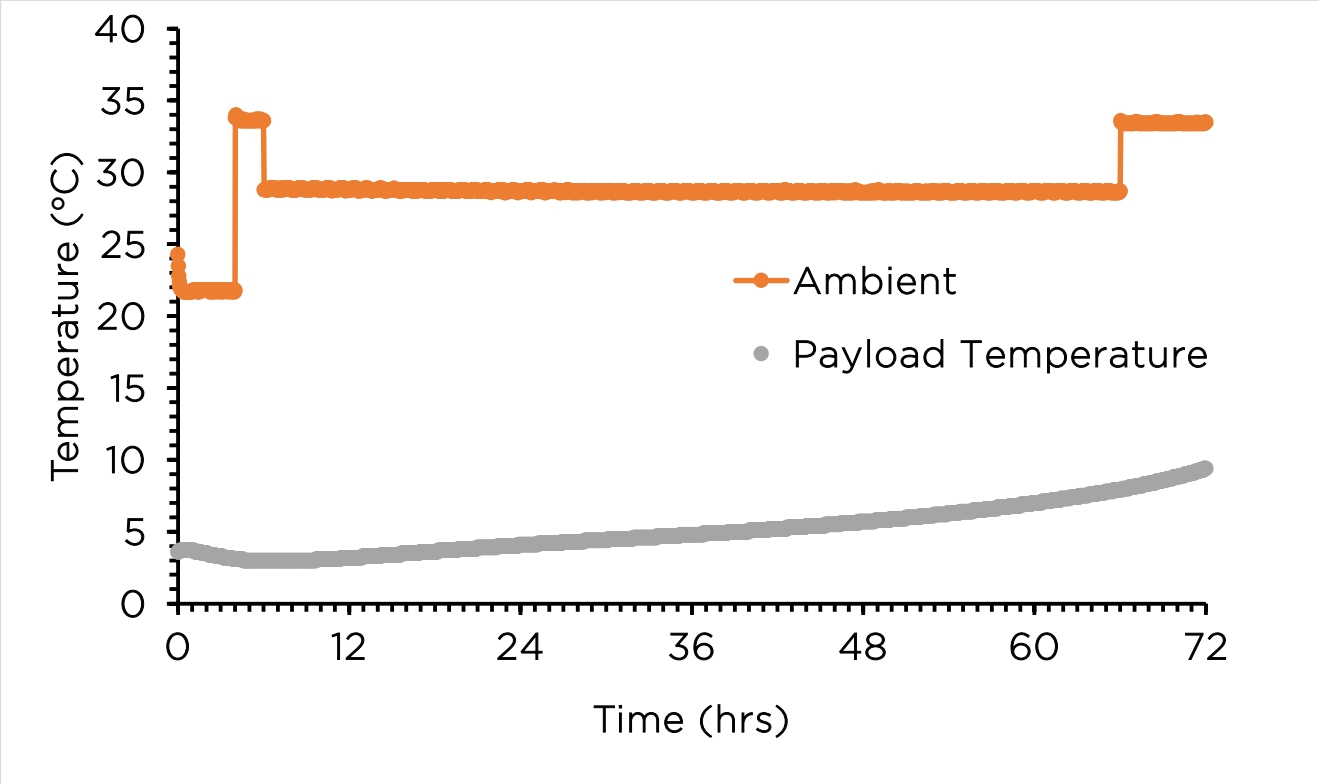
Average Payload Temperature: 2.6 °C | Test Result: Pass

5.4.3 Blood Products 2-8°C | Summer Ambient | Minimum Payload Configuration

Test setup:

Test payload	1 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Summer Ambient
Test duration	72 hours

Thermal performance plot:



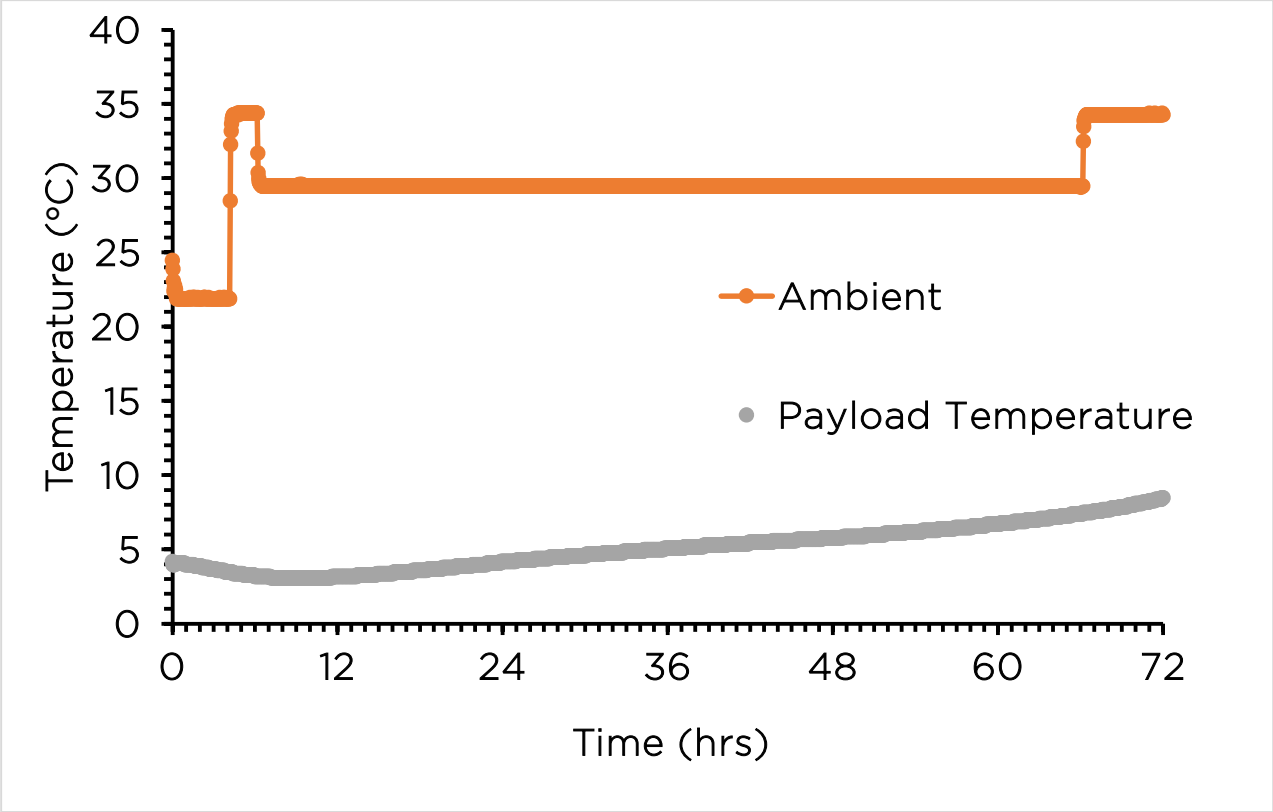
Average Payload Temperature: 4.1 °C | Test Result: Pass

5.4.4 Blood Products 2-8°C | Summer Ambient | Maximum Payload Configuration

Test setup:

Test payload	10 x 300mL mock blood unit kept refrigerated (1-6°C) for 12 hours
Ambient temperature	Summer Ambient
Test duration	72 hours

Thermal performance plot:



Average Payload Temperature: 4.3 °C | Test Result: Pass