Drafted by: Tyler Rapp (Packaging Solutions Architect),
Approved by: Dr. Arif Rahman (Director of Research & Development)

Validation Guide for the MaxPlus Blood Cooler®

Intended for 1 to 6°C bedside storage of refrigerated blood products

Website: https://www.packmaxq.com/blood-coolers
Reference materials: https://www.packmaxq.com/blood-coolers

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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. You may also contact the technical support line – (405)-466-5629 or sales@packmaxq.com – Please list "Validation guidance for MaxPlus Blood Cooler" in the subject line.

System Overview:

The MaxPlus Blood Cooler® is exclusively designed and validated for hospital transfusion services for bedside storage of Red Blood Cells or thawed plasma (1 – 6 °C) for up to 24 hours.

System Components:

- MaxPlus Blood Cooler®
- KB365 gel packs (2 units)
- Payload Insert

MaxPlus Blood Shipper® Specifications:

- Outer dimensions : 11.125" x 11.125" x 11.6875"
- Inner dimensions : 8" x 7.875" x 8.125"
- System Weight: 7.544 lbs. (Excluding payload)
- Payload:
  - Type: Red Blood Cells
  - Capacity: 1 to 3 units of pRBC or chilled plasma
  - Temperature for RBC or chilled plasma: 1 – 6 °C
  - Validated storage duration: up to 24 hours

Durability qualification:

Polypropylene plastic used for the new MaxPlus Blood 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.

Validation test cases:

The MaxPlus Blood Cooler is validated for 2 different operational test cases. The test cases are listed below:

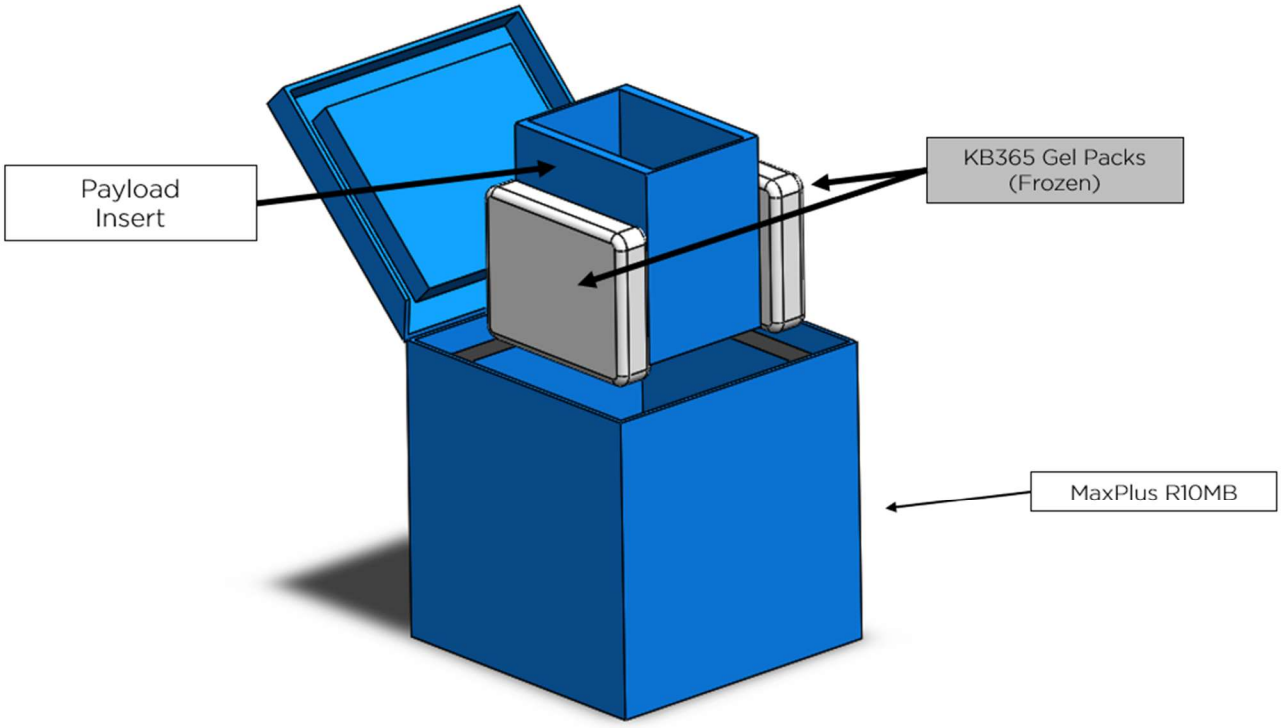
1. Validation test case # 1 – Maximum payload bedside storage testing

This test validates the MaxPlus Blood Cooler for storing the maximum number of cold RBC units (3 units) or cold PL units (3 units) between 1 to 6°C. This test case simulates operational scenario where the cooler is issued with maximum number of units and can maintain required temperature for up to 24 hours.

