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# Design Qualification Report for the MaxPlus Chilled Platelet Shipper

**Intended for 1-10°C transport of chilled platelets**

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## 1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the MaxPlus Refrigerated Platelet Shipper (SKU#U17RPLT48). The report addresses basic system requirements, components breakdown, packing methods and temperature compliance data captured for the U17RPLT48 to transport chilled platelets at 1-10°C for a minimum of 48 hours.

## 2. Requirements Summary:

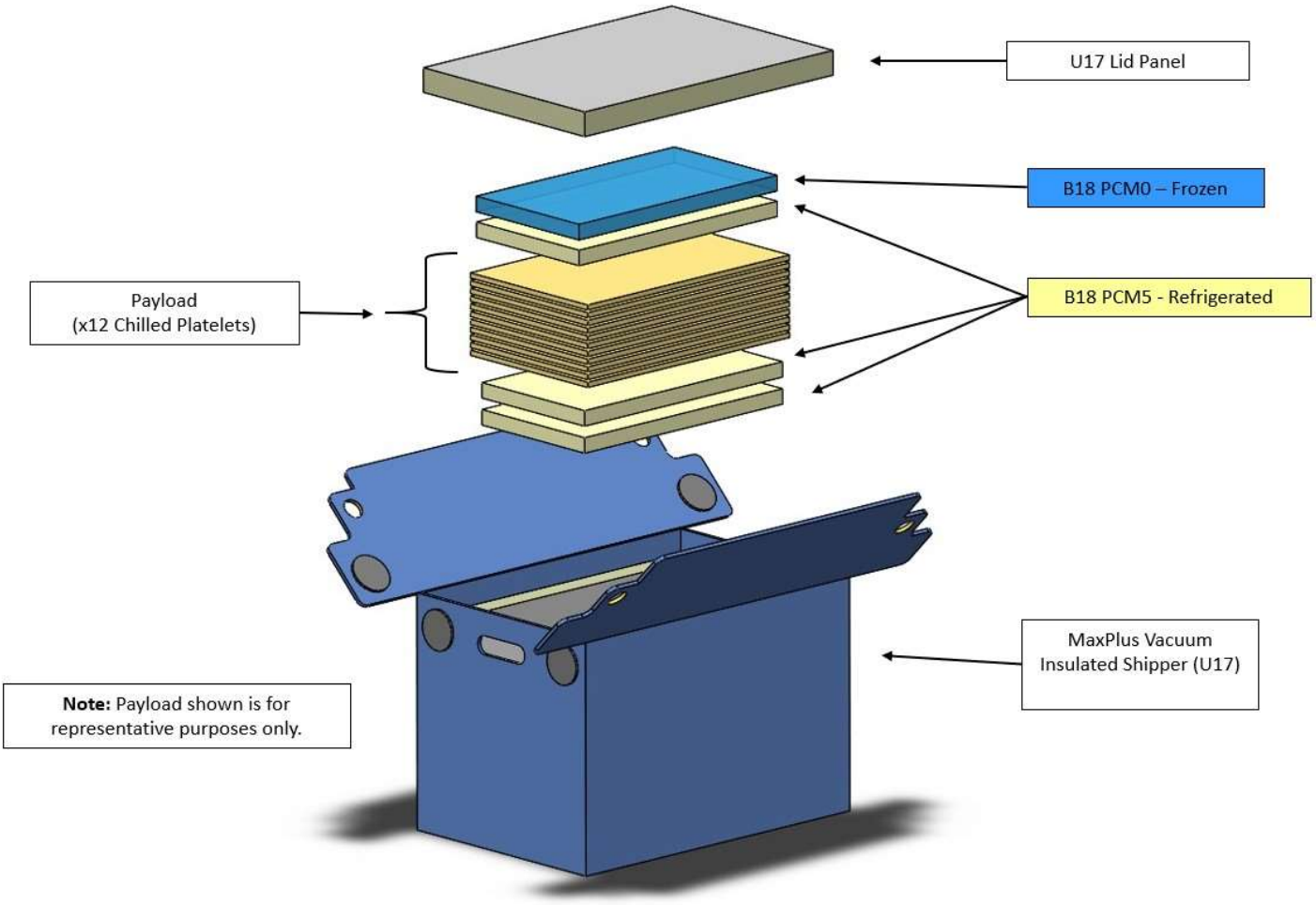
| | |
|---|---|
| Payload type | Chilled PR Platelets |
| Payload form factor | Cerus Intercept® PR platelet units |
| Payload volume | 350-400mL per unit |
| Payload capacity | Up to 12x Cerus units |
| Payload temperature | 1-10°C |
| Validation | 48 hours against ISTA 7E standards |

