New MaxPlus MTP Cooler® 2.0

- with enhanced infection control compliance -

Validation Guide

Version 2.1
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Exclusive system for bedside storage of Red Blood Cells (1 – 6 °C), Thawed Plasma (cooling down to 1 – 6 °C), and Platelets (20 – 24 °C) in a single cooler

SKU # MTP18X12

Website: https://www.packmaxq.com/mtp-2-0-cooler

Reference materials: https://www.packmaxq.com/mtp-2-0-reference-materials

Brochure: MTP 2.0 Brochure

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NOTE: If you need any help in executing the test cases listed in this guide please contact your MaxQ sales representative for help. We may also contact the technical support line – 405-466-5629 or sales@packmaxq.com – Please list "Validation guidance for MTP Cooler" in the subject line.

System Overview:

The new MaxPlus MTP Cooler® is exclusively designed and validated for hospital transfusion services for bedside storage of Red Blood Cells (1 – 6 °C), Thawed Plasma (cooling down to 1 – 6 °C), and Platelets (20 – 24 °C) in a single cooler.

System Components:

- MaxPlus MTP Cooler®
- S6 gel pack (2 units)
- BP0P gel pack (white bottle with white cap, 3 units)
- PCM22 gel pack (white bottle with red cap, 1 unit)

MTP Cooler Specifications:

- **Outer dimensions**: 18.9”x18.4”x15”
- **Inner dimensions**: 15”x10.5”x9”
- **System Weight:** 21 lbs. (Excluding payload)
- **Payload:**
  - Type: Red Blood Cells, Plasma (Cold or Warm), and Platelet
  - Capacity: 2 to 6 units of RBC, 2 to 6 units of Plasma, 1 to 2 units of Platelets
  - Temperature for cold RBC/Plasma: 1 – 6 °C
  - Temperature for thawed Plasma: Cooling down towards 1-6°C
  - Temperature for Platelets: 20-24°C
  - Validated storage duration: 12 hours

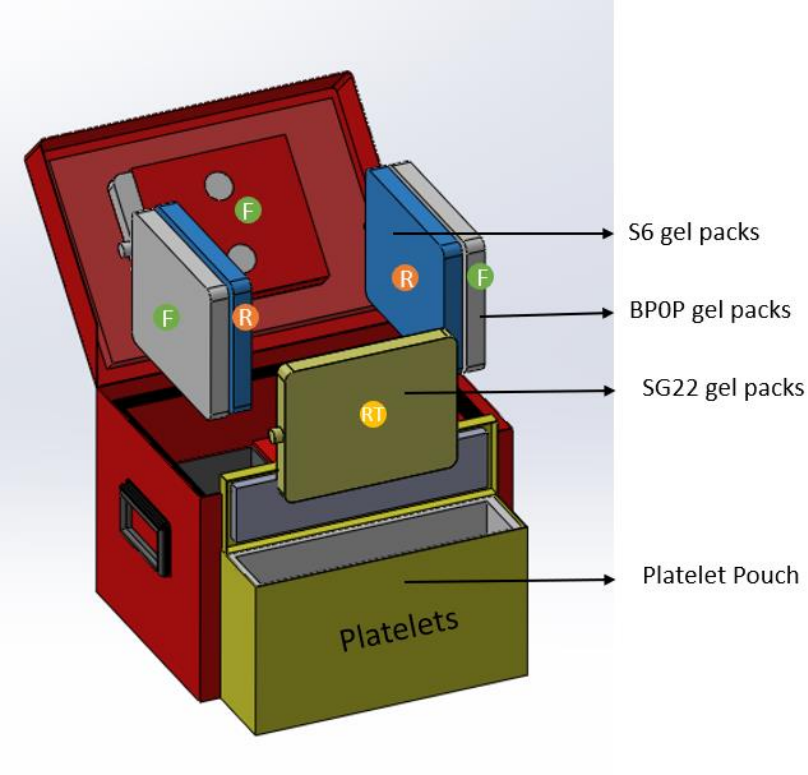
Durability qualification:

Polypropylene plastic used for the new MaxPlus MTP Cooler® has a high tensile strength (5500 psi) that allows it to withstand fairly heavy load despite being lightweight. Its high resistance to repeated loading makes it an ideal candidate for living hinges[1]. The material is highly resistant to chemicals and can be cleaned using organic solvents, standard lab / OR cleaning agents and wipes.

[1] Karger-Kocsis, József. "Fatigue performance of polypropylene and related composites." *Polypropylene*. Springer, Dordrecht, 1999. 227-232.

