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Validation Guide for the MaxPlus Blood Cooler®

Intended for 20 to 24°C bedside storage of room temperature 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 Platelets (20 - 24 °C) for up to 24 hours.

System Components:

- MaxPlus Blood Cooler®
- S10 Coolant Bottle (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**: 7.5 lbs. (Excluding payload)
- **Payload:**
 - Type: Platelets
 - Capacity: 1 to 3 units of PLTs
 - Temperature for PLTs: 20 - 24 °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.

Validation test cases:

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

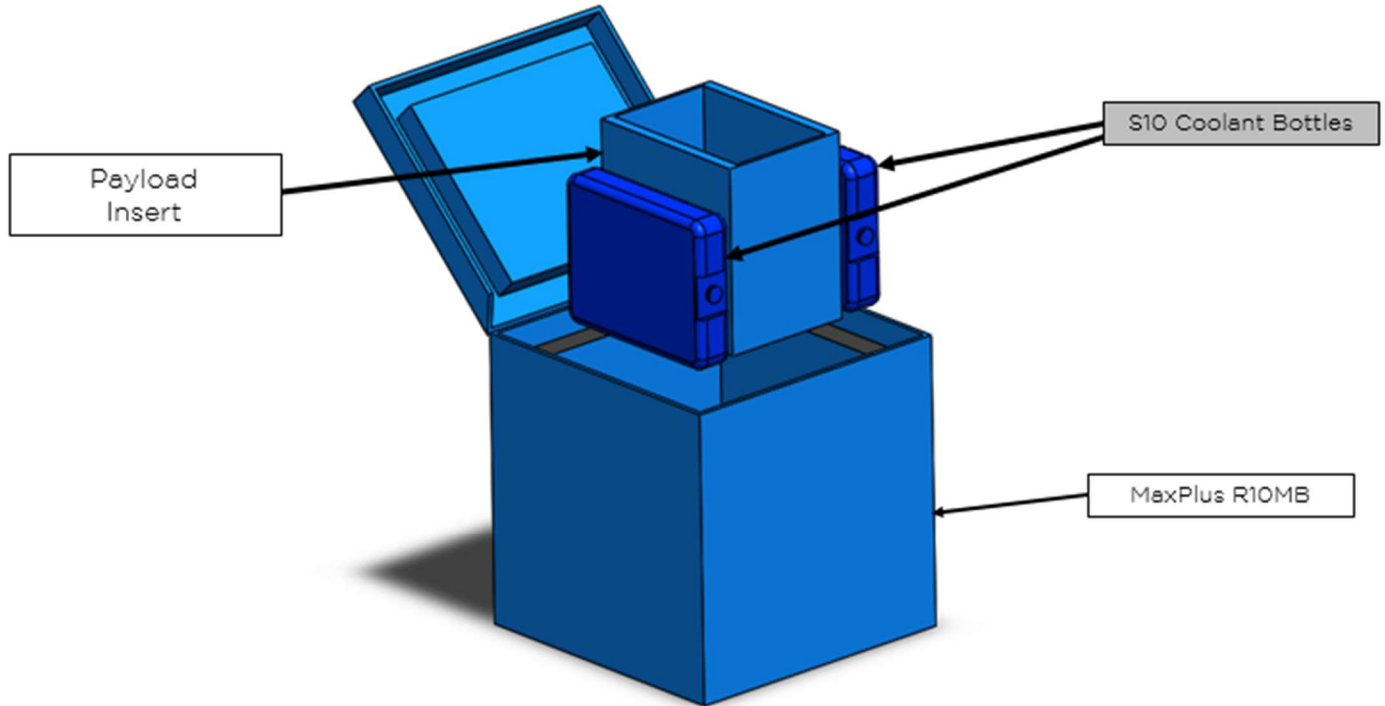
1. Validation test case # 1 – Maximum payload bedside storage testing

This test validates the MaxPlus Blood Cooler for storing the maximum number of **room temperature PLT units (3 units)** between 20 to 24°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 **room temperature units (1 unit)** between 20 to 24°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 (x2) S10 coolant bottles 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 S10 coolant bottles has been qualified for up to 24 hours (20 to 24°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 20 to 24°C without any excursions if the temperature exposure of the packed system is not within the tested temperature range.

Gel pack preparation

- (x2) S10 coolant bottles should be preconditioned in an incubator or controlled room temperature at $(23^{\circ}\text{C} \pm 1^{\circ}\text{C})$ for a minimum of 24 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.
 - Room temperature PLT simulant units shall be stored in an incubator or controlled room temperature at $(23^{\circ}\text{C} \pm 1^{\circ}\text{C})$ for a minimum of 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 air gap between the units and they stay together (Figure 2).

