

MaxPlus Multi-Product Shipper (Small, Local distribution)

SKU # UNIV-LD-S-VIP

Design Qualification Report

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Referenced Documents	-



Project Information:

Project Number	DTV071-0520
Project Lead	Arif Rahman
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Test Location	MaxQ Research LLC 8712 W 6th Ave Stillwater, OK 74075

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1. Requirements Summary:

Payload type and capacity	Red Blood Cells: 1 to 10 units (1-10°C) Platelets: 1 – 12 units (20 – 24°C) Plasma: 1 – 6 units (< -18°C)
Available payload volume	5L
Required payload temperature	Red Blood Cells: 1-10°C (± 0.5°C), Platelets: 20 – 24°C (± 0.5°C), Plasma: below -18°C (± 0.5°C),
Ambient temperature profile used for testing	ISTA 7E based 24 hour profile

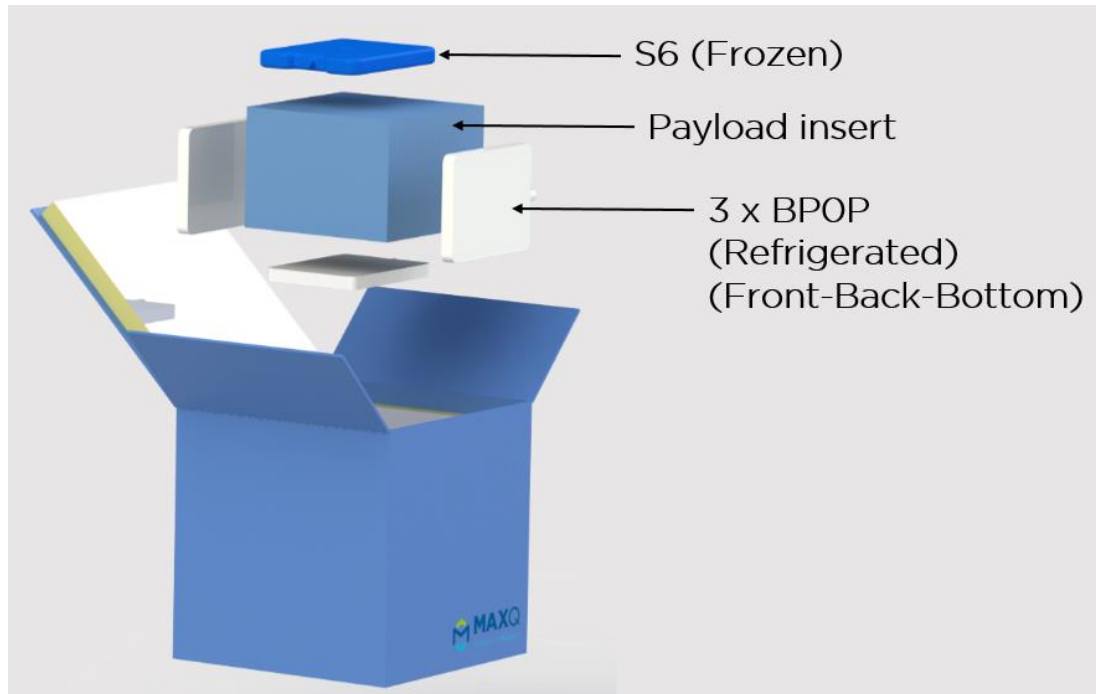
2. Design Summary:

- Outer Shell: Corrugated plastic (Blue), highly reusable with snap lock
- Outer Dimensions: 13.0" x 12.5" x 12" (l x w x h)
- Payload Dimensions: 8.75" x 7" x 5.75" (l x w x h)
- Payload Volume: 5L
- Phase Change Coolant:
 - Refrigerated payload configuration: 1 x Frozen S6 (blue) bottle, 3 x Refrigerated BPOP (white) bottle
 - Controlled room temperature payload configuration: 2 x PCM22 (white) bottle
 - Frozen payload configuration: 5 lbs. of Dry ice
- System Weight (excluding payload):
 - Refrigerated payload configuration: 14.5 lbs.
 - Controlled room temperature payload configuration: 12.4 lbs.
 - Frozen payload configuration: 13 lbs. (including Dry ice)

3. Payload-specific pack-out:

Product: Refrigerated Red Blood Cells or Plasma

3.1 Pack-out model for Refrigerated payload



3.2 Gel pack pre-conditioning procedure:

- Charge One S6 bottle (Blue) in freezer (-20°C for a minimum of 12 hours).
- Charge three BPOP bottle (White) in the refrigerator (1-6 °C for a minimum of 12 hours).