Packaging assembly illustration

***Red blood cells compartment (RBC):** System is designed to hold 2 to 6 refrigerated red blood cell units between 1 to 6 °C (AABB Storage requirement)



Gel pack arrangement:

3 x Frozen – 2 against left and right walls, 1 on lid

2 x Refrigerated – 2 against left and right walls

1 x Room Temperature – 1 in Platelet Pouch

***Plasma compartment (PL):** System is designed to hold 2 to 6 units of either liquid plasma from refrigerator between 1 to 6 °C or warm plasma from the thawing equipment cooling down towards 1 to 6 °C.

Platelet compartment (PLT): The Platelet pouch is designed to hold 1-2 platelet units between 20 to 24 °C.

Validation test cases:

The new MaxPlus MTP Cooler® is validated for 6 different operational test cases. The test cases are listed below:

1. Validation test case # 1 – Maximum warm payload bedside storage testing

   This test validates the new MaxPlus MTP Cooler for storing maximum number of **cold RBC units (6 units)** between 1 to 6°C and storing maximum number of **warm PL (6 units)** cooling down towards 1 to 6°C. This test case simulates operational scenario where the new MTP cooler is issued with warm plasma products and can maintain required temperature for a minimum of 12 hours.

2. Validation test case # 2 – Maximum cold payload bedside storage testing

   This test validates the new MaxPlus MTP Cooler for storing maximum number of cold RBC units (6 units) and maximum number of cold PL units (6 units) between 1 to 6°C. This test case simulates operational scenario where the new MaxPlus MTP cooler is issued with **refrigerated products (both RBC and PL)** and can maintain required temperature for a minimum of 12 hours.

3. Validation test case # 3 – Minimum cold payload bedside storage testing

   This test validates the new MaxPlus MTP Cooler® for storing minimum number of **cold RBC units (2 units)** and minimum number of **cold PL units (2 units)** between 1 to 6°C. This test case simulates operational scenario where the MTP cooler is issued with all refrigerated products (RBC and PL) for patients in *Pediatric care* and can maintain required temperature for a minimum of 12 hours.

4. Validation test case # 4 – Warm payload depletion testing

   This test case simulates operational scenario where the new MaxPlus MTP Cooler® is issued with maximum **warm plasma (6 units)** cooling down towards 1 to 6°C and maximum **cold RBC units (6 units)** between 1 to 6°C. Subsequently, 1 unit of cold RBC and 1 unit of warm PL were removed from the cooler every 15 minutes until only 1 unit of cold RBC and 1 unit of warm PL are left in the cooler. This simulates operational scenario where the patient is being infused with the blood products every 15 minutes. The cooler is tested to maintain required temperature for a minimum of 12 hours.

5. Validation test case # 5 – Cold payload depletion testing

   This test case simulates operational scenario where the new MaxPlus MTP Cooler® is issued with maximum number of cold plasma **(6 units)** and maximum number of cold RBC **(6 units)**. Subsequently, 1 unit of cold RBC and 1 unit of cold PL were removed from the cooler every 15 minutes until only 1 unit of cold RBC and 1 unit of cold PL are left in the cooler. This simulates operational scenario where the patient is being infused with the blood products. The cooler is tested to maintain required temperature (1-6°C) for a total of 12 hours.

6. Validation test case # 6 – Platelet testing

   This test case simulates operational scenario where the new MaxPlus MTP Cooler™ is issued with maximum number of cold RBC units (6) and maximum

number of cold PL units (6), and 1 unit of Platelet placed inside the Platelet compartment. The cooler is placed inside a NIST traceable calibrated environmental chamber maintaining a constant ambient of 18°C (64.4°F, to simulate a colder OR) and the platelet simulant inside the Platelet compartment maintained between 20 to 24°C for a minimum of 12 hours. This test case simulates the maximum hold time scenario for the platelet product.

Pack-out instructions:

Instructions for internal facility usage (NO BENCH TIME):

Step 1: Charge three BP0P gel packs in freezer (below -20°C), two S6 gel packs in the refrigerator (1-6 °C) and one SG22 gel pack in the platelet incubator (22°C) for a minimum of 12 hours. *Please refer to 'Gel pack preparation' for detailed instruction.*

Step 2: Place two frozen BP0P gel packs against the two opposite walls of the container and one in the designated lid pouch. (Refer to packaging assembly illustration on page 1)

Step 3: Place two refrigerated S6 gel packs against the two opposite walls of the container making sure to place them on the **inside face** of the frozen gel packs to avoid putting blood components in close contact with frozen coolant.

