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Design Qualification Report for the MaxPlus Platelet Shipper

Intended for 20-24°C transport of room temperature platelets

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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 Platelet Shipper (SKU#U17PLT30). The report addresses basic system requirements, components breakdown, packing methods, and temperature compliance data for the U17PLT30 to transport room temperature platelets at 20-24◦C for a minimum of 30 hours.

2. Requirements Summary:

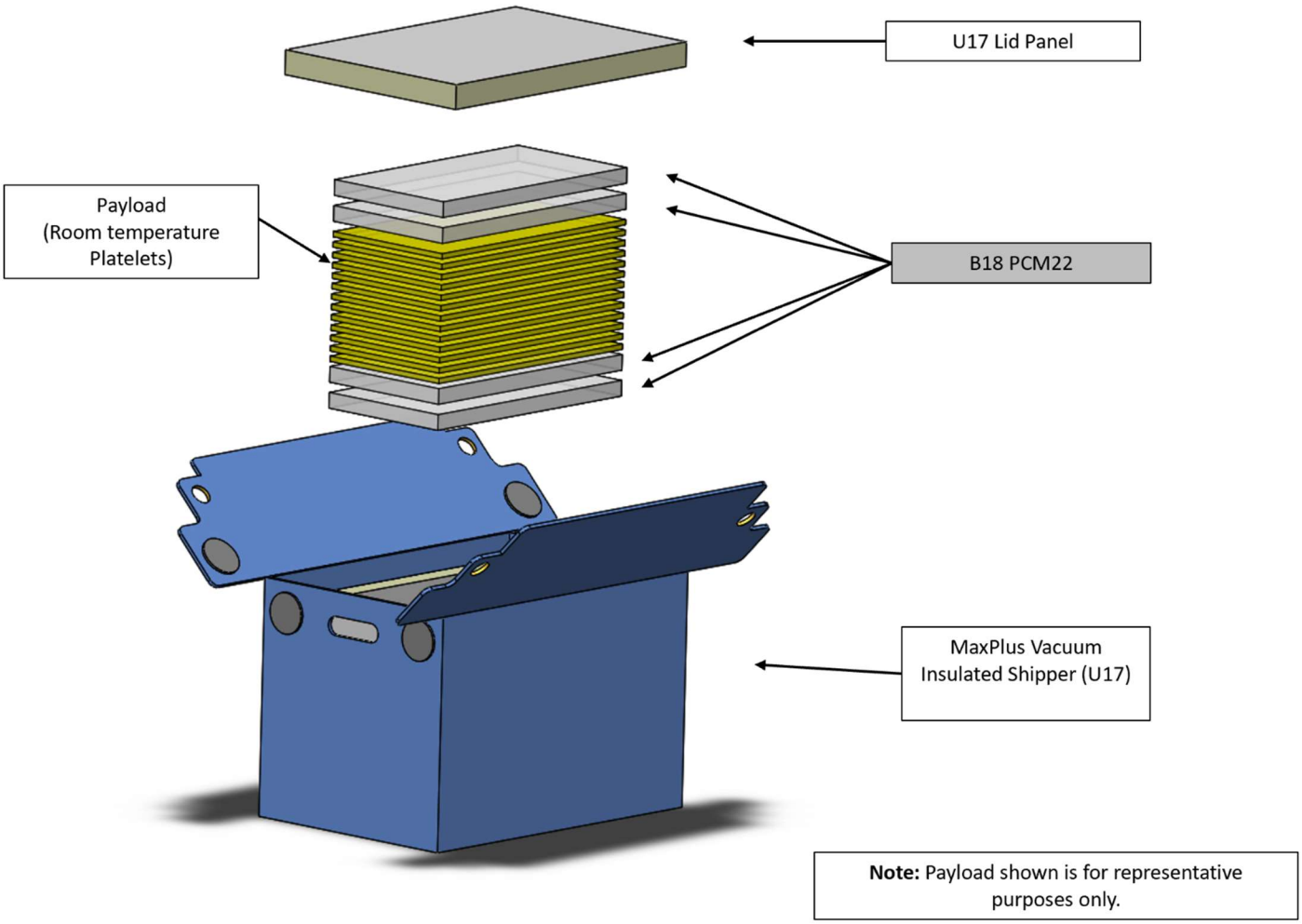
Payload type	Room temperature PR Platelets
Payload form factor	Cerus Intercept® PR platelet units
Payload volume	250-400mL per unit
Payload capacity	Up to 12x Cerus units
Payload temperature	20-24°C
Validation	30 hours against modified ISTA 7D standards