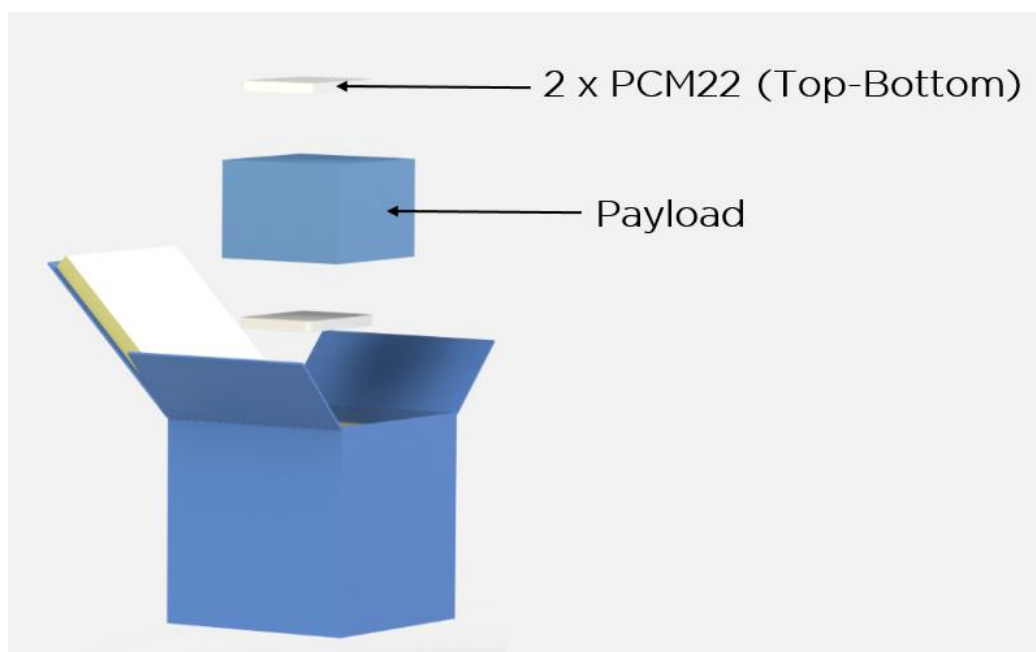
3.3 Pack-out procedure:

- **Step 1:** Place one **refrigerated BPOP bottle** (White) in bottom of the shipper.
- **Step 2:** Place the payload insert on top of the refrigerated BPOP bottle
- **Step 3:** Place two **refrigerated BPOP bottle** (White) in front and back of the payload insert

- **Step 4:** Place refrigerated payload (RBC, refrigerated Plasma, etc.) inside the payload insert.
- **Step 5:** Place the **frozen S6 bottle** (Blue) on top of the payload insert
- **Step 6:** Close the container lid and lock the lid buckle.

Product: Controlled Room Temperature Platelets

3.4 Pack-out model for Controlled room temperature payload



3.5 Gel pack pre-conditioning procedure:

- Charge two PCM22 bottle (White, red cap) at room temperature (20-24 °C for a minimum of 12 hours). If room temperature is not controlled, recommend storing the PCM22 bottles in the platelet incubator.