## 3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic, highly reusable
- Outer Dimensions: 17.25 x 11 x 11.5in (LWH)
- Payload Dimensions: 14 x 8 x 8 (LWH)
- System Weight (excluding payload): 14.5 lbs.
- Phase Change Coolant: B18 PCM5 coolant bottle (x3), B18 PCM0 coolant bottle (x1)

## 4. Packing Methods

### 4.1 U17RPLT48 Packout Schematic:



### 4.2 U17RPLT48 Coolant Conditioning Procedure:

- Charge one B18 PCM0 coolants (Blue) in a standard deep freezer (< -20 °C) for a minimum 24 hours.
- Charge three B18 PCM5 coolants (Yellow) in a refrigerator (< 4°C ± 1°C) for a minimum 24 hours.

### 4.3 U17RPLT48 Packing Instructions:

1) Place two refrigerated B18 PCM5 coolant bottles (Yellow) in the container.
2) Load desired number of chilled platelet units (up to x12 units).
3) Place one refrigerated B18 PCM5 coolant (Yellow) on top of the payload units.
4) Remove one frozen B18 PCM0 coolant (Blue) from freezer and place on top.
5) Place the insulation lid panel on last (**Note:** Black gasket material facing down).
6) Close lid flaps and equip tamper evidence solution to the left and right-side gromets.
7) The container is now ready for transport. No packaging tape required

**Note:** If packing less than the maximum number of payload units, use a room temperature bubble wrap material to fill any empty space on top of the last B18 PCM5 coolant. 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 MaxPlus Refrigerated Platelet Shipper (SKU# U17RPLT48) with B18 PCM5 coolant bottle (x3) and a B18 PCM0 coolant bottle (x1) is designed to maintain chilled platelet units between 1-10°C for a minimum of 48 hours. Four different test cases were conducted to demonstrate the shipper's ability to meet the extreme ambient requirements:

- Minimum payload – winter exposure
- Maximum payload – winter exposure
- Minimum payload – summer exposure
- Maximum payload – summer exposure

Thermal chambers with NIST traceable calibration were programmed with 48-hour summer and winter ISTA-7E 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 Pass/Fail Criteria:

The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria**: Payload temperature was maintained between 1-10°C (±0.5°C) during the 48 hours of test duration.

**Fail Criteria**: Payload temperature went above 10°C (±0.5°C) or below 1°C (±0.5°C) during the 48 hours of test duration.

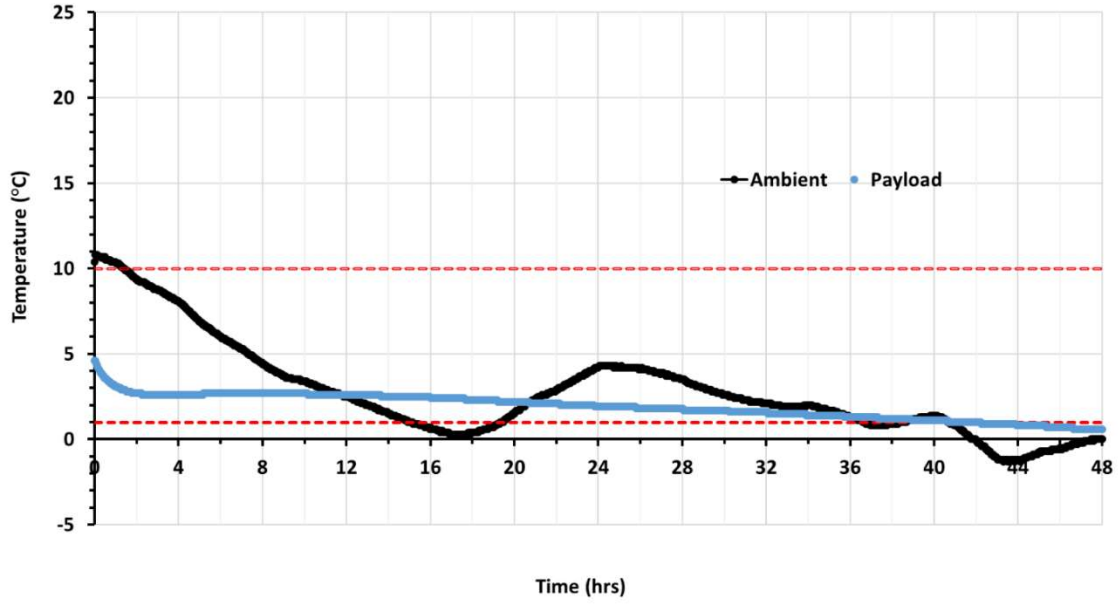
## 5.3 Test Results:

### 5.3.1 Chilled Platelets 1-10°C | Winter Ambient | Minimum Payload

Test setup:

| | |
|---|---|
| Test payload | 1 x 350-400mL Cerus intercept platelet unit kept at 1-6°C for 12 hours |
| Ambient temperature | Winter Ambient |
| Test duration | 48 hours |

Thermal performance plot:




Observations: The following table summarizes payload temperature data.

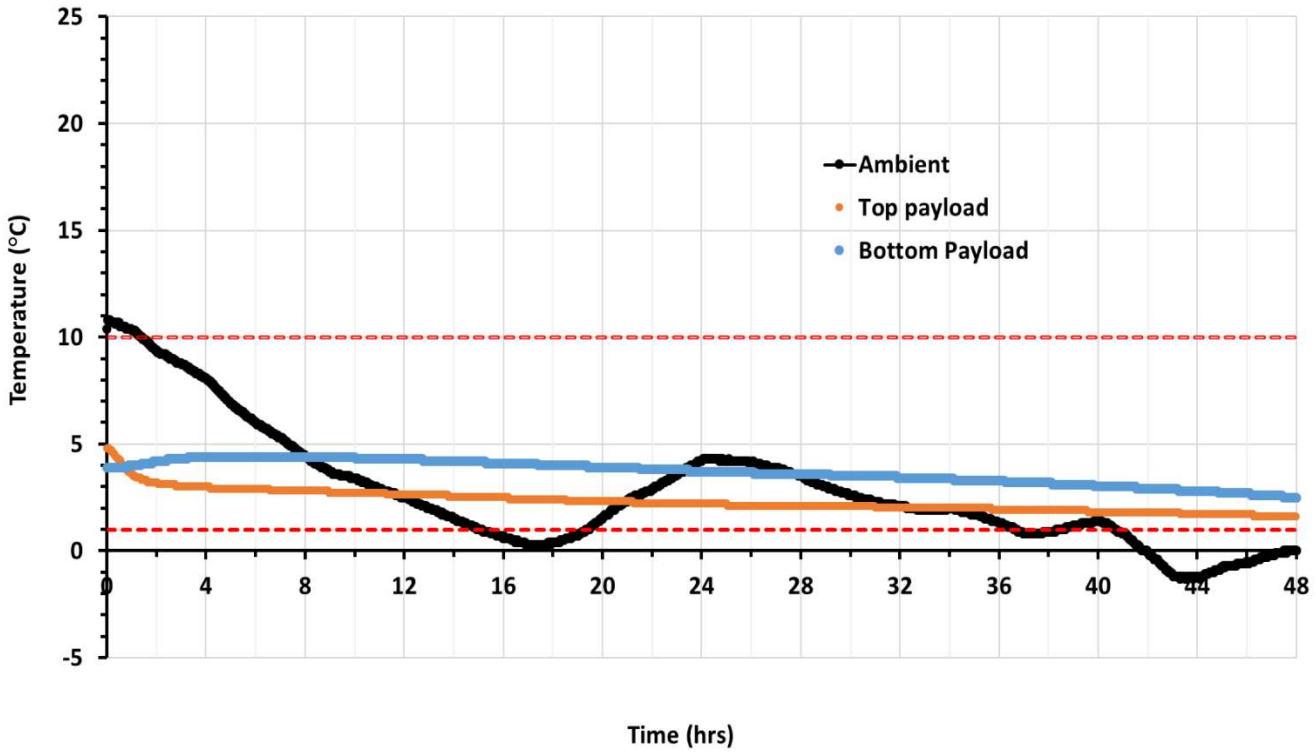
| Total time (hours) payload-maintained 1-10°C | Minimum payload temperature during tested duration |
|---|---|
| 43 | 0.6°C @ 48 hours |