3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic, highly reusable
- Outer Dimensions: 17.25in x 11in x 11.5in (LWH)
- Payload Dimensions: 14in x 8in x 8in (LWH)
- System Weight (excluding payload): 18 lbs.
- Phase Change Coolant: B18 PCM22 coolant bottle (x4)

4. Packing Methods

4.1 U17PLT30 Packout Schematic:



4.2 U17PLT30 Coolant Conditioning Procedure:

- Charge four B18 PCM22 coolants in an incubator or controlled room temperature at (23°C ± 1°C) for a minimum of 24 hours.

4.3 U17PLT30 Packing Instructions:

1) Place two B18 PCM22 coolants in the bottom of the container.
2) Load desired number of platelet units directly on top of the bottom coolant bottles.
3) Place both of the remaining B18 PCM22 coolants on top of the payload units
4) Place the lid on top (Note: black gasket material facing down).
5) Equip the proper tamper evidence solution to the left and right-side grommets and Velcro the flaps down.
6) 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 PCM22 coolant bottle. 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 U17PLT30 Platelet Shipper with B18 PCM22 coolant bottles (x4) is designed to maintain platelet units between 20-24°C for a minimum of 30 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 modified 30-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 30 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

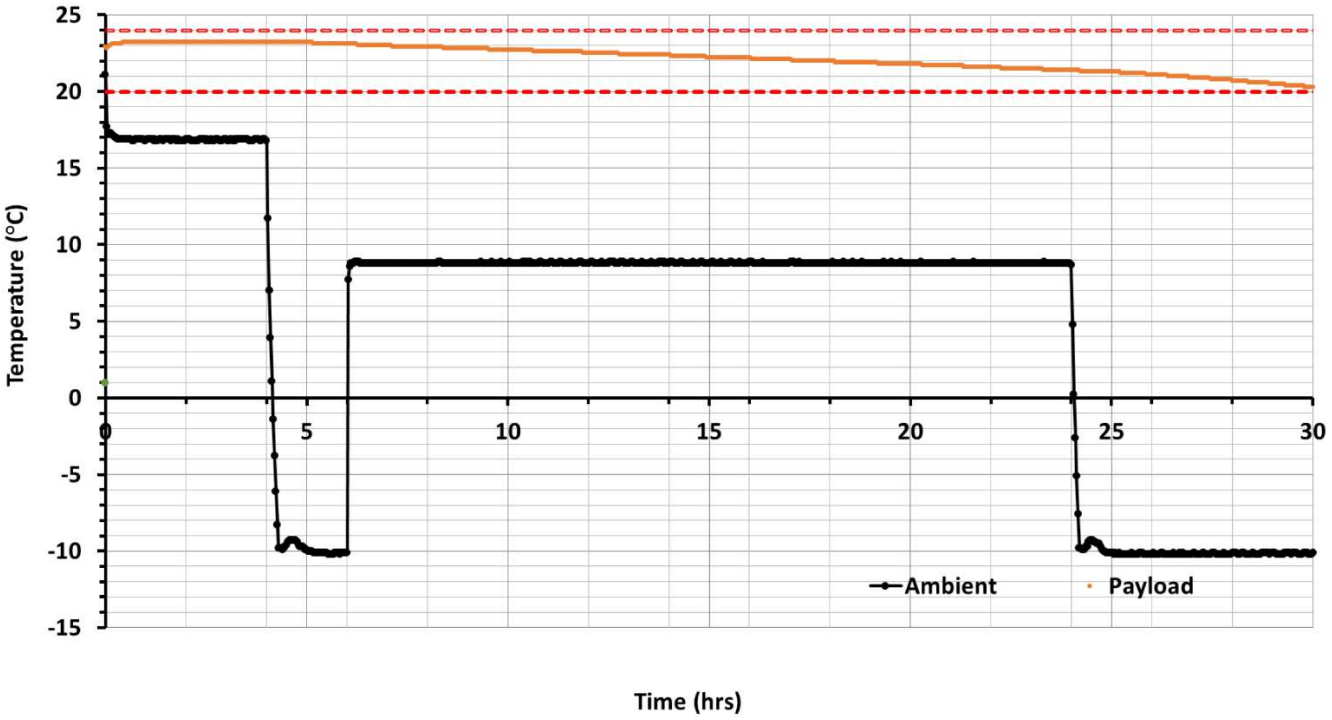
5.2 Test Results:

5.2.1 Platelets maintained at 20-24°C | **Winter Ambient** | Minimum Payload Configuration

Test setup:

Test payload	1 x 350-400mL Cerus intercept platelet unit kept at 20°C to 24°C for 12 hours
Ambient temperature	Winter Ambient
Test duration	30 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

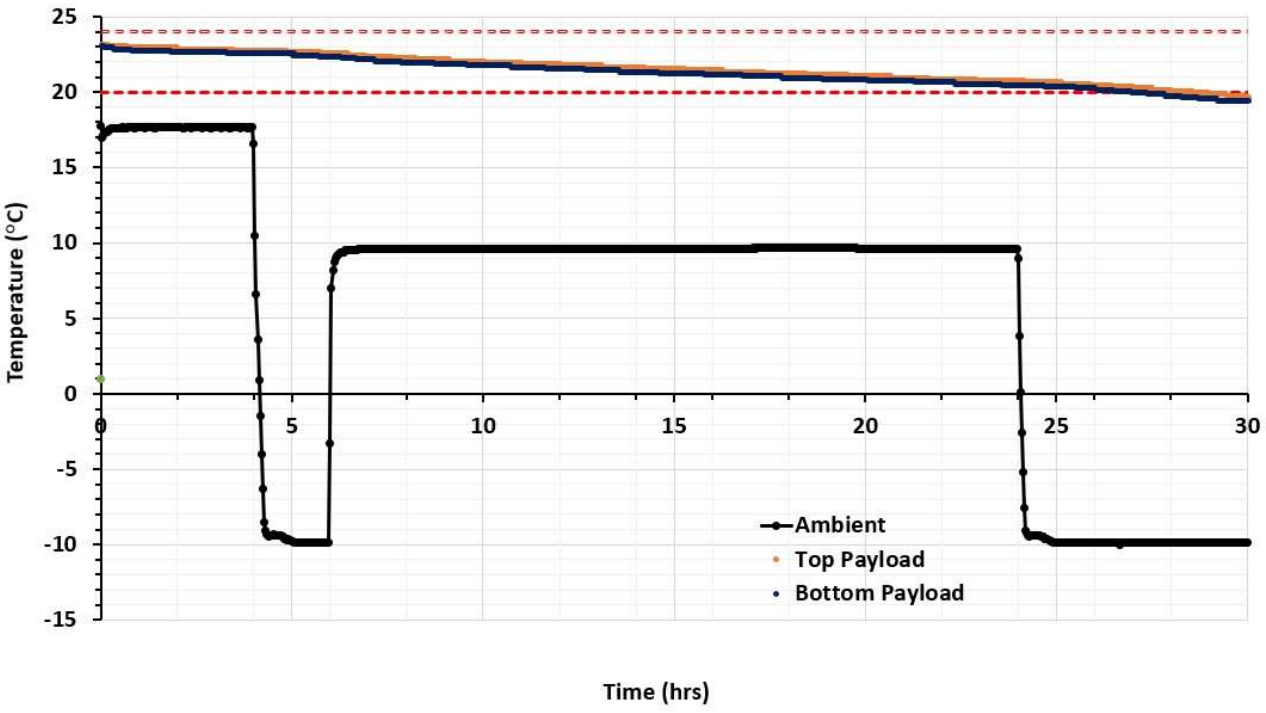
Total time (hours) payload-maintained 20 -24°C	**Minimum payload temperature during tested duration**
30	20.3°C @ 30 hours