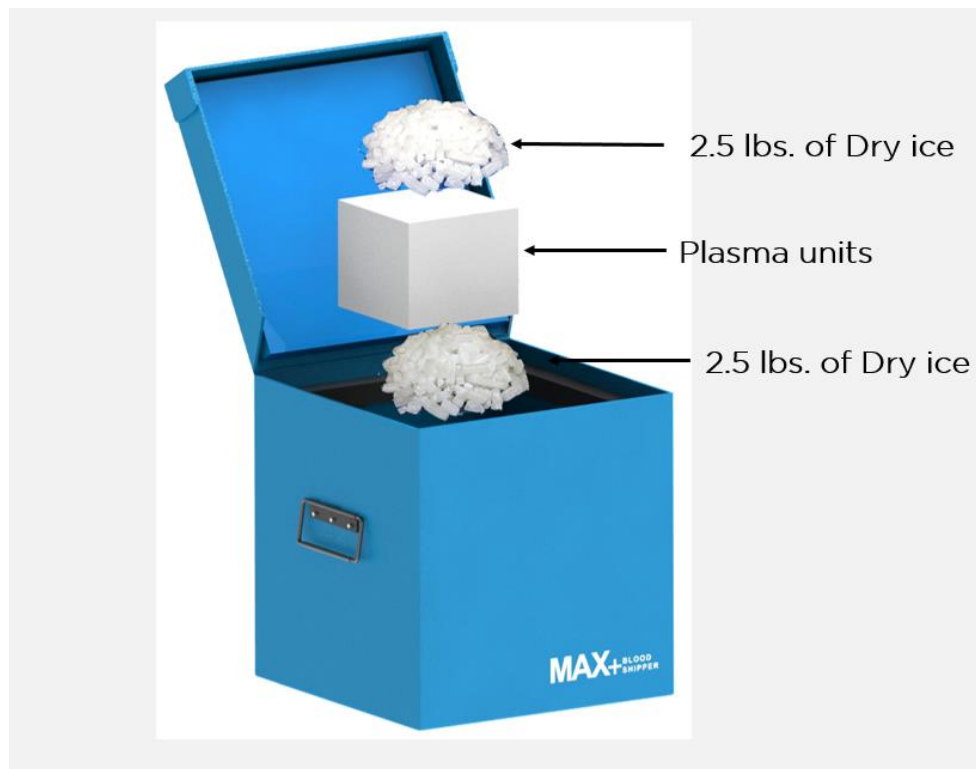
3.6 Pack-out procedure:

- **Step 1:** Place one **PCM22 bottle** (White) in bottom of the shipper.
- **Step 2:** Place the payload insert on top
- **Step 3:** Place platelet units (payload) inside the payload insert.
- **Step 4:** Place the last **PCM22 bottle** on top of the payload insert

- **Step 5:** Close the container lid and lock the lid buckle.

Product: Frozen Plasma

3.7 Pack-out model for Frozen payload



3.8 Gel pack pre-conditioning procedure:

- No coolants used. Dry ice pellets are used for the pack-out.

Note: Dry ice is hazardous. Please follow appropriate safety procedure while handling dry ice.

3.9 Pack-out procedure:

- **Step 1:** Place 2.5 lbs. of dry ice pellets (approximate, packed in a bag) in bottom of the shipper.

- **Step 2:** Place frozen plasma units from back to front of the shipper on their side.
Note: To avoid plasma unit breakage, fill any empty space with bubble wrap or similar packaging material.
- **Step 3:** Place 2.5 lbs. of dry ice pellets (approximate, packed in a bag) on top of the payload units.
- **Step 4:** Close the container lid and lock the lid buckle.