2. Validation test case # 2 – Minimum payload bedside storage testing

This test validates the MaxPlus Blood Cooler for storing the minimum number of cold RBC units (1 unit) or cold PL units (1 unit) between 1 to 6°C. This test case simulates operational scenario where the cooler is issued with minimum number of units and can maintain required temperature for up to 24 hours.

Packaging assembly illustration:



Pack-out instructions (Test case 1 and 2):

Pack-out Procedure:

Step 1: Place two KB365 gel packs against two opposite walls of the container (refer to packaging assembly on page 4).

Step 2: Place the payload insert.

Step 3: Place payload (blood products) inside the container.

Disclaimer: The MaxPlus Blood Shipper packed with two KB365 gel packs has been qualified for up to 24 hours (1 to 6°C) for internal bedside storage (ambient between 18 to 24°C) in the described laboratory tests. The ambient temperature and weather profile for a

specific location may vary. MaxQ cannot guarantee that the payload can maintain 1 to 6°C without any excursions if the temperature exposure of the packed system is not within the tested temperature range.

Gel pack preparation

- Two KB365 gel packs should be pre-conditioned inside a freezer (< -20°C) for a minimum of 12 hours.

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.

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.

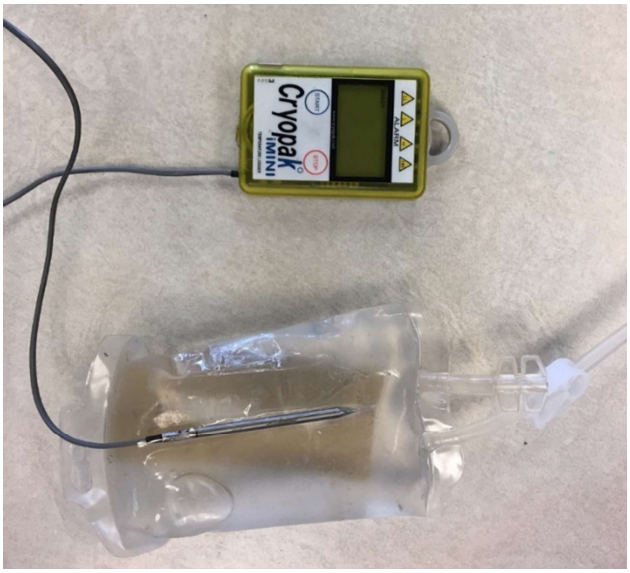


Figure 1

- Place another unit on top of the first unit in 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).

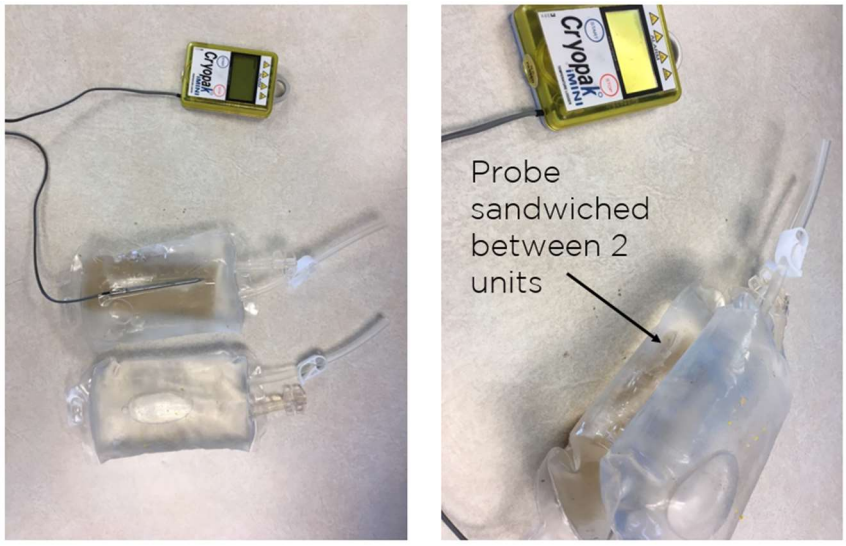


Figure 2

Pre-condition the data logger with the payload unit attached:

- For cold products: the refrigerator should be between 1 to 6°C for at least 2 hours to eliminate any chance of a temperature spike.