5.2.2 Platelets maintained at 20-24°C | **Winter Ambient** | Maximum Payload Configuration

Test setup:

Test payload	12 x 350-400mL Cerus Intercept platelet units kept at 20°C to 24°C for 12 hours
Ambient temperature	Winter Ambient
Test duration	30 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

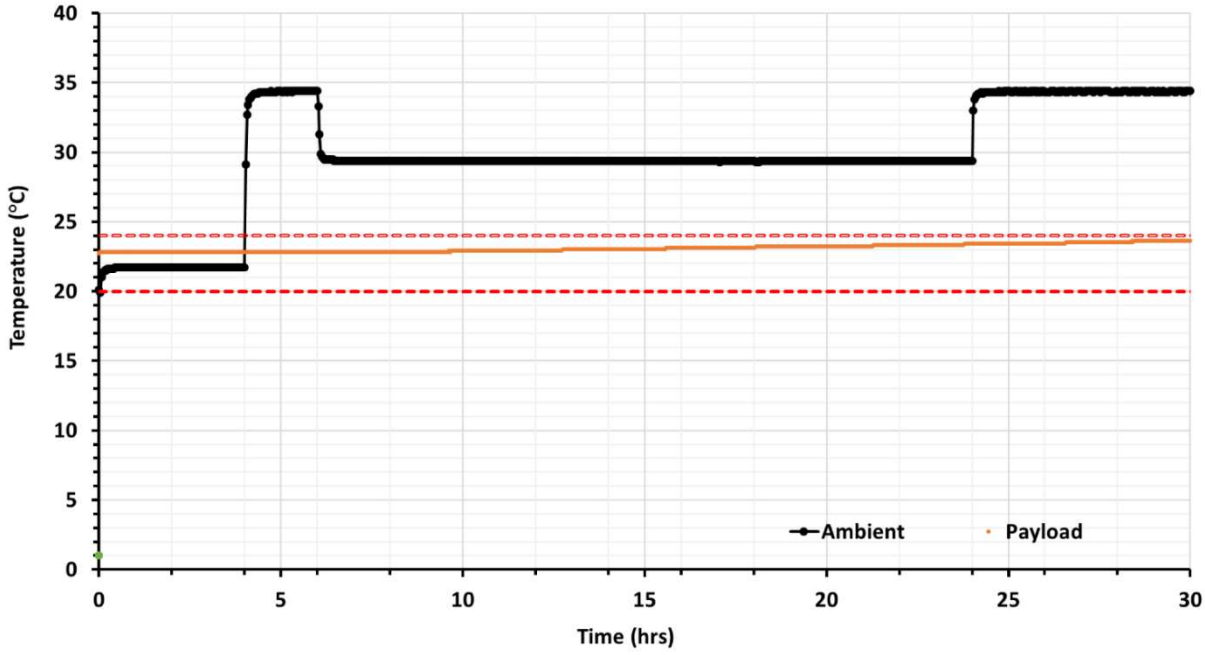
Total time (hours) payload-maintained 20 -24°C		**Minimum payload temperature during tested duration (°C)**	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
28.9	27.3	19.7°C @ 30 hours	19.5°C @ 30 hours

5.2.3 Platelets maintained at 20-24°C | **Summer Ambient** | Minimum Payload Configuration

Test setup:

Test payload	1 x 350-400mL Cerus intercept platelet unit kept at 20°C to 24°C for 12 hours
Ambient temperature	Summer Ambient
Test duration	30 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

