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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).



System Components:

- MaxPlus Blood Cooler®
- S6 gel pack (2 units)
- BPOP Bottles (3 units)

MaxPlus Blood Shipper® Specifications:

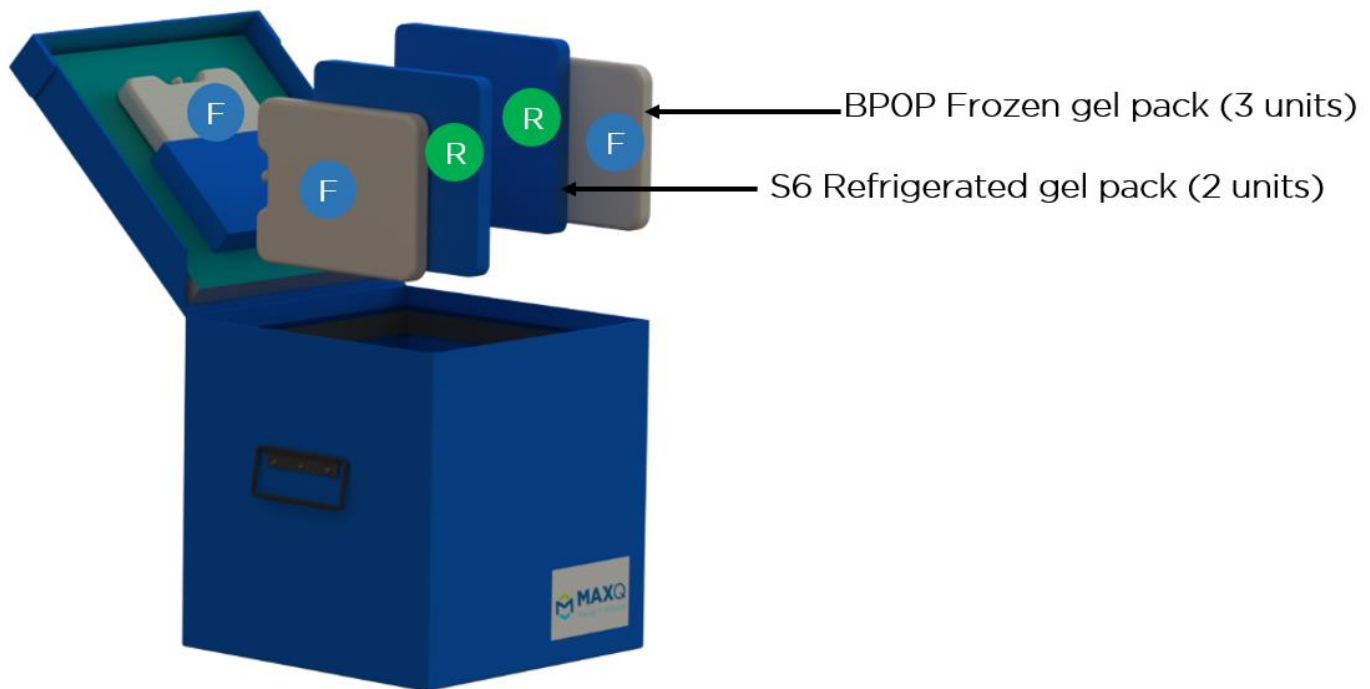
- **Outer dimensions:** 13.25" x 13.25" x 13.25"
- **Inner dimensions:** 10" x 10" x 10"
- **System Weight:** 13.3 lbs. (Excluding payload)
- **Payload:**
 - Type: Red Blood Cells
 - Capacity: 2 to 10 units of RBC
 - Temperature for RBC: 1 – 6 °C
 - Validated storage duration: up to 24 hours

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 hinges¹. 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:



Gel pack arrangement

-  3 x Frozen - 2 against Left and Right wall and 1 on the lid
-  2 x Refrigerated - 2 against Left and Right frozen gel packs

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 maximum number of **cold RBC units (10 units) or cold PL units (10 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 a minimum of 24 hours.