Pack-out variations

None listed.

Other use considerations

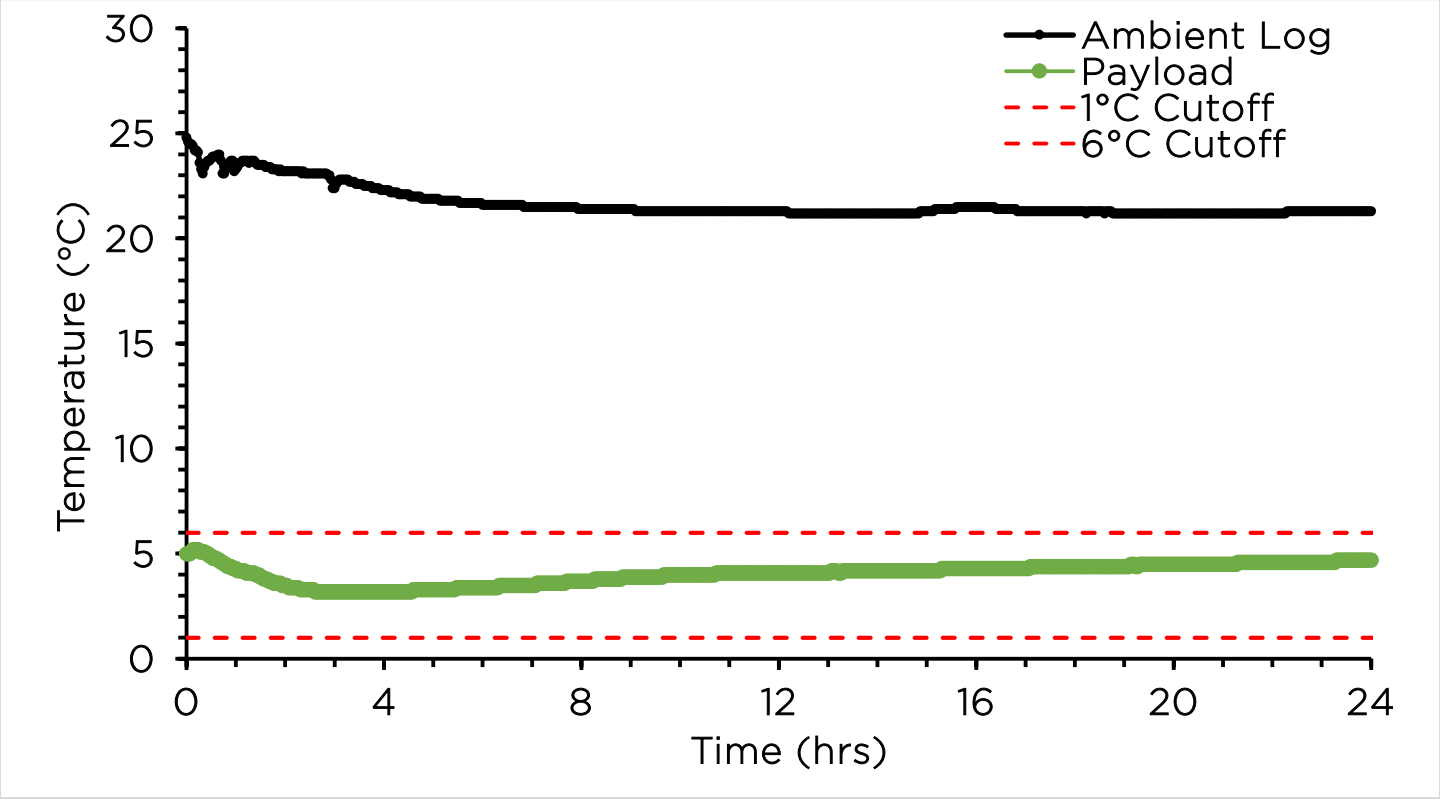
None listed.