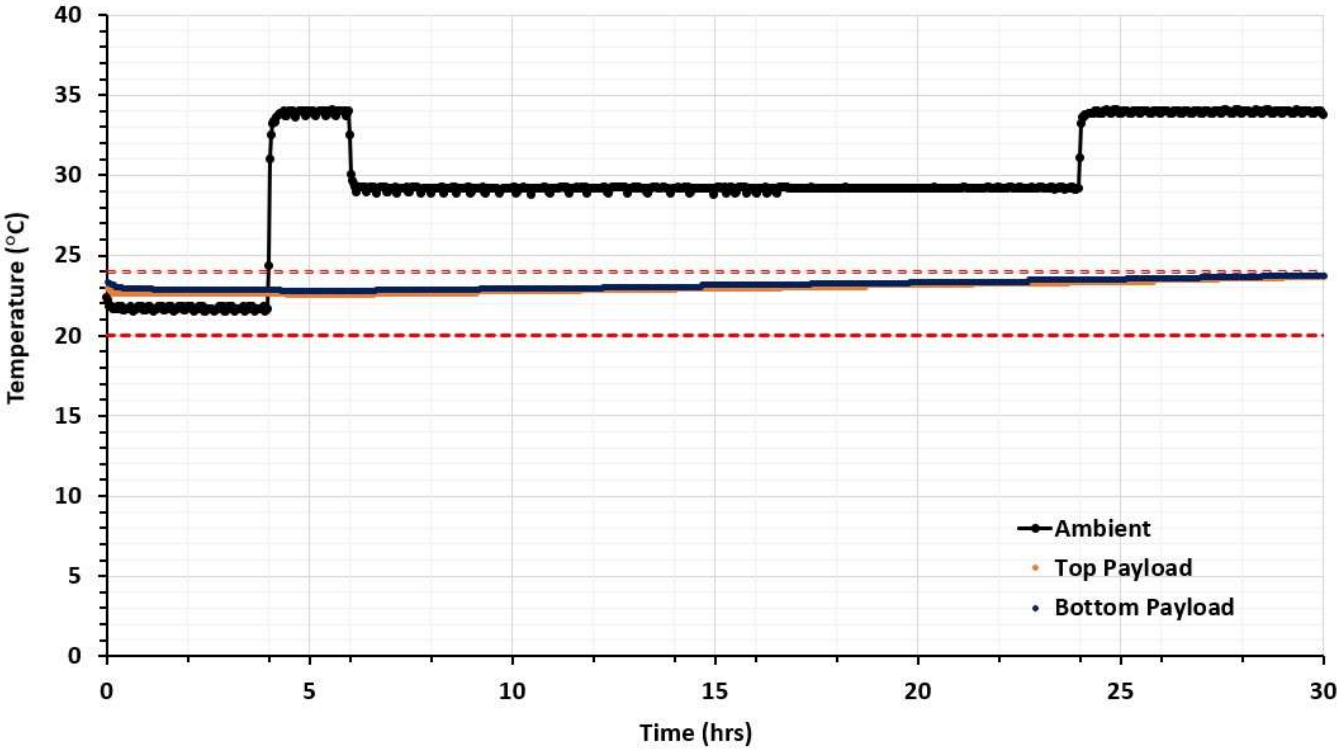
Total time (hours) payload-maintained 20 -24°C	**Maximum payload temperature during tested duration (°C)**
30	23.6°C @ 30 hours

5.2.4 Platelets maintained at 20-24°C | **Summer Ambient** | Maximum Payload Configuration

Test setup:

Test payload	12 x 350-400mL Cerus Intercept platelet units kept at 20°C to 24°C for 12 hours
Ambient temperature	Summer Ambient
Test duration	30 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 20 -24°C		**Maximum payload temperature during tested duration (°C)**	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
30	30	23.7°C @ 30 hours	23.8°C @ 30 hours