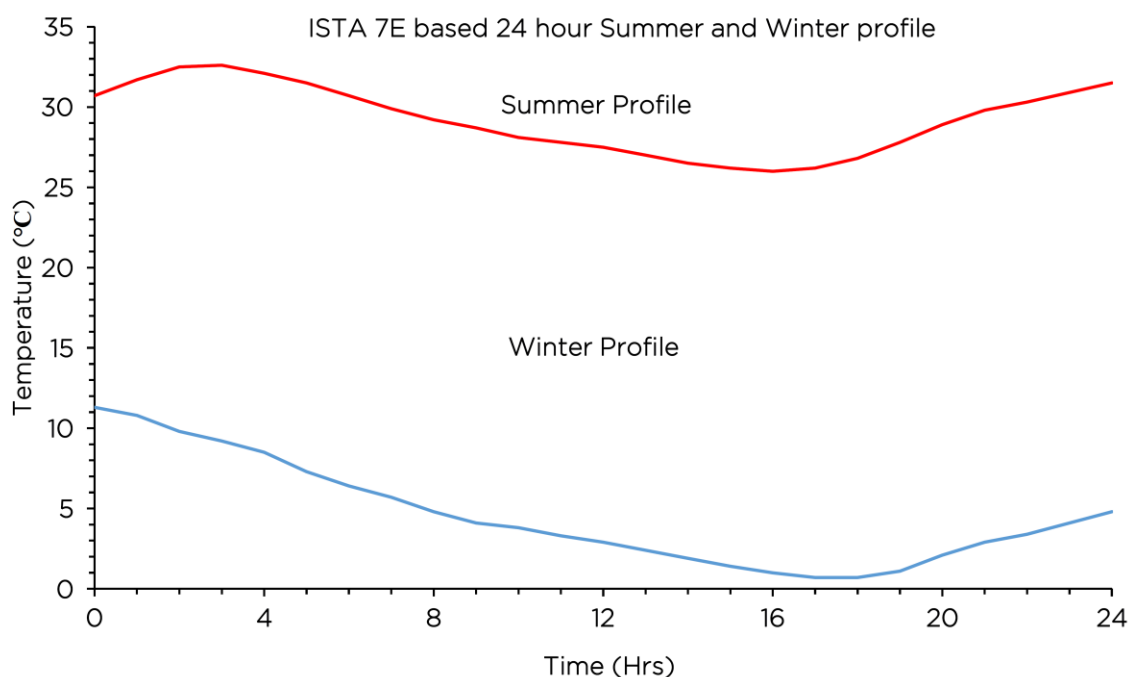
Disclaimer: The MaxPlus Multi-Product Shipper (Small size, 5L) packed as described above has been qualified for up to 24 hours of transport (1 – 10°C ($\pm 0.5^\circ\text{C}$), 20 – 24°C ($\pm 0.5^\circ\text{C}$)) in the described laboratory tests. The ambient temperature profile for a specific location may vary. MaxQ cannot guarantee that the payload can maintain required temperature without any excursions if the ambient temperature exposure of the packed system is not within the tested temperature range.

4. Thermal Performance Testing

4.1 Ambient profiles used for testing

4.1.1 Refrigerated Configuration:

The MaxPlus multi-product shipper was exposed to the following ISTA 7E based summer and winter ambient profiles inside a precision environmental chamber for performance testing.