Step 4: Place your RBC and Plasma units inside the container and close the cooler lid, ensuring that it is sealed properly. *For validation of the cooler please refer to 'Data logger preparation' and 'Payload preparation' for detailed instruction.*

Note: RBC units from the refrigerator and warm Plasma units from the thawing equipment (or refrigerator) should be placed in separate specifically labeled compartments each.

Step 5: Take the SG22 gel pack from the platelet incubator and place it inside of the platelet pouch.

Step 6: Place 1-2 units of Platelet units inside the platelet pouch in front of the coolant bottle.

Step 7: Close the platelet pouch lid making sure the front latch is properly connected.

Disclaimer: The new MaxPlus MTP Cooler® 2.0 (MTP18 X12) packed with two S6 gel packs, three BP0P gel packs and one SG22 gel pack has been qualified for a minimum of **12 hours to hold 1 to 6°C for RBC units and cooled Plasma units (or cooling down towards 1 to 6°C for warm Plasma units), and 20 to 24°C for Platelet unit (**ambient between 18 to 25°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 range without any

excursions if the ambient temperature exposure of the packed system is not within the tested temperature range.

Gel pack preparation

- Three BP0P gel pack bottles (white bottle with white cap) should be pre-conditioned inside a freezer (below -20°C) for a minimum of 12 hours. The BP0P gel pack bottles should be placed lying flat inside the freezer to avoid non-uniform freezing of the coolant.
- Two S6 gel pack bottles (clear / blue bottle) should be pre-conditioned inside a refrigerator (1-6°C) for a minimum of 12 hours.
- SG22 gel pack bottle (white bottle with red cap) should be kept inside the Platelet incubator at 22°C for a minimum of 12 hours prior to use.

Payload preparation

- Payload used for validation test should be pre-conditioned at appropriate temperature for at least 12 hours prior to start of the test.
    - Cold RBC/Plasma simulant units shall be stored inside refrigerator (1-6°C) for at least 12 hours
    - Warm Plasma simulant units can come from the thawing equipment at or below 37°C. Please note that MaxQ used a NIST traceable calibrated environmental chamber to condition the simulated warm plasma units at 37°C prior to testing for at least 12 hours
    - Platelet simulant unit shall be stored in the platelet incubator at 22°C for at least 12 hours prior to testing

Data Logger preparation

- It is recommended to perform cooler validation using NIST traceable data logger with external probe that can be affixed to the surface of the payload bag*. Packaging tape can be used to affix the external probe to one of the payload units.

*Please note that measuring the core temperature by inserting the metal probe inside the blood bag is also possible and will be considered a valid test.

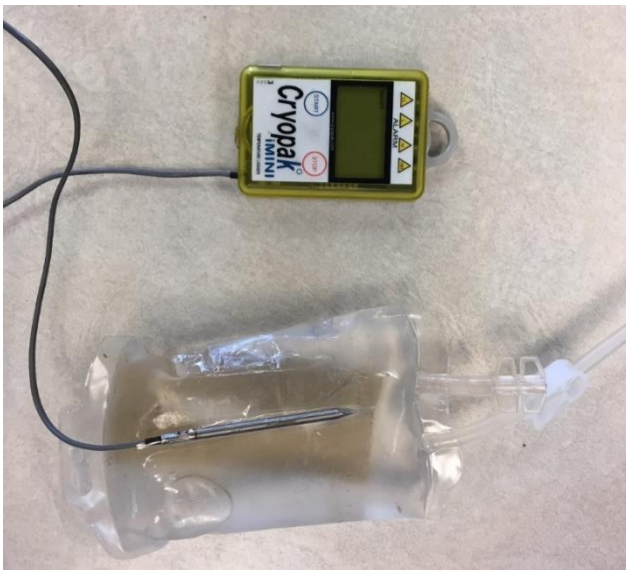


Figure 1

- Place another unit on top of the first unit such a way that the probe is sandwiched between 2 units. For validation purposes, you can use a rubber band around both the units such a way that it will make sure there is no airgap between the units and they stay together (Figure 2).

Figure 2

Pre-condition the data logger with the payload unit inside

- For cold products: the refrigerator between 1 to 6°C for at least 2 hours to eliminate any chance of temperature spike.
- For room temperature products: the platelet incubator at 22°C for at least 2 hours

- Please note that for warm products the payload can be used right away from the thawing equipment at or below 37°C. However, the probe shall be affixed to the bag after the simulant is taken out from the thawing equipment as shown above.