2. Validation test case # 2 – Payload depletion testing

This test case simulates operational scenario where the cooler is issued with maximum number of cold plasma **(10 units) or** maximum number of cold RBC **(10 units)**. Subsequently, 2 units of payload were removed from the cooler every 1 hour until only 2 units of payload are left in the cooler. This simulates operational scenario where the patient is being infused with the blood products periodically. The cooler is tested to maintain required temperature (1-6°C) for a total of 24 hours.

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

Pack-out Procedure:

Step 1: Place two units of frozen BPOP gel packs against the container walls.

Step 2: Place two refrigerated S6 gel packs against the frozen BPOP gel packs.

Step 3: Insert the last frozen BPOP gel pack into the pouch attached to the lid.

Step 4: Place payload (blood products) inside the container.

Step 5: Close the container lid making sure that the lid is sealed properly.

Disclaimer: The MaxPlus R12X24 Cooler packed with three frozen BPOP gel packs and two refrigerated S6 gel packs has been qualified for **20+ hours (1 to 6°C) for internal facility usage** (ambient between 20 to 28°C) in the described laboratory tests. The ambient temperature 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

- Three BPOP 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 BPOP 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.

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.

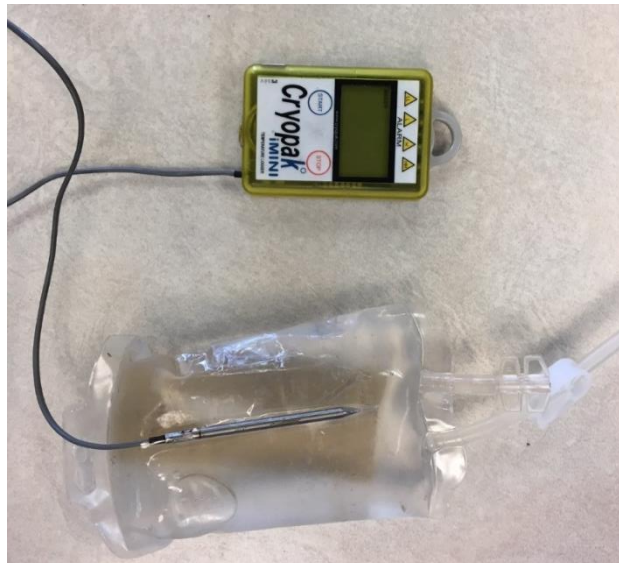


Figure 1

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

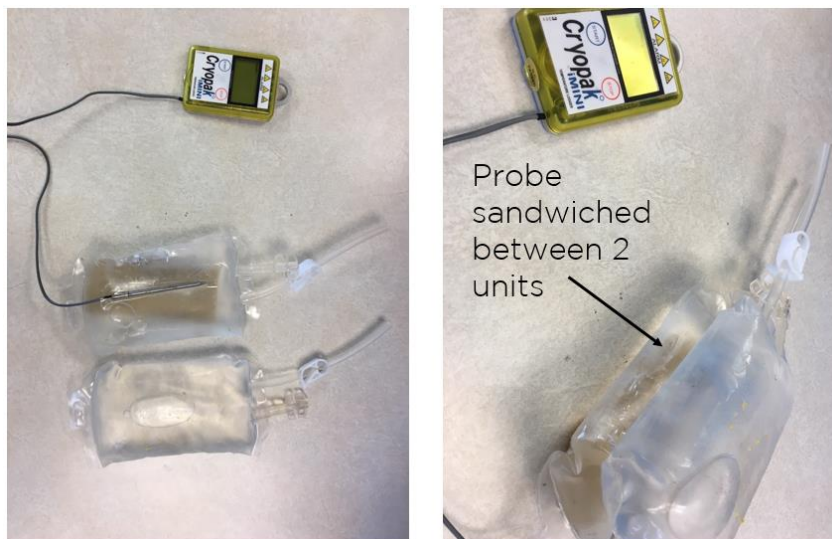


Figure 2

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

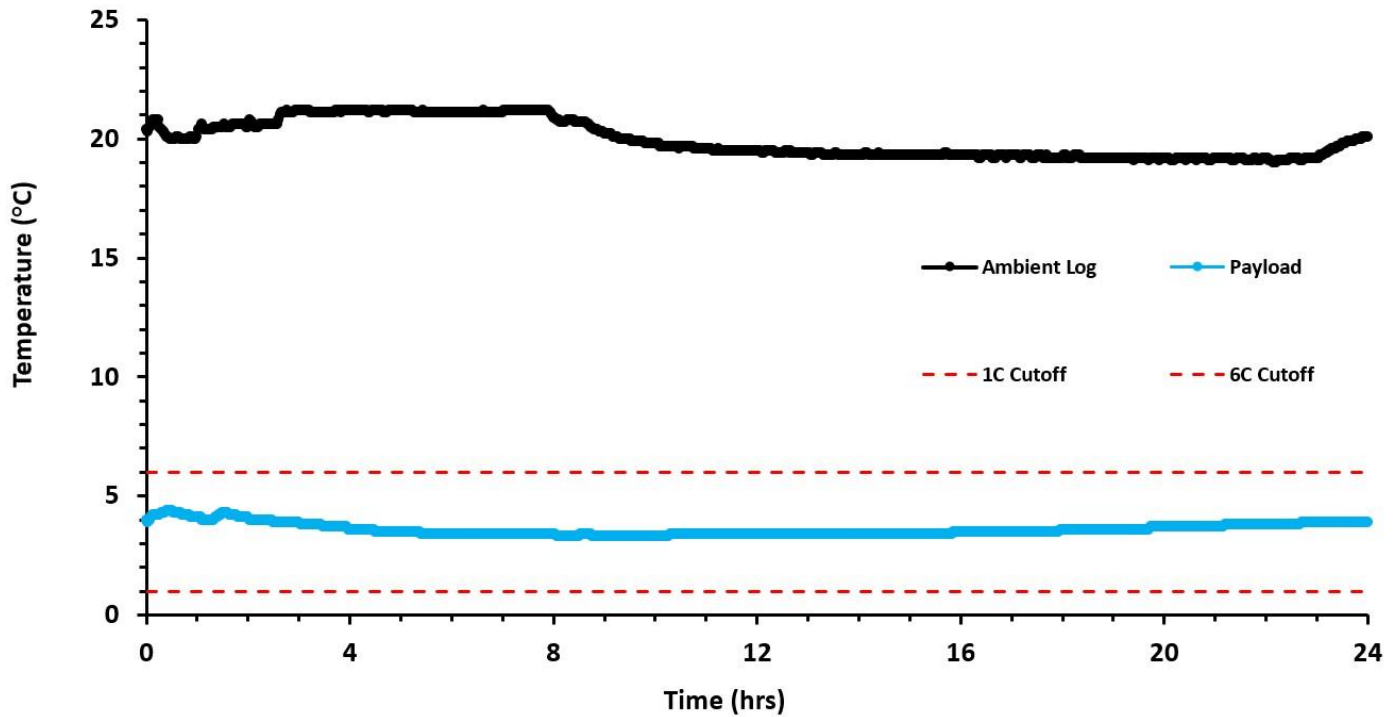
Validation of MaxPlus R12X24 cooler for any other payload configuration other than the recommended one will result in shorter validation duration. MaxPlus R12X24 cooler can be validated for **12-16 hours** when issued with a minimum of 2 units of payload. Please contact MaxQ Research at sales@packmaxq.com if your validation test criteria are different than what is listed in this validation guide.