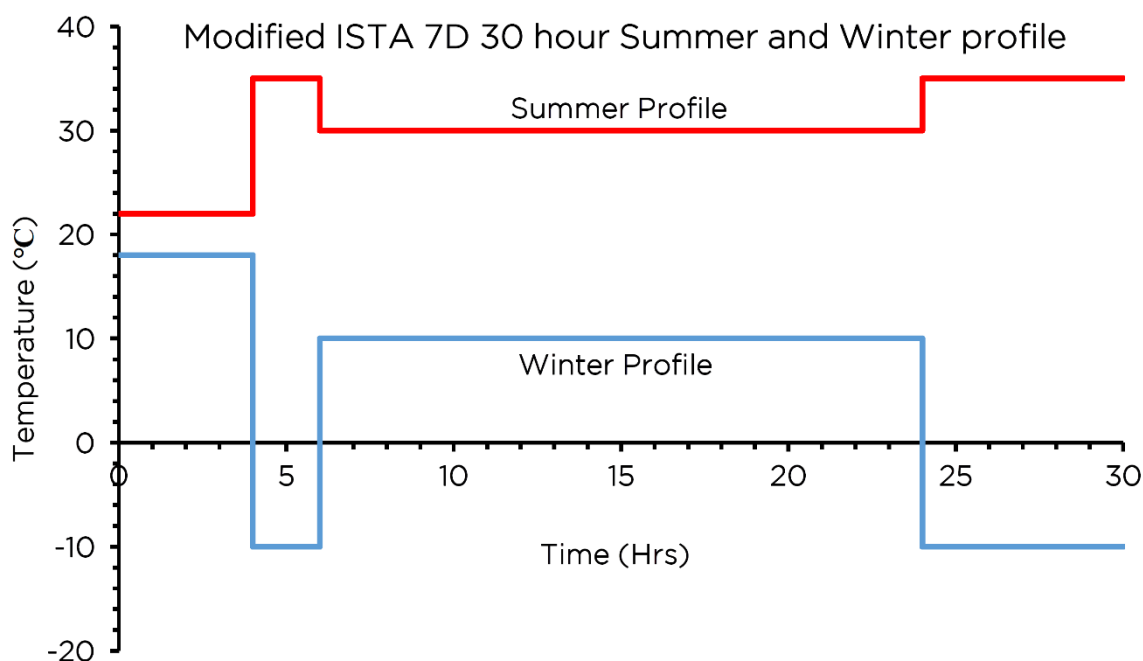


4.1.2 Controlled Room Temperature Configuration:

MaxQ's MaxPlus multi-product Shipper was exposed to the following summer and winter ambient profiles (based on modified ISTA 7D standards, added 6 hours of 30°C for Summer and 6 hours of 10°C for Winter to the existing profiles) inside a precision temperature regulated thermal chamber for performance validation testing.

Summer 30 hour profile: 22°C for 4 hours → 35°C for 2 hours → 30°C for 18 hours → 35°C for 6 hours

Winter 30 hour profile: 18°C for 4 hours → -10°C for 2 hours → 10°C for 18 hours → -10°C for 6 hours



4.2 Shipper performance evaluation

The MaxPlus multi-product shipper was packed according to the instructions specified above (Page # 3 - 5), and exposed to both the summer and winter ambient profiles in a NIST calibrated programmable thermal chamber. No payload/minimum payload was used inside the payload insert to simulate worst case scenario. NIST calibrated precision temperature loggers was placed inside the payload insert and temperature was recorded every 2 minutes during the test duration. At the end of test cycle, payload simulant temperature data was analyzed and the shipper performance was evaluated according to the following criteria:

Refrigerated payload testing:

Pass Criteria: Payload temperature stayed between 1-10°C ($\pm 0.5^\circ\text{C}$) during the 24 hours of test duration

Fail Criteria: Payload temperature went below 2°C ($\pm 0.5^\circ\text{C}$) or above 8°C ($\pm 0.5^\circ\text{C}$) during the 24 hours of test duration

Controlled room temperature payload testing:

Pass Criteria: Payload temperature stayed as close as possible 20-24°C ($\pm 0.5^\circ\text{C}$) during the 24 hours of test duration

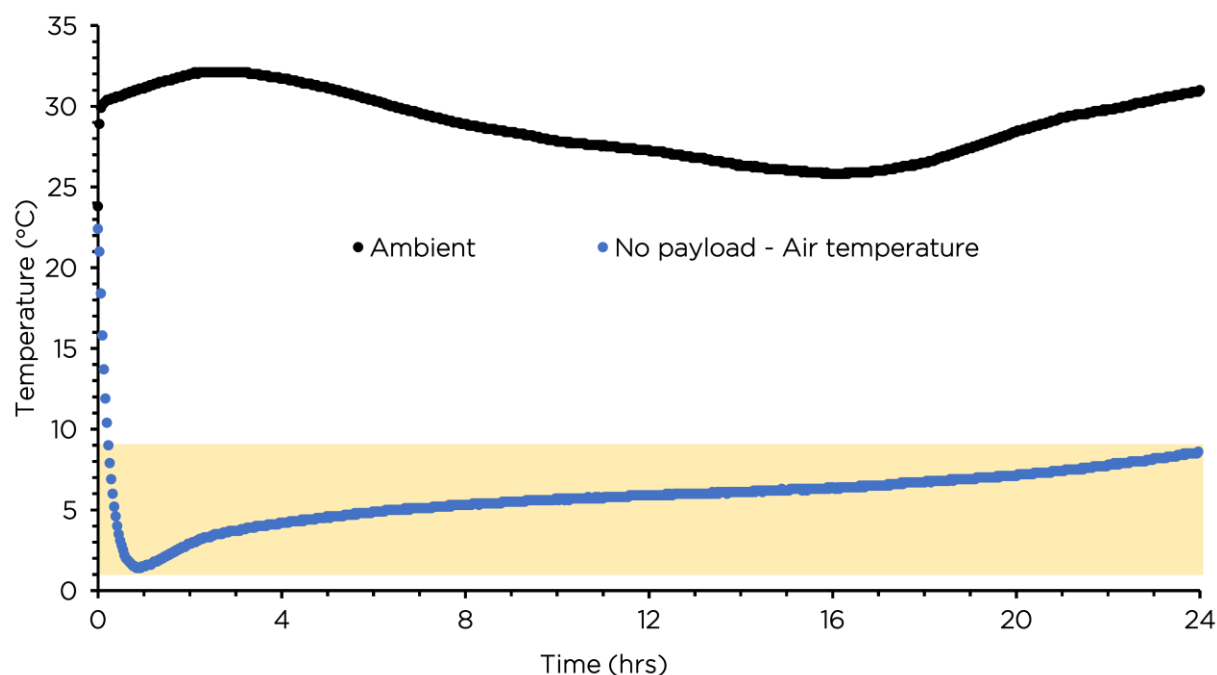
Fail Criteria: Payload temperature went below 20°C ($\pm 0.5^\circ\text{C}$) or above 24°C ($\pm 0.5^\circ\text{C}$) during the 24 hours of test duration