Pack-out variations

The new MaxPlus MTP Cooler® has been validated using BP0P gel packs bottles (white) pre-conditioned inside a commercial freezer that maintains temperature between -20°C to -30°C. Using a plasma freezer (< -26°C) to pre-condition the BP0P gel pack bottles (White) will not change the validation protocol or validation duration.

Other use considerations

None listed.

Validation Test Data: Case # 1, Maximum Warm Payload Stationary Testing

MaxPlus MTP Cooler Maximum Warm Payload Bedside Storage Testing
(6 x Cold Red Blood Cells + 6 x Warm Plasma Simulants)
Ambient: Internal facility

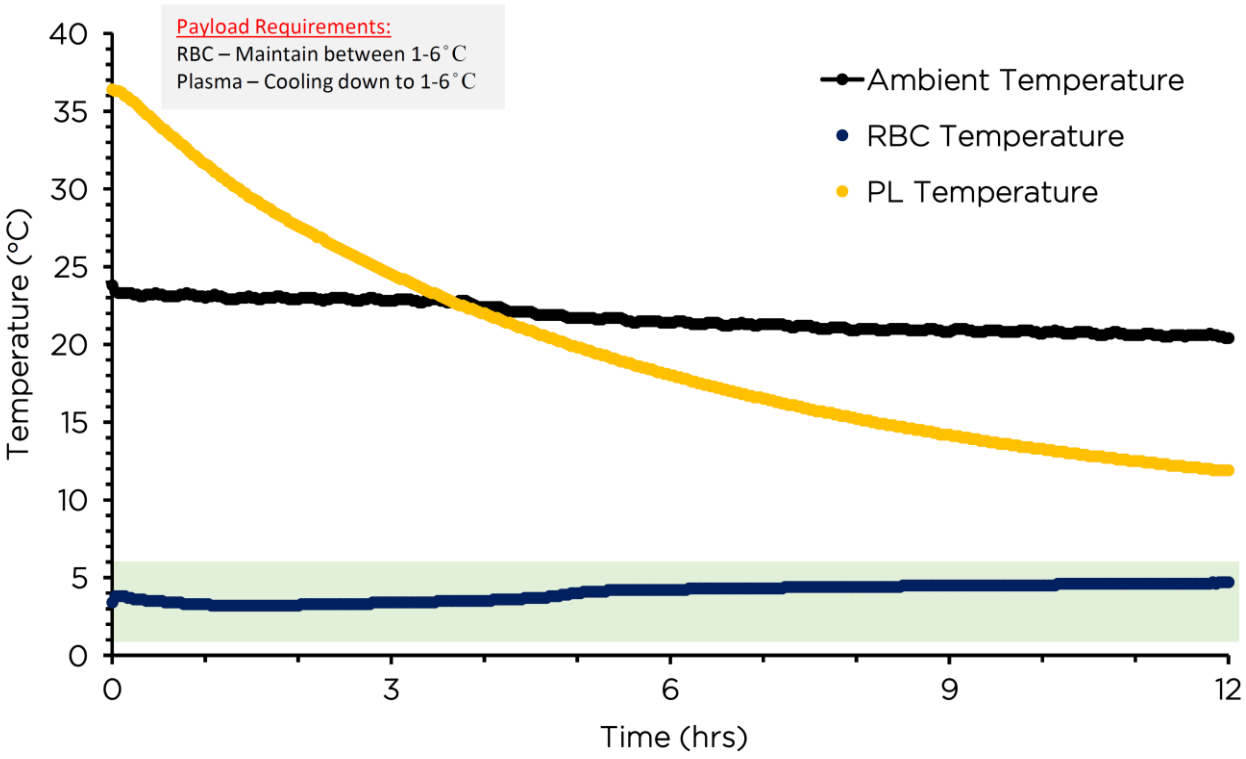
Test setup:

Container	MaxPlus 18.5" container (MTP18)
Gel packs	S6 (2 units), BP0P (3 units), SG22 (1 unit)
Preconditioning	Three BP0P gel packs stored at -20°C for 24 hours and two S6 gel packs stored in the refrigerator (2-6°C)
Test payload	**RBC**: 6 units of 300mL water bags from refrigerator (2 – 6 °C) **Warm plasma:** 6 units of 300mL water bags from incubator (30-35 °C)
Temperature data loggers	RBC temperature – MaxQ Logger 31* Plasma temperature – MaxQ Logger 32* Ambient temperature – MaxQ Logger 33* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 23°C
Test duration	12 hours