Validation Case # 1: Maximum Payload Bedside (1 to 6°C)

Test setup:

Container	MaxPlus Blood Cooler (R10MB)
Gel packs	KB365 (2 units)
Preconditioning	Two KB365 gel packs stored at -20°C for 24 hours
Test payload	Maximum: 3 units of 300mL water bags
Temperature data loggers	Payload Temperature – MaxQ Logger 13* Ambient temperature – MaxQ Logger 16*
Ambient temperature	18 to 28°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 3 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 24 hours.

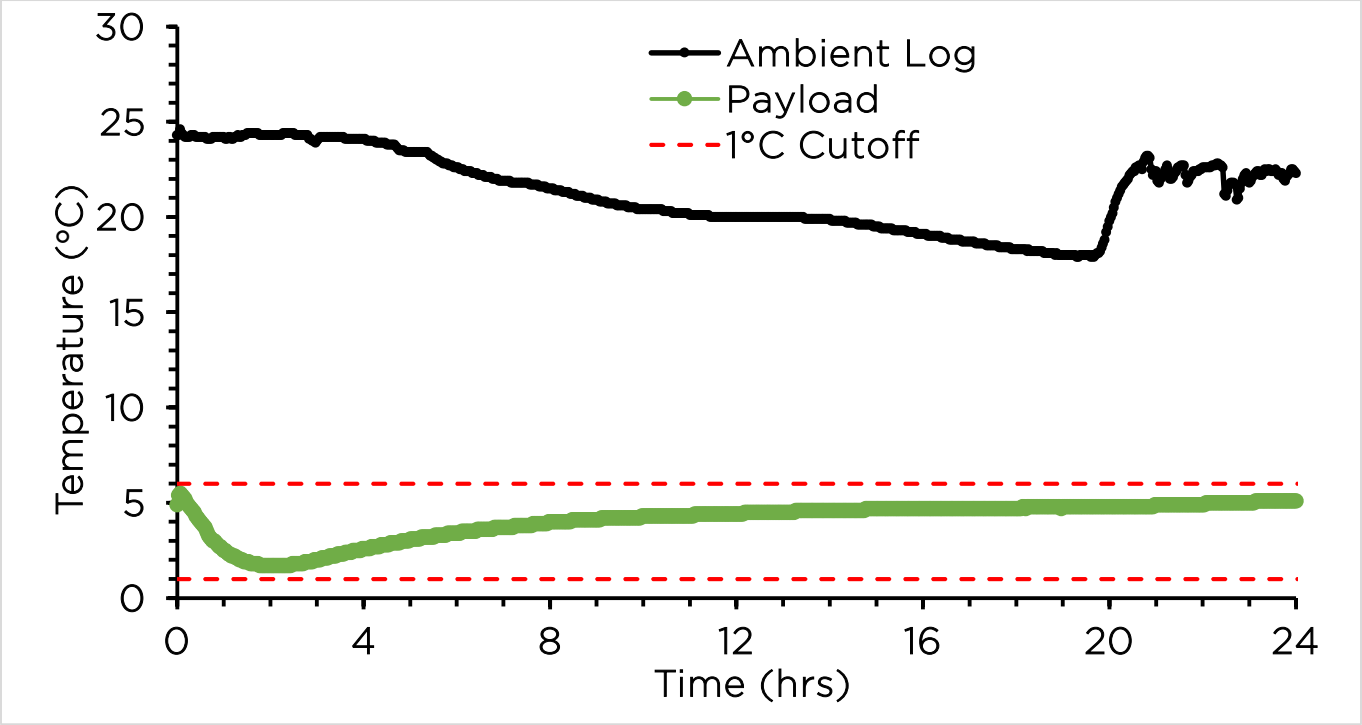
Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	5°C	4.7°C

Validation Case # 2: Minimum Payload Testing (1 to 6°C)

Test setup:

Container	MaxPlus Blood Cooler (R10M)
Gel packs	KB365 (2 units)
Preconditioning	Two KB365 stored at (-20ºC) for 24 hours
Test payload	Minimum: 1 x 300mL water bag
Temperature data loggers	Payload temperature – MaxQ Logger 9 Ext* Ambient temperature – MaxQ Logger 9 Int*
Ambient temperature	18 to 25°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (minimum payload: 1 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 24 hours.

Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	4.9°C	5.1°C