4.3 Test results:

Test Case 1: Refrigerated payload transport - Summer Ambient

Container	UNIV-LD-S-VIP
Gel packs	1 x S6 bottle (Blue), 3 x BPOP bottle (White)
Preconditioning	Charge 1 x S6 bottle (Blue) in the freezer (below -20 °C) and 3 x BPOP bottle (White) in the refrigerator (1-6°C) for 12 hours
Test payload	No Payload - Air temperature was measured
Temperature data loggers	Air temperature - MaxQ Logger 19* Ambient temperature - MaxQ Logger 27* *NIST traceable temperature data loggers. Certificates available upon request. *Loggers were set to record temperature every 2 mins
Ambient temperature	Summer (Section 4.1.1)
Test duration	24 hours

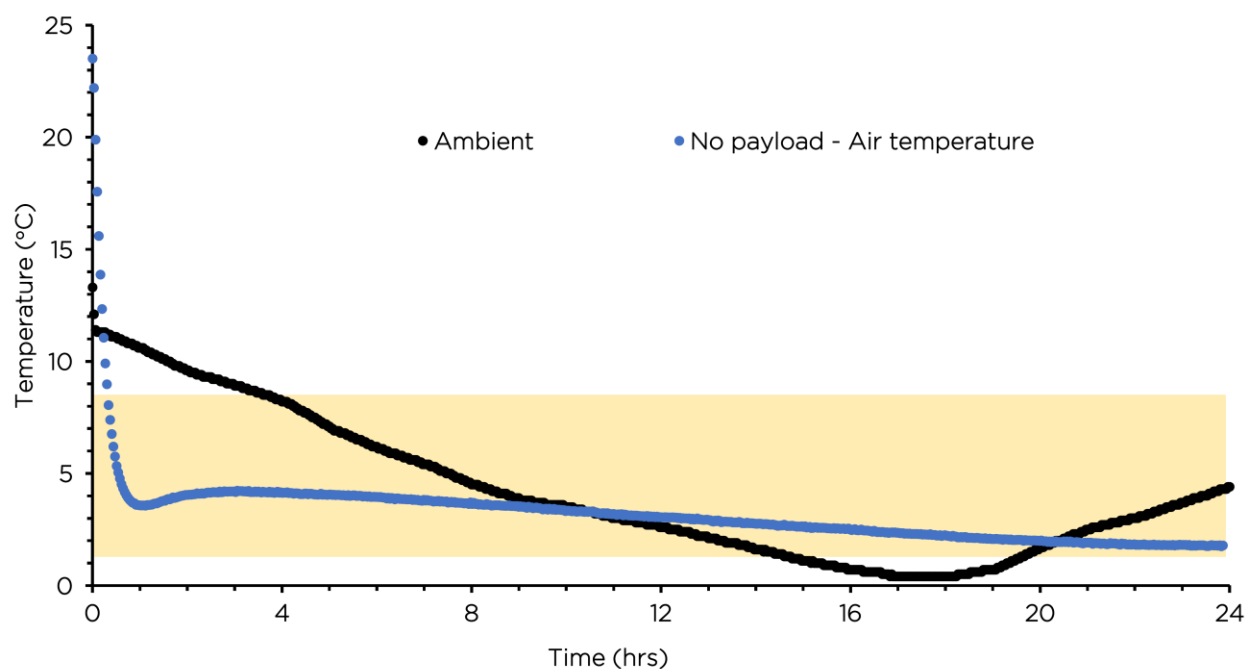
Performance Graph:



Test Result: **Pass** Minimum Temperature: 1.5°C Maximum Temperature: 8.5°C

Test Case 2: Refrigerated payload transport – winter ambient

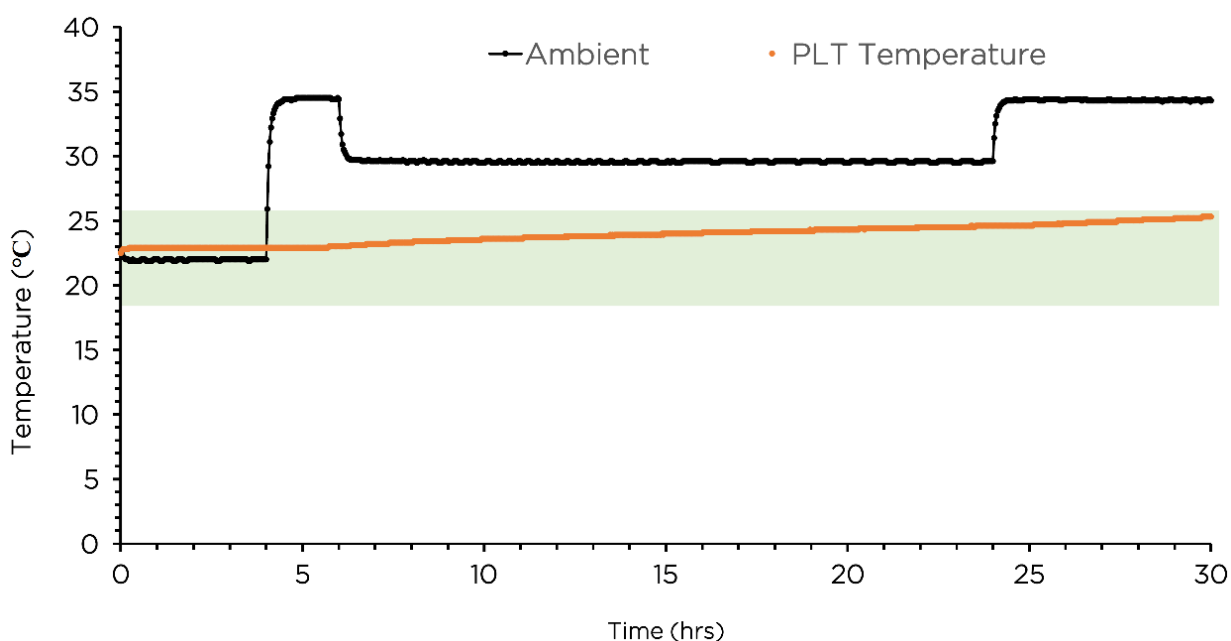
Container	UNI-LD-S-VIP
Gel packs	1 x S6 bottle (Blue), 3 x BPOP bottle (White)
Preconditioning	Charge 1 x S6 bottle (Blue) in the freezer (below -20 °C) and 3 x BPOP bottle (White) in the refrigerator (1-6°C) for 12 hours
Test payload	No Payload – Air temperature was measured
Temperature data loggers	Air temperature – MaxQ Logger 19* Ambient temperature – MaxQ Logger 27* *NIST traceable temperature data loggers. Certificates available upon request. *Loggers were set to record temperature every 2 mins
Ambient temperature	Winter (Section 4.1.1)
Test duration	24 hours