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
RBC	3.4	4.7	Pass
Warm Plasma	36.4	11.9	Pass

Performance graph



Validation Test Data: Case # 2, Maximum Cold Payload Bedside Storage Testing

MaxPlus MTP Cooler Maximum Cold Payload Bedside Storage Testing
(6 x Cold Red Blood Cells + 6 x Cold Plasma Simulants)
Ambient: Internal facility

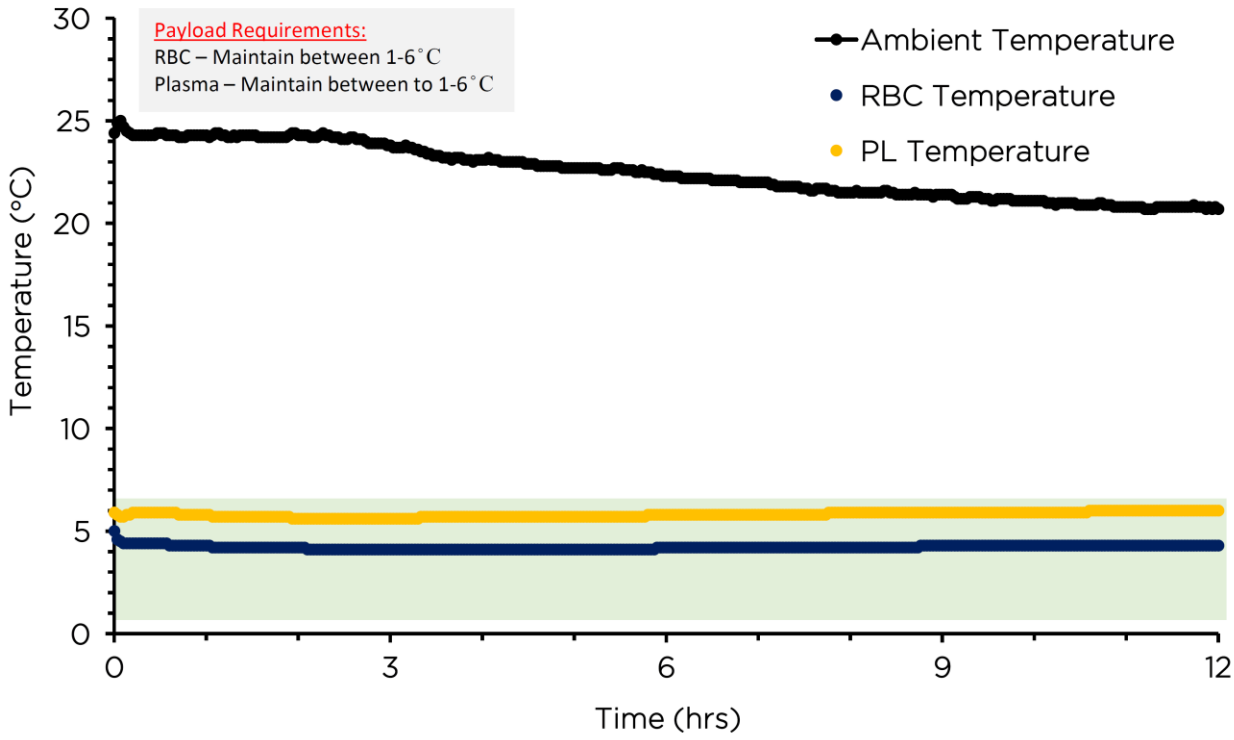
Test setup:

Container	MaxPlus 18.5" container (MTP18)
Gel packs	S6 (2 units), BP0P (3 units), SG22 (1 unit)
Preconditioning	Three BP0P gel packs stored at -20°C for 24 hours and two S6 gel packs stored in the refrigerator (2-6°C)
Test payload	**RBC:** 6 units of 300mL water bags from refrigerator (2 – 6 °C) **Cold plasma**: 6 units of 300mL water bags from refrigerator (2 – 6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger 23* Plasma temperature – MaxQ Logger 32* Ambient temperature – MaxQ Logger 20* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 23°C
Test duration	12 hours

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
pRBC	5.0	5.6	Pass
Cold Plasma	5.9	4.3	Pass

Performance graph



Validation Test Data: Case # 3, Minimum Cold Payload Bedside Storage Testing

MaxPlus MTP Cooler Minimum Cold Payload Bedside Storage Testing
(2 x Cold Red Blood Cells + 2 x Cold Plasma Simulants)
Ambient: Internal facility