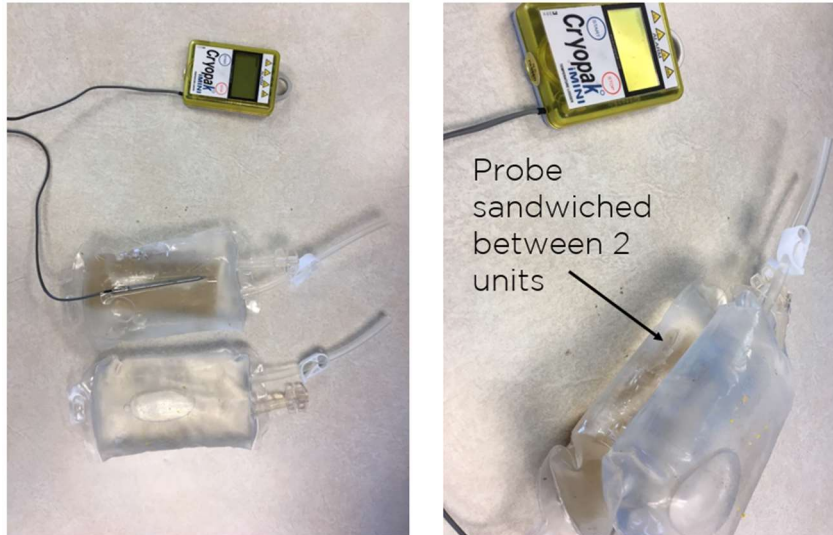


Figure 2

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

Pack-out variations

None listed.

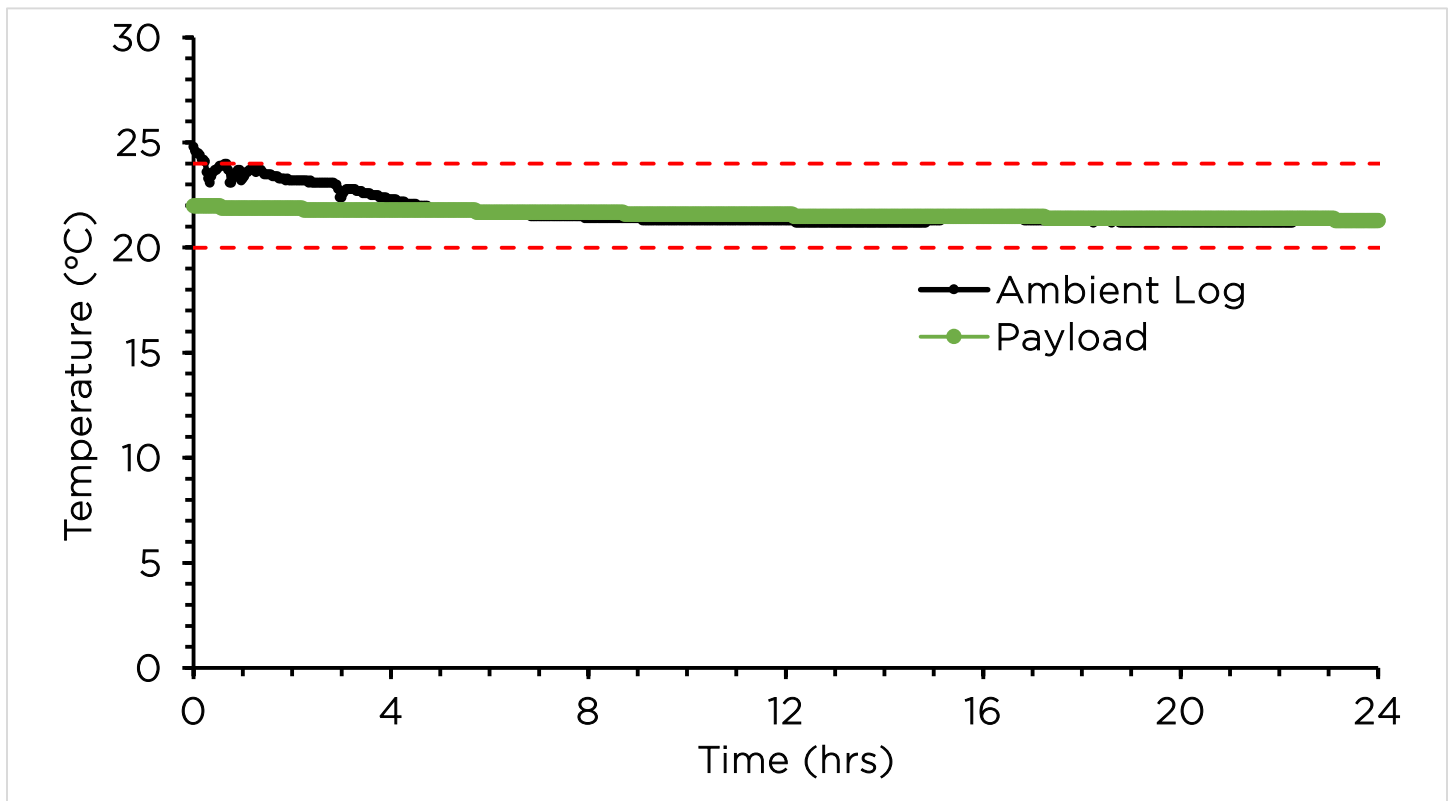
Other use considerations

None listed.