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

Test setup:

Container	MaxPlus Blood Cooler (R12X24)
Gel packs	S6 (2 units), BPOP (3 units)
Preconditioning	Three BPOP white gel packs stored at -20°C for 12 hours and two S6 blue gel packs stored in the refrigerator (1-6°C) for 12 hours
Test payload	<u>Maximum:</u> 10 units of 300mL water bags
Temperature data loggers	Payload Temperature – MaxQ Logger 24* Ambient temperature – MaxQ Logger 18*
Ambient temperature	18 to 24°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 10 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)	3.6°C	5.3°C

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

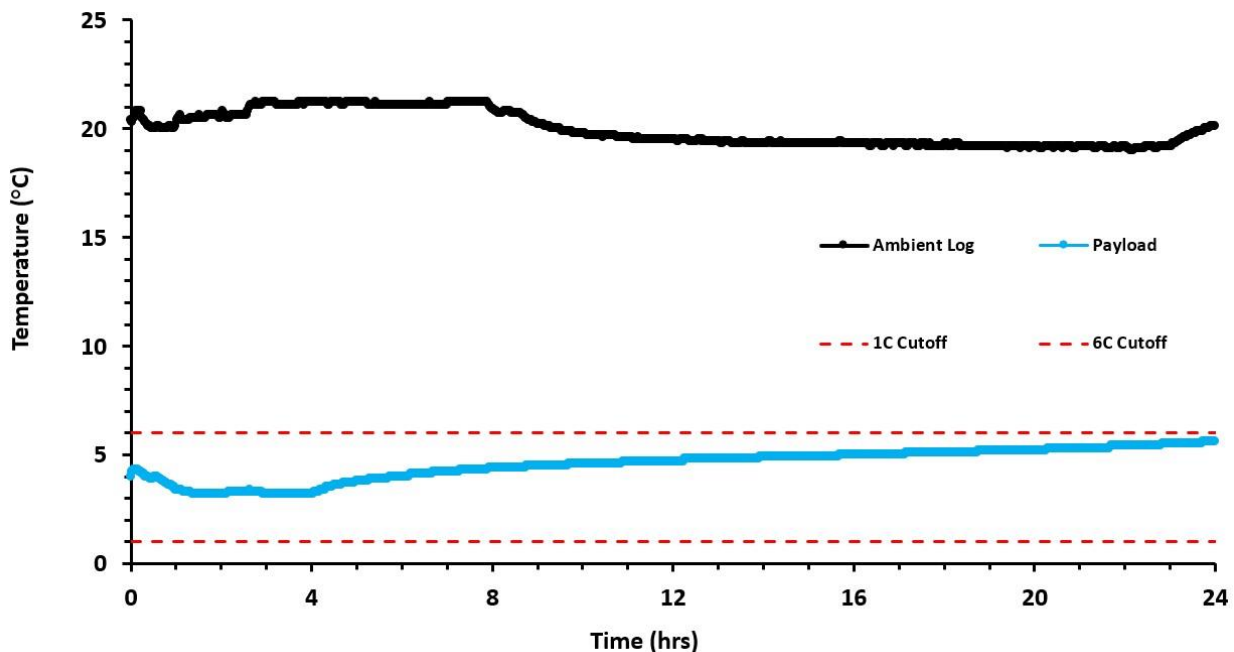
Test setup:

Container	MaxPlus Blood Cooler (R12X24)
Gel packs	S6 (2 units), BPOP (3 units)
Preconditioning	Three BPOP white gel packs stored at (-20°C) for 12 hours and two S6 blue gel packs stored in the refrigerator (2-6°C) for 12 hours
Test payload	<u>Minimum*</u> : 2 units of 300mL water bags (See below)
Temperature data loggers	Payload temperature – MaxQ Logger 9* Ambient temperature – MaxQ Logger 18*
Ambient temperature	18 to 24°C
Test duration	24 hours

Product depletion test protocol:

- The cooler was packed with maximum payload (10 x 300mL simulant units filled with water) following instructions provided.
- At the end of every hour, the cooler was opened and 2 units were taken out.
- The process was repeated for a total of 4 hours (removing 2 units / hour)
- At the end of 4 hours, two units were removed and the last 2 units were left inside the cooler for the next 20 hours (Total test duration: 24 hours).
- Temperature of the units inside the cooler was recorded and presented in the graph below.

Thermal performance



Analysis: Temperature of simulated products (minimum payload: 2 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 24 hours.

Test duration	Time = 0 hours	<u>Time = 24 hours</u>
Simulated product Temperature (°C)	3.9	5.5