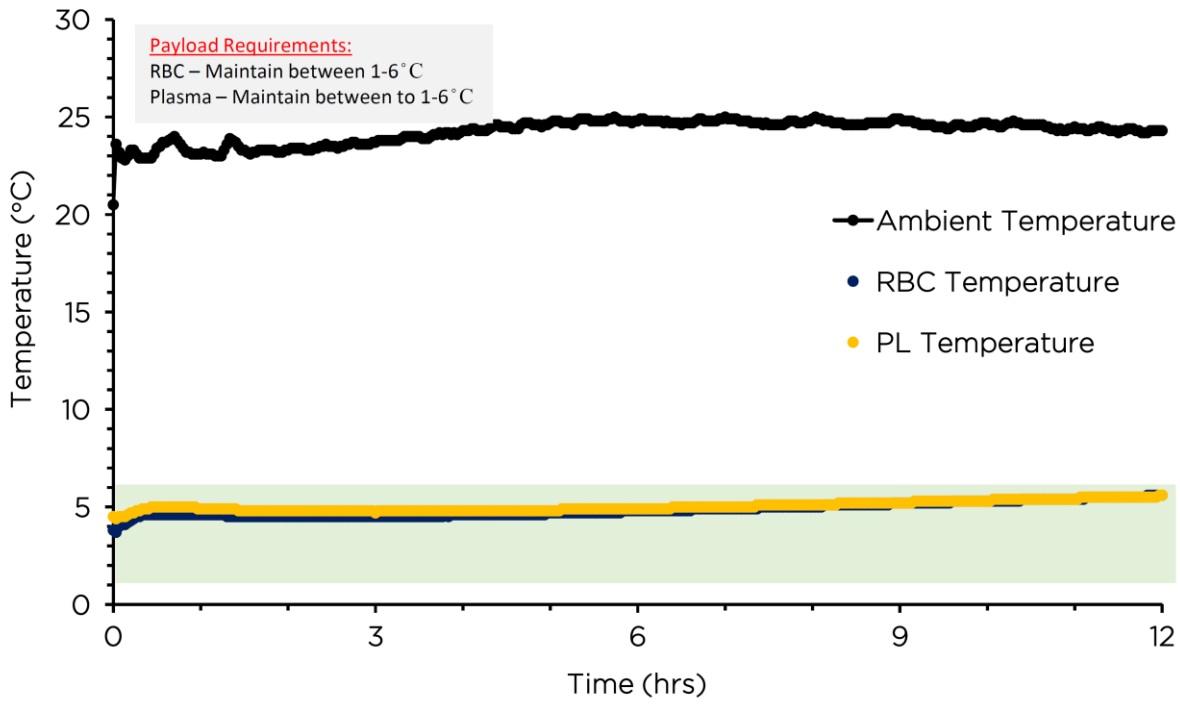
Test setup:

Container	MaxPlus 18.5" container (MTP18)
Gel packs	S6 (2 units), BP0P (3 units), SG22 (1 unit)
Preconditioning	Three BP0P gel packs stored at -20°C for 24 hours and two S6 gel packs stored in the refrigerator (2-6°C)
Test payload	**RBC:** 2 units of 300mL water bags from refrigerator (2 – 6 °C) **Cold plasma**: 2 units of 300mL water bags from refrigerator (2 – 6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger 32* Plasma temperature – MaxQ Logger 31* Ambient temperature – MaxQ Logger 20* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 23°C
Test duration	12 hours

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
pRBC	3.8	5.6	Pass
Cold Plasma	4.5	5.6	Pass

Performance graph



Validation Test Data: Case # 4, Warm Payload Depletion Testing

MaxPlus MTP Cooler Warm Payload Depletion Testing
(6 x Cold Red Blood Cells + 6 x Warm Plasma Simulants)
Ambient: Internal facility

Test setup:

Container	MaxPlus 18.5" container (MTP18)
Gel packs	S6 (2 units), BP0P (3 units), SG22 (1 unit)
Preconditioning	Three BP0P gel packs stored at -20°C for 24 hours and two S6 gel packs stored in the refrigerator (2-6°C)
Test payload	**RBC:** 6 units of 300mL water bags from refrigerator (2 – 6 °C) **Warm plasma**: 6 units of 300mL water bags from incubator (30-35 °C)
Temperature data loggers	RBC temperature – MaxQ Logger 32* Plasma temperature – MaxQ Logger 20* Ambient temperature – MaxQ Logger 19* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 23°C
Test duration	12 hours