### 5.3.2 Chilled Platelets 1-10°C | Winter Ambient | Maximum Payload

Test setup:

| | |
|---|---|
| Test payload | 12 x 350-400mL Cerus Intercept platelet units kept at 1-6°C for 12 hours |
| Ambient temperature | Winter Ambient |
| Test duration | 48 hours |

Thermal performance plot:




Observations: The following table summarizes payload temperature data.

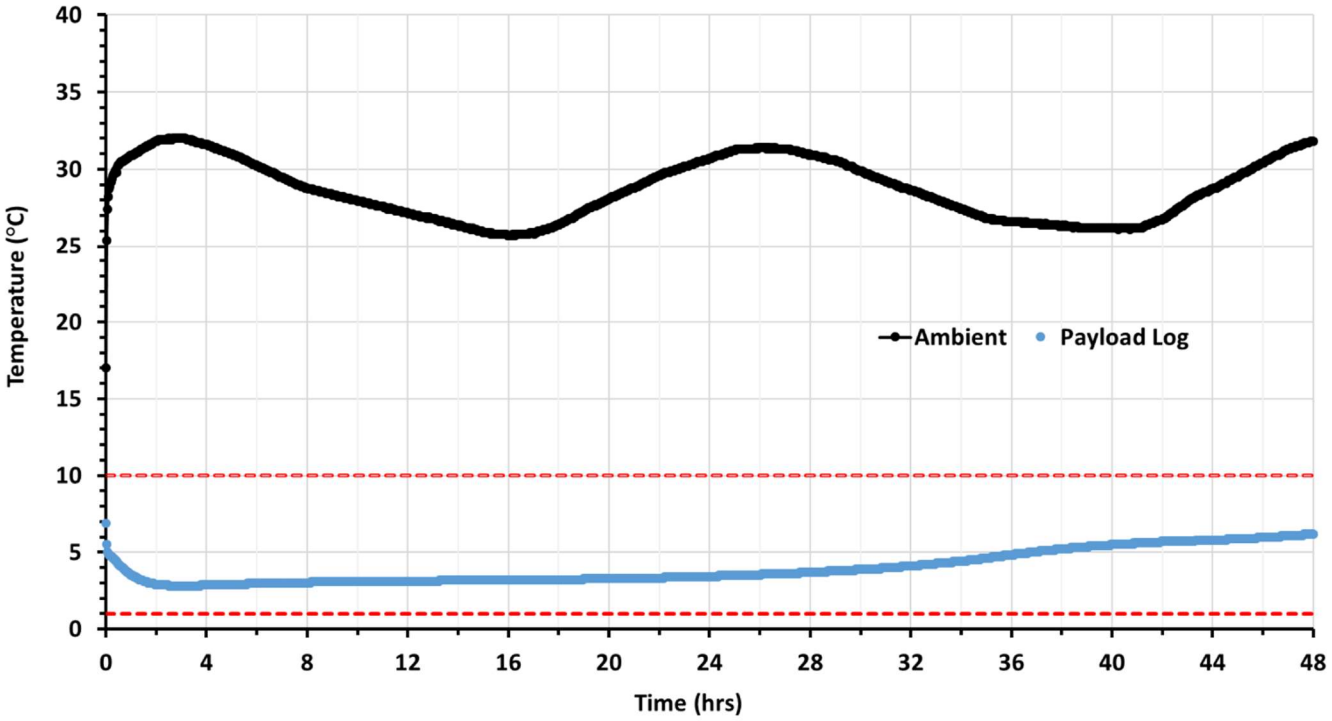
| **Total time (hours) payload-maintained 1-10°C** | | **Minimum payload temperature during tested duration (°C)** | |
|---|---|---|---|
| Top Payload | Bottom Payload | Top Payload | Bottom Payload |
| 48 | 48 | 1.6°C @ 48 hours | 2.5°C @ 48 hours |

### 5.3.3 Chilled Platelets 1-10°C | Summer Ambient | Minimum Payload

Test setup:

| | |
|---|---|
| Test payload | 1 x 350-400mL Cerus intercept platelet unit kept at 1-6°C for 12 hours |
| Ambient temperature | Summer Ambient |
| Test duration | 48 hours |

Thermal performance plot:




Observations: The following table summarizes payload temperature data.