Validation Case # 1: Maximum Payload Bedside (20 to 24°C)

Test setup:

Container	MaxPlus Blood Cooler (RT10MB)
Gel packs	S10 coolant bottle (2 units)
Preconditioning	(x2) S10 coolant bottles stored at CRT (23°C ± 1°C) for 24 hours
Test payload	Maximum: 3 units of 300mL water bags
Temperature data loggers	Payload Temperature - MaxQ Logger 24* Ambient temperature - MaxQ Logger 37*
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 20-24°C temperature range for a total of 24 hours.

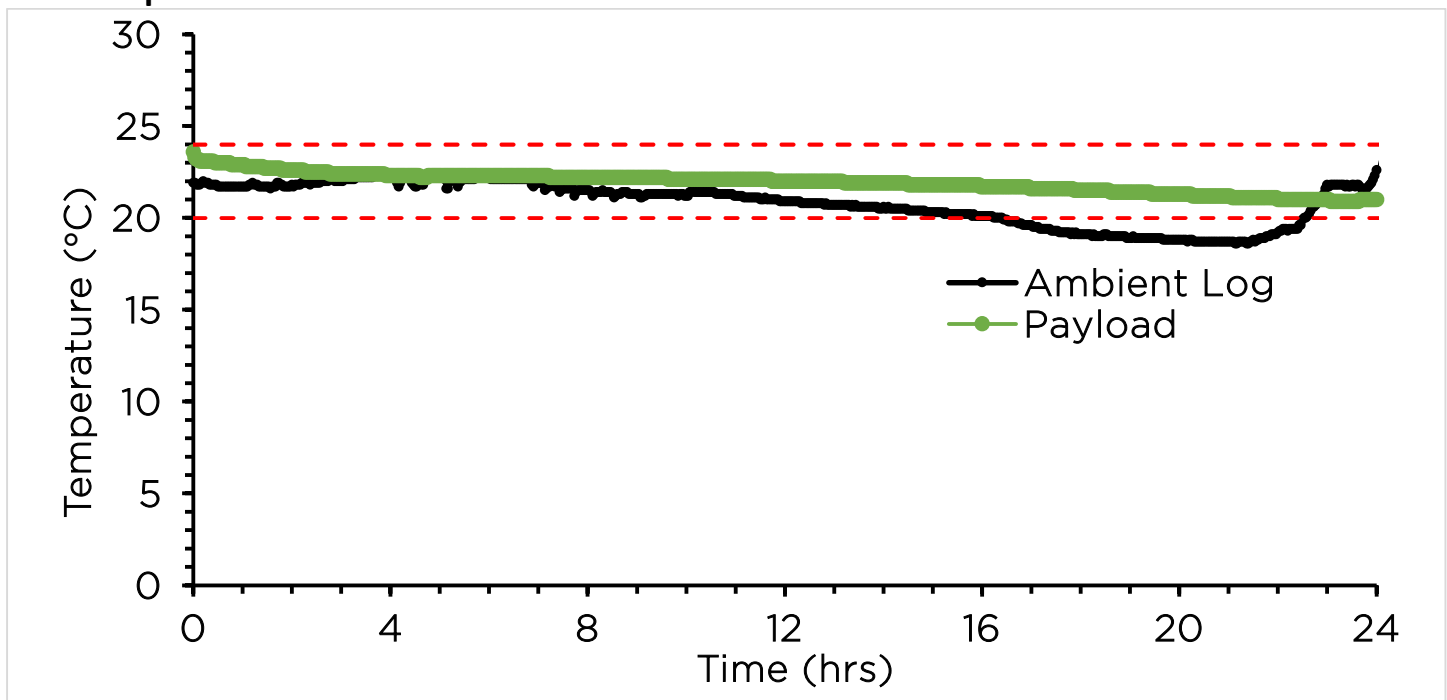
Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	22°C	21.3°C

Validation Case # 2: Minimum Payload Testing (20 to 24°C)

Test setup:

Container	MaxPlus Blood Cooler (RT10MB)
Gel packs	S10 coolant bottle (2 units)
Preconditioning	(x2) S10 coolant bottles stored at CRT (23°C ± 1°C) for 24 hours
Test payload	Minimum: 3 units of 300mL water bags
Temperature data loggers	Payload Temperature - MaxQ Logger 24* Ambient temperature - MaxQ Logger 37*
Ambient temperature	18 to 28°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (minimum payload: 1 units) inside the cooler stayed within the required 20-24°C temperature range for a total of 24 hours.

Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	23.6°C	21°C