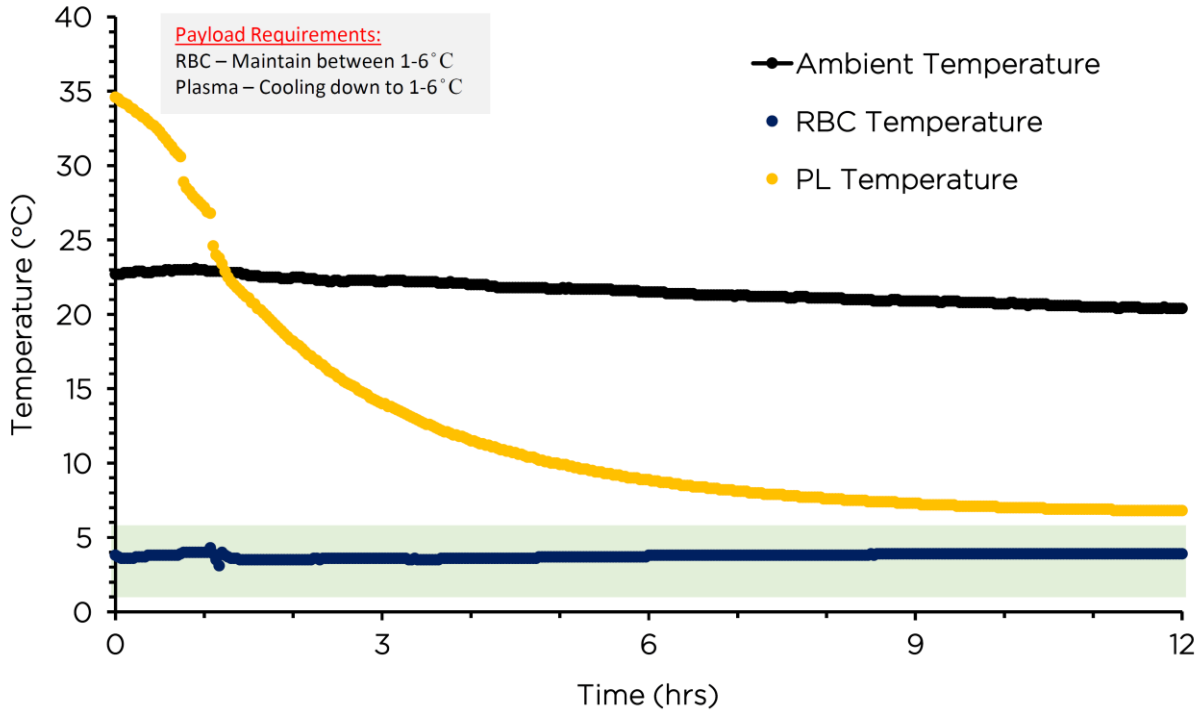
Product depletion test protocol:

- The cooler was packed with maximum payload (6 x 300mL RBC simulant units and 6 x 300mL Plasma simulant units) following instructions provided in Page # 2.
- After every 15 minutes, the cooler was opened and 1 unit of RBC simulant and 1 unit of Plasma simulant were taken out to simulate real world usage of the cooler.
- The process was repeated for a total of 1 hour and 15 minutes (removing 2 units / 15 minutes)
- After 1 hour and 15 minutes only 1 unit of RBC simulant and 1 unit of plasma simulant remained and were left inside the cooler for the next 10 hours and 45 minutes (Total test duration: 12 hours).
- Temperature of the last unit inside the cooler was recorded and presented in the graph below.

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
pRBC	3.8	3.9	Pass
Warm Plasma	34.6	6.8	Pass

Performance graph



Validation Test Data: Case # 5, Cold Payload Depletion Testing

MaxPlus MTP Cooler Cold Payload Depletion Testing
(6 x Cold Red Blood Cells + 6 x Cold Plasma Simulants)
Ambient: Internal facility

Test setup:

Container	MaxPlus 18.5" container (MTP18)
Gel packs	S6 (2 units), BP0P (3 units), SG22 (1 unit)
Preconditioning	Three BP0P gel packs stored at -20°C for 24 hours and two S6 gel packs stored in the refrigerator (2-6°C)
Test payload	**RBC:** 6 units of 300mL water bags from refrigerator (2 – 6 °C) **Cold plasma**: 6 units of 300mL water bags from refrigerator (2 – 6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger 32* Plasma temperature – MaxQ Logger 23* Ambient temperature – MaxQ Logger 20* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 23°C
Test duration	12 hours

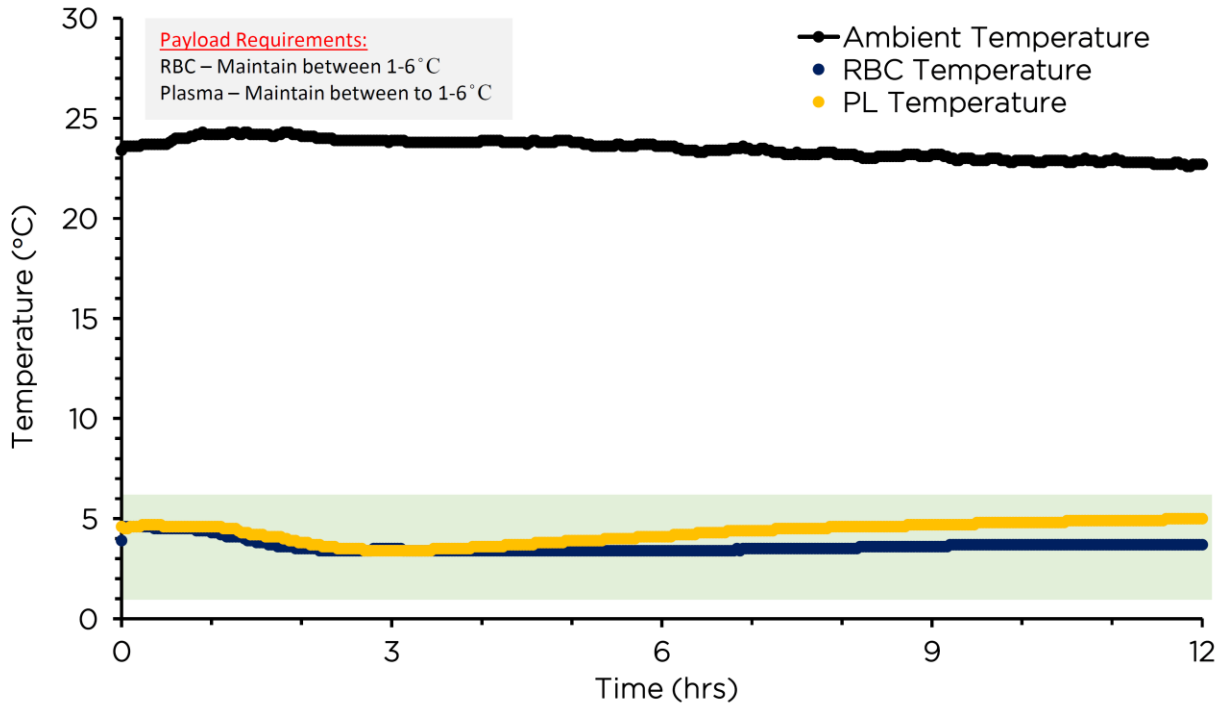
Product depletion test protocol:

- The cooler was packed with maximum payload (6 x 300mL RBC simulant units and 6 x 300mL Plasma simulant units) following instructions provided in Page # 2.
- After every 15 minutes, the cooler was opened and 1 unit of RBC simulant and 1 unit of Plasma simulant were taken out to simulate real world usage of the cooler.
- The process was repeated for a total of 1 hour and 15 minutes (removing 2 units / 15 minutes)
- After 1 hour and 15 minutes only 1 unit of RBC simulant and 1 unit of plasma simulant remained and were left inside the cooler for the next 10 hours and 45 minutes (Total test duration: 12 hours).
- Temperature of the last unit inside the cooler was recorded and presented in the graph below.

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
pRBC	3.9	3.7	Pass
Warm Plasma	4.6	5.0	Pass

Performance graph



Validation Test Data: Case # 6, Platelet Testing

MaxPlus MTP Cooler Platelet Testing
(1 x Platelet unit + 6 x Cold Red Blood Cells + 6 x Cold Plasma Simulants)
Ambient: 18℃ in thermal chamber

Test setup:

Container	MaxPlus 18.5” container with PLT pouch (MTP18)
Test payload	**PLT**: 1 unit of 300mL water bags from incubator (22 °C)
Temperature data loggers	PLT temperature – MaxQ Logger 29* Ambient temperature – MaxQ Logger 20* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	18°C
Test duration	12 hours

Thermal performance results

Payload temperature (°C)			**Result**
	Start Time - 0 hrs.	**End Time - 12 hrs.**	
PLT	22.7	20.0	Pass

Performance graph