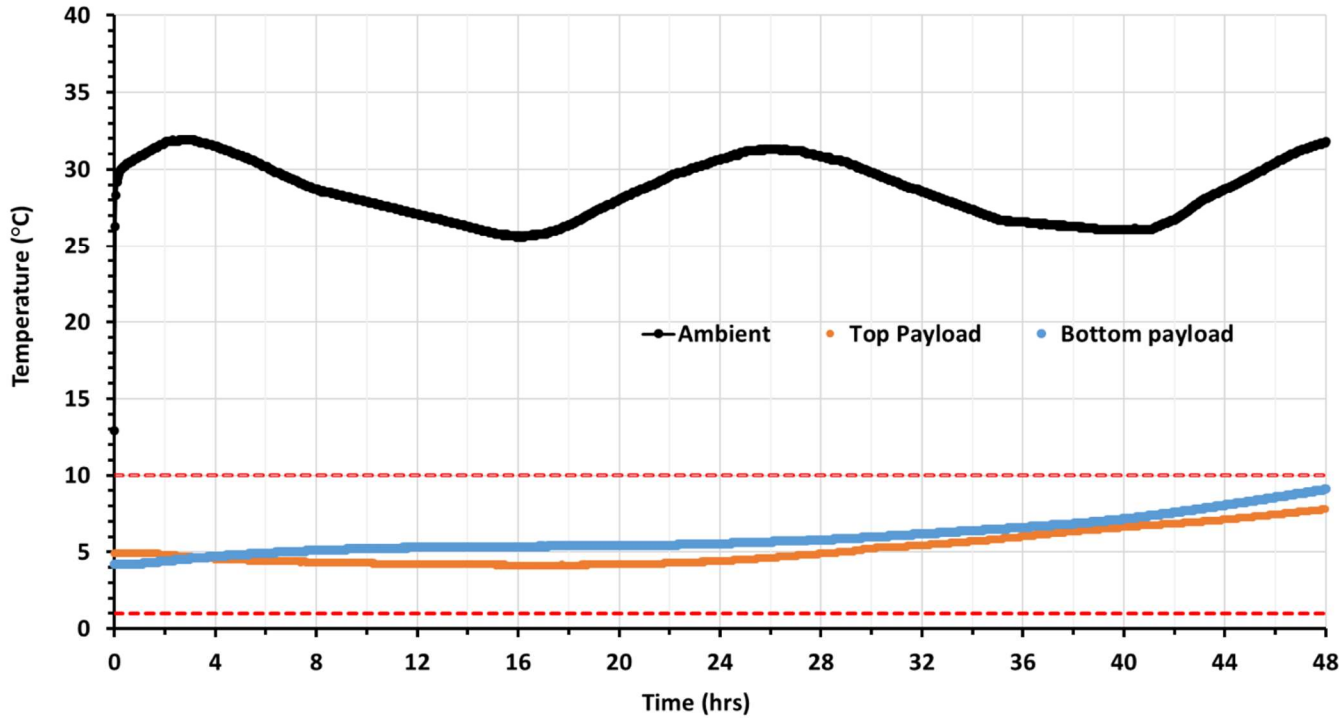
| Total time (hours) payload-maintained 1-10°C | Maximum payload temperature during tested duration (°C) |
|---|---|
| 48 | 6.2°C @ 48 hours |

### 5.3.4 Chilled Platelets 1-10°C | Summer Ambient | Maximum Payload

Test setup:

| | |
|---|---|
| Test payload | 12 x 350-400mL Cerus Intercept platelet units kept at 1-6°C for 12 hours |
| Ambient temperature | Summer Ambient |
| Test duration | 48 hours |

Thermal performance plot:




Observations: The following table summarizes payload temperature data.

| **Total time (hours) payload-maintained 1-10°C** | | **Maximum payload temperature during tested duration (°C)** | |
|---|---|---|---|
| Top Payload | Bottom Payload | Top Payload | Bottom Payload |
| 48 | 48 | 7.8°C @ 48 hours | 9.1°C @ 48 hours |