Performance Graph:


Test Result: **Pass** Minimum Temperature: 1.7°C Maximum Temperature: 4.3°C

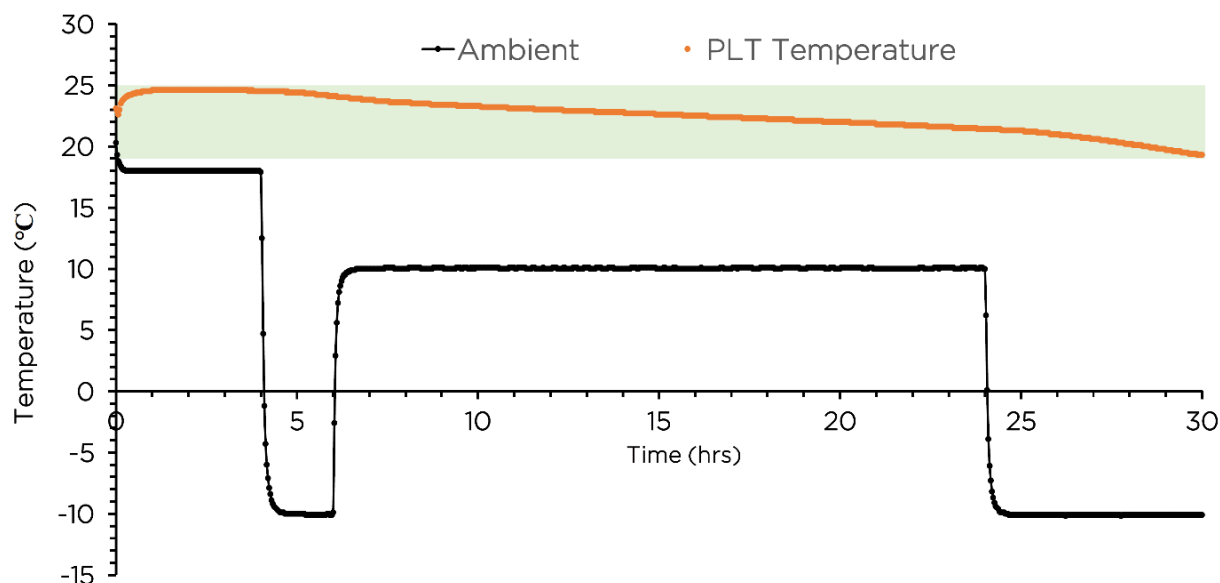
Test Case 3: Controlled room temperature payload transport – Summer ambient

Container	UNIV-LD-S-VIP
Gel packs	2 x PCM22 bottle (White)
Preconditioning	Charge 2 x PCM22 bottle (White) at room temperature 20-24 °C for a minimum of 12 hours
Test payload	1 unit of 300mL water bag stored at 22 °C for 24 hours
Temperature data loggers	Payload temperature – MaxQ Logger 19* Chamber temperature – MaxQ Logger 17* *NIST traceable temperature data loggers. Certificates available upon request. *Loggers were set to record temperature every 2 mins
Ambient temperature	Summer (Section 4.1.2)
Test duration	24 hours

Performance Graph:

Test Result: Pass
Average Payload Temperature: 23.9°C

Test Case 4: Controlled room temperature payload transport – Winter ambient

Container	UNIV-LD-S-VIP
Gel packs	2 x PCM22 bottle (White)
Preconditioning	Charge 2 x PCM22 bottle (White) at room temperature 20-24 °C for a minimum of 12 hours
Test payload	1 unit of 300mL water bag stored at 22 °C for 24 hours
Temperature data loggers	Payload temperature – MaxQ Logger 19* Chamber temperature – MaxQ Logger 17* *NIST traceable temperature data loggers. Certificates available upon request. *Loggers were set to record temperature every 2 mins
Ambient temperature	Winter (Section 4.1.2)
Test duration	24 hours

Performance Graph:

Test Result: Pass
Average Payload Temperature: 22.6°C