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Design Qualification Report for the MaxPlus Single-use RBC 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 MaxPlus Single-use RBC Shipper (SKU#1RBC20X48). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the 1RBC20X48 to transport refrigerated blood products at 1-10°C for a minimum of 48 hours.

2. Requirements Summary:

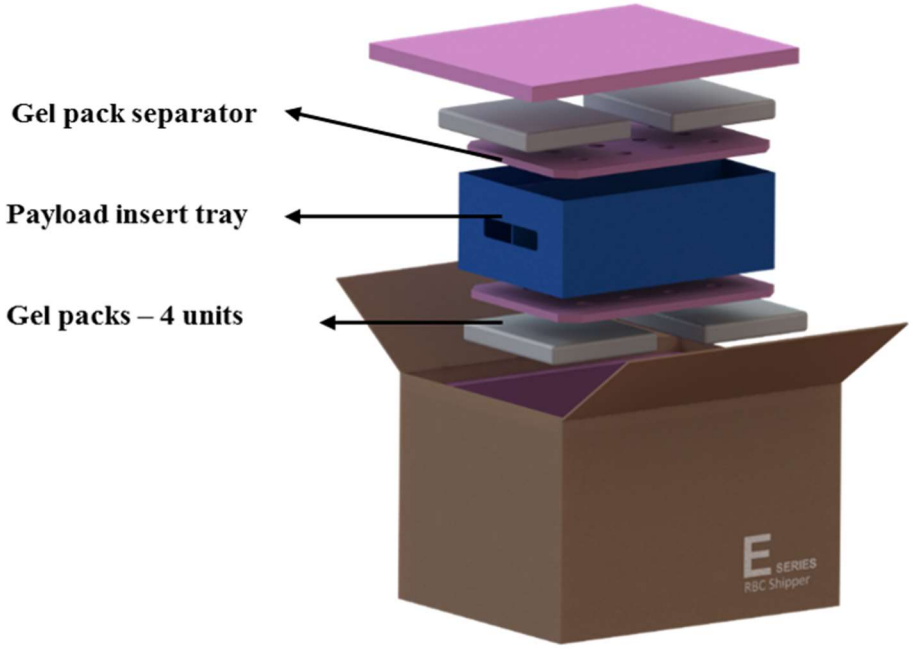
Payload type	Refrigerated blood products
Payload form factor	Standard blood bag
Payload volume	300-350mL per unit
Payload capacity	3 - 20 x units
Payload temperature	1-10°C
Validation	48 hours against ISTA 7D standards

3. Product Summary and Components:

- Outer Shell Material: Corrugated cardboard, single-use
- Outer Dimensions: 20in x 15in x 13in (LWH)
- Payload Dimensions: 15.25in x 11in x 5.5in (LWH)
- System Weight (excluding payload): 22 lbs.
- Gel Packs: EC4 (x4)
- Foam separators (x2): 15.25in x 11in x 1in, reusable

4. Packing Methods

4.1 1RBC20X48 Packout Schematic:



4.2 1RBC20X48 Coolant Conditioning Procedure:

- Charge four (x4) EC4 Gel packs in a freezer (< -20°C) for a minimum of 24 hours.

4.3 1RBC20X48 Packing Instructions:

1) Place two frozen EC4 gel packs in the bottom of the container side-by-side.
2) Lay foam gel pack separator on top of the EC4 gel packs.
3) Place the payload insert tray into the container.
4) Load payload units into the payload insert tray and place the remaining gel pack foam separator on top.
5) Take the remaining two EC4 gel packs out of the freezer and place side-by-side on the top foam separator.
6) Close the container lid making sure that the lid is sealed properly and apply packaging tape

Note: If packing less than the maximum number of payload units into the payload insert, use a room temperature bubble wrap material to fill any empty space. This is to mitigate product movement and breakage during transit. The bubble wrap does not

harm nor help the thermal performance of the shipper, it is simply a supportive medium for product protection.

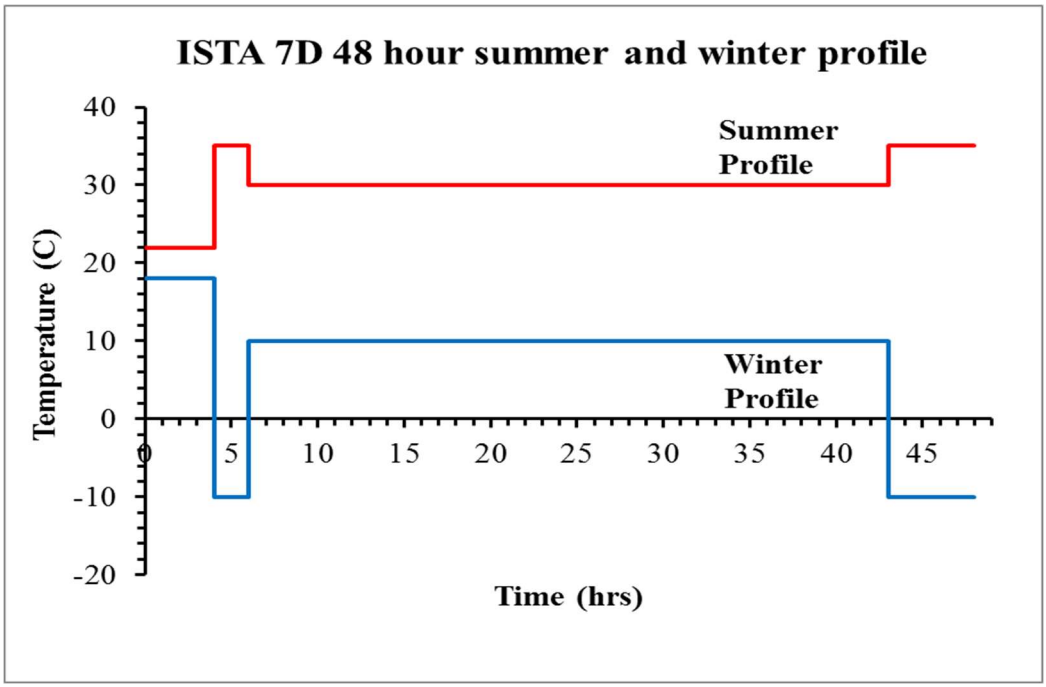
5. Design Qualification Test Methods and Results:

5.1 Test Methods: The presented 1RBC20X48 single-use Shipper with EC4 gel packs (x4) 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 single-use shipper was exposed to the following summer and winter ambient profiles (based on 48-hour ISTA 7D standard profiles) 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



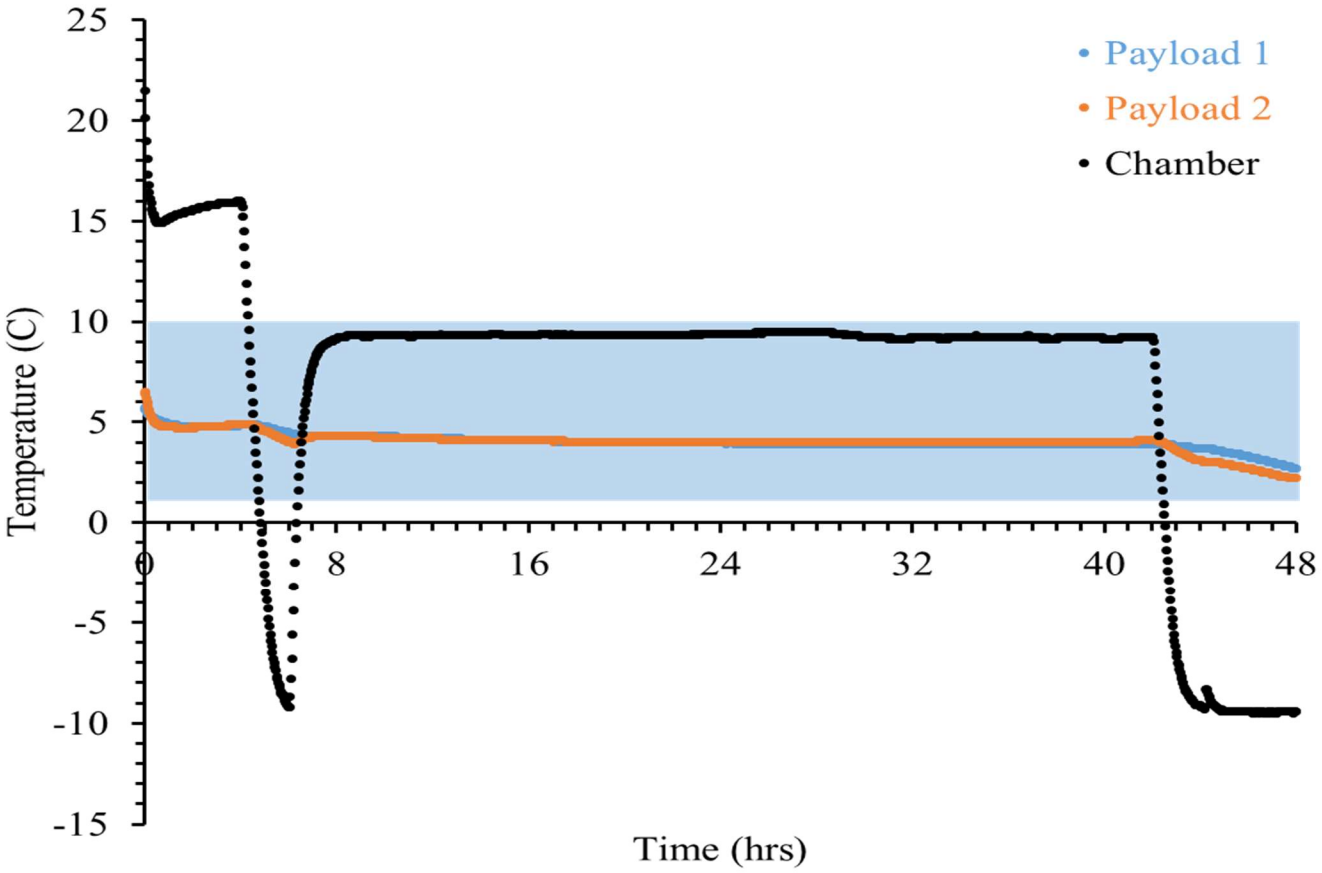
5.2 Test Results:

5.2.1 Blood products maintained at 1-10°C | Winter Ambient | Maximum Payload Configuration

Test setup:

Test payload	20 x 350 mock pRBC units kept at 1-6°C for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours
Test Result	Passed

Thermal performance plot:



5.2.2 Blood products maintained at 1-10°C | Summer Ambient | Maximum Payload Configuration

Test setup:

Test payload	20 x 350 mock pRBC units kept at 1-6°C for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours
Test Result	Passed

Thermal performance plot: