

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

Validation Guide for the MaxPlus EMT Cooler®

Exclusive system designed for emergency field transfusions of refrigerated blood products in fixed / rotary wing air ambulances and/or ground transport vehicles.



Website: <https://www.packmaxq.com/blood-coolers>

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

Table of Contents

System Overview:	3
System Components:	3
MaxPlus EMT Shipper® Specifications:	3
Durability qualification:	4
Packaging assembly illustration:	4
Validation test cases:	4
1. Validation test case # 1 – Room temperature storage followed by extreme Summer ambient	5
2. Validation test case # 2 – Room temperature storage followed by extreme Winter ambient	5
3. Validation test case # 3 – Immediate Summer ambient	5
4. Validation test case # 4 – Immediate Winter Ambient	5
Pack-out instructions (All Test Cases):	5
Gel pack preparation	5
Payload preparation	6
Data Logger preparation	6
Pre-condition the data logger with the payload unit attached:	7
Pack-out variations	7
Other use considerations	7
Validation Case # 1: Room temperature storage followed by extreme Summer ambient	8
Validation Case # 2: Room temperature storage followed by extreme Winter ambient	9
Validation Case # 3: Immediate Summer Ambient	10
Validation Case # 4: Immediate Winter ambient	11
Revision History:	12

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 EMT Cooler is exclusively designed and validated for transporting and storing refrigerated blood products for emergency pre-hospital transfusions. The cooler maintains a transport or storage temperature between 1 – 6 °C for 24+ hours.



System Components:

- MaxPlus EMT Cooler®
- Front buckle for secured handling
- PCM5 coolant cassettes (blue plastic cassette, 2 units)
- PCMO coolant brick (White foam brick, 1 unit)

MaxPlus EMT Shipper® Specifications:

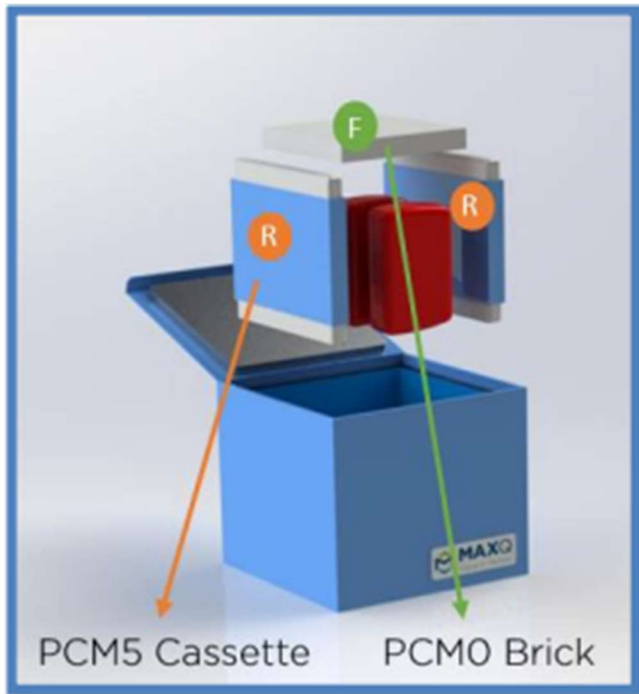
- Outer dimensions : 10.875" x 10.5" x 9.5"
- Inner dimensions : 8" x 7.625" x 8"
- System Weight: 7.5 lbs. (Excluding payload)
- Payload:
 - Type: Refrigerated blood products (Red Blood Cells, Chilled Plasma, Whole Blood Units)
 - Capacity: 1 to 4 units of pRBC, chilled plasma, or whole blood
 - Temperature for RBC or chilled plasma: 1 – 6 °C
 - Validated storage duration: up to 21 hours at controlled room temperature followed by 3 hours of continuous transport at extreme ambient conditions or 3 hours of immediate transport in extreme ambient conditions.

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:

1 x Frozen PCM0 brick – on top of PCM5 cassettes

2 x Refrigerated PCM5 cassettes – against left and right walls

Validation test cases:

The MaxPlus EMT Cooler was validated to hold 1 to 6°C with four 300-350mL mock blood units inside the container using a temperature data logger with an external metal probe taped to the surface of a mock blood unit. The cooler was validated under two different operational scenarios:

- (1) 3-hour STAT transport using a helicopter immediately after the shipper was packed
- (2) 21 hours of internal storage (in a temperature controlled aircraft hangar, blood bank or flight location) followed by 3 hours of emergency medical transport in fixed / rotary wing air ambulance and/or ground vehicle.

To simulate extreme temperatures during emergency medical transport, the cooler was

exposed to a summer high temperature of 60°C and a winter low temperature of -10°C for the entire simulated transit duration of 3 hours.

1. Validation test case # 1 – Room temperature storage followed by extreme Summer ambient
2. Validation test case # 2 – Room temperature storage followed by extreme Winter ambient
3. Validation test case # 3 – Immediate Summer ambient
4. Validation test case # 4 – Immediate Winter Ambient

Pack-out instructions (All Test Cases):

Pack-out Procedure:

Step 1: Place refrigerated PCM5 cassettes against left and right walls of the container. (refer to packaging assembly on page 4).

Step 2: Place payload units into the cooler between the PCM5 cassettes.

Step 3: Place frozen PCM0 brick on top of the PCM5 cassettes as shown in the packaging assembly.

Step 4: Close the cooler lid, ensuring the buckle is fastened and the lid is sealed properly.

Disclaimer: The MaxPlus EMT Cooler (EMT10V24) packed with two PCM5 cassettes and one PCM0 brick has been qualified for up to 24 hours to hold whole blood units (or combination of pRBC's and Liquid Plasma) between 1 to 6°C for 21 hours of internal storage followed by 3 hours of emergency medical transport or 3 hours of immediate issue in fixed / rotary wing air ambulances and/or ground vehicles (extreme temperatures) 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 ambient temperature exposure of the packed system is not within the tested temperature range.

Gel pack preparation

- One PCM0 brick (1.8 lbs.) should be pre-conditioned inside a freezer (below -18°C) for a minimum of 24 hours. The PCM0 bricks should be placed lying flat inside the freezer to avoid non-uniform freezing of the coolant.
- Two PCM5 cassettes (1.1 lbs. each) should be pre-conditioned inside a refrigerator (1-6°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.
 - 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.

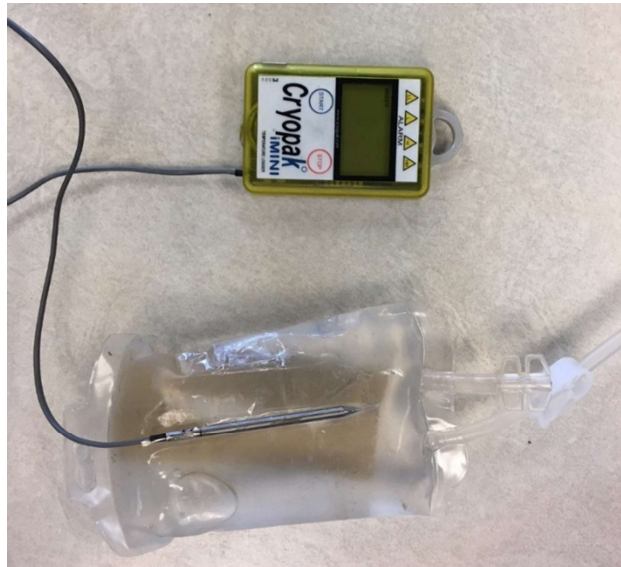


Figure 1

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).

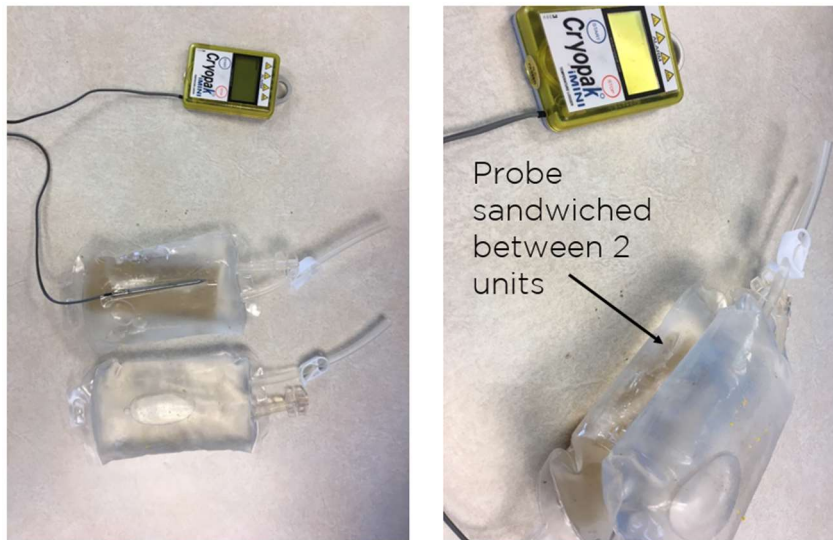


Figure 2

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

- o 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

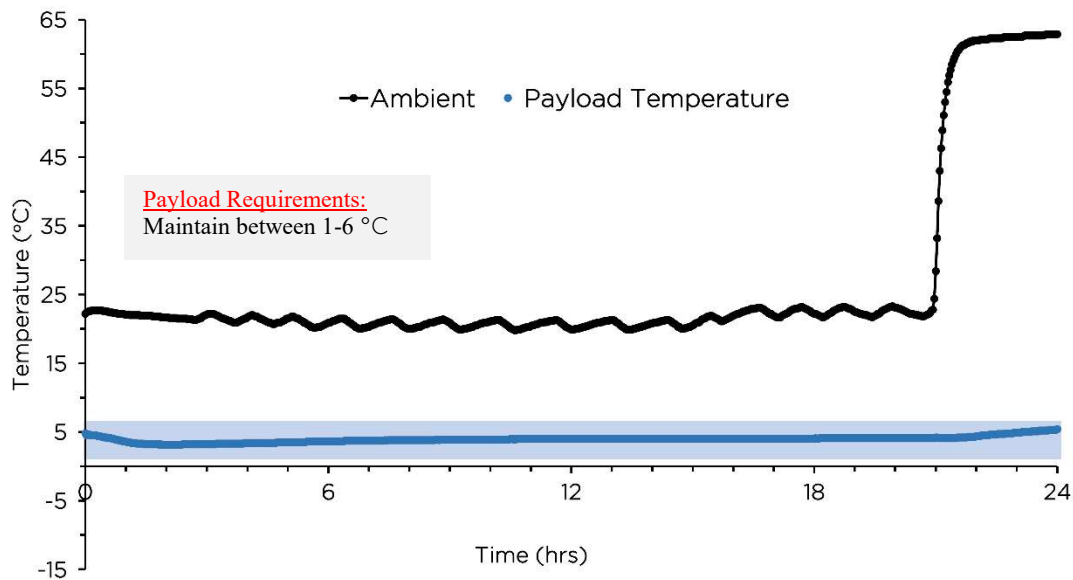
Validation of the MaxPlus EMT cooler for any other payload configuration other than the recommended one will result in shorter validation duration. Please contact MaxQ Research at sales@packmaxq.com if your validation test criteria is different than what is listed in this validation guide.

Validation Case # 1: Room temperature storage followed by extreme Summer ambient

Test setup:

Container	EMT10V24
Gel packs	PCM5 Cassette (2 units) PCM0 brick (1 unit)
Preconditioning	Two PCM5 cassettes stored in the refrigerator at 1-6°C for 24 hours and one PCM0 brick stored in the freezer (< -18°C) for 24 hours
Test payload	Four 300-350mL mock blood units from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature - MaxQ Logger 19* Ambient temperature - MaxQ Logger 16*
Ambient temperature	21 hours of 22°C → 3 hours of 60°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 4 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 24 hours.

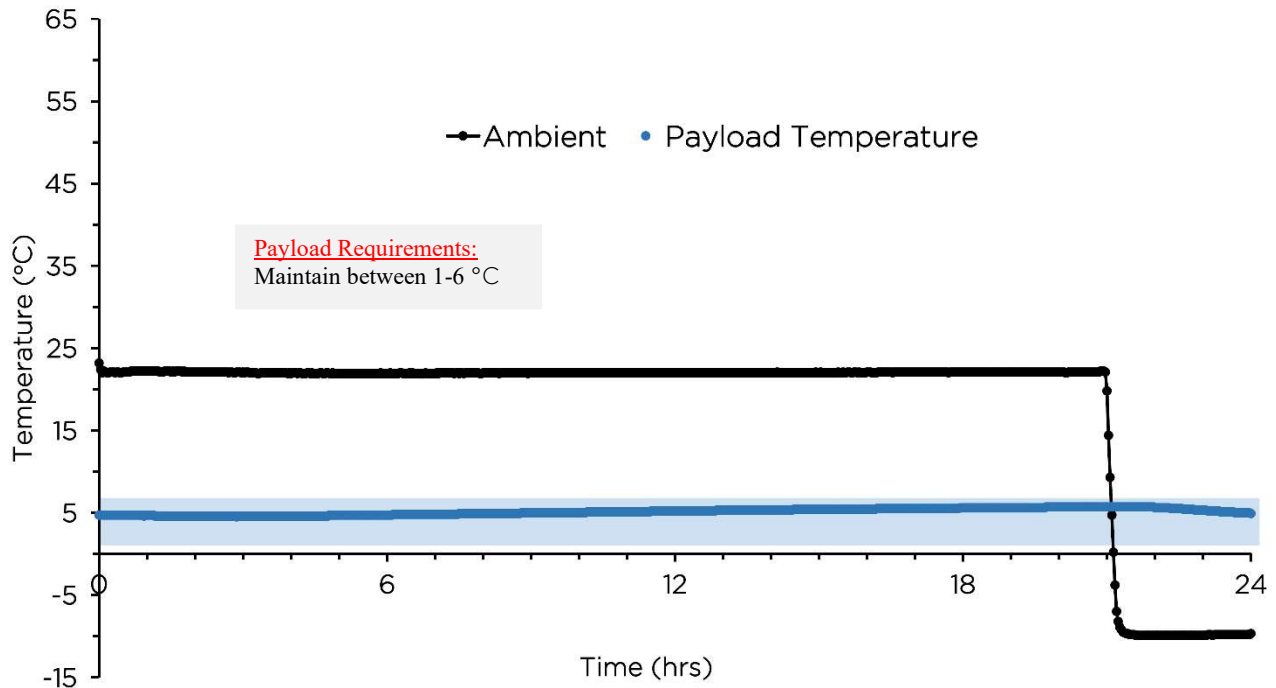
Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	5.0	5.6

Validation Case # 2: Room temperature storage followed by extreme Winter ambient

Test setup:

Container	EMT10V24
Gel packs	PCM5 Cassette (2 units) PCM0 brick (1 unit)
Preconditioning	Two PCM5 cassettes stored in the refrigerator at 1-6°C for 24 hours and one PCM0 brick stored in the freezer (< -18°C) for 24 hours
Test payload	Four 300-350mL mock blood units from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature - MaxQ Logger 10* Ambient temperature - MaxQ Logger 4*
Ambient temperature	21 hours of 22°C → 3 hours of -10°C
Test duration	24 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 4 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 24 hours.

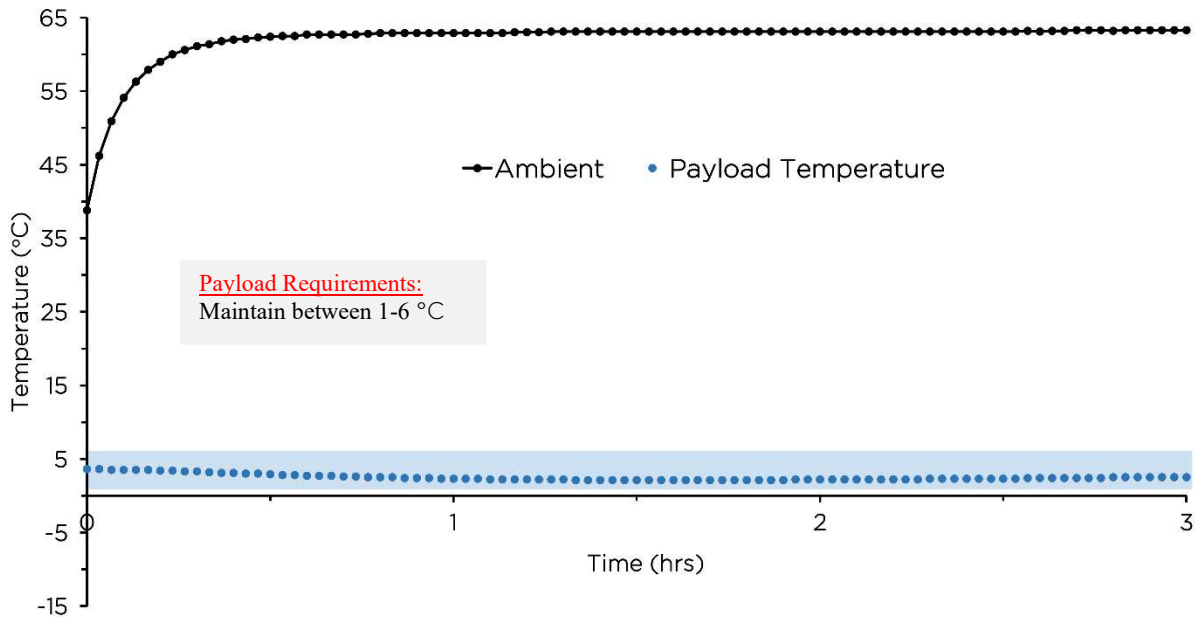
Test duration	Time = 0 hours	Time = 24 hours
Simulated product Temperature (°C)	4.8	3.9

Validation Case # 3: Immediate Summer Ambient

Test setup:

Container	EMT10V24
Gel packs	PCM5 Cassette (2 units) PCM0 brick (1 unit)
Preconditioning	Two PCM5 cassettes stored in the refrigerator at 1-6°C for 24 hours and one PCM0 brick stored in the freezer (< -18°C) for 24 hours
Test payload	Four 300-350mL mock blood units from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature - MaxQ Logger 19* Ambient temperature - MaxQ Logger 16*
Ambient temperature	60°C
Test duration	3 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 4 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 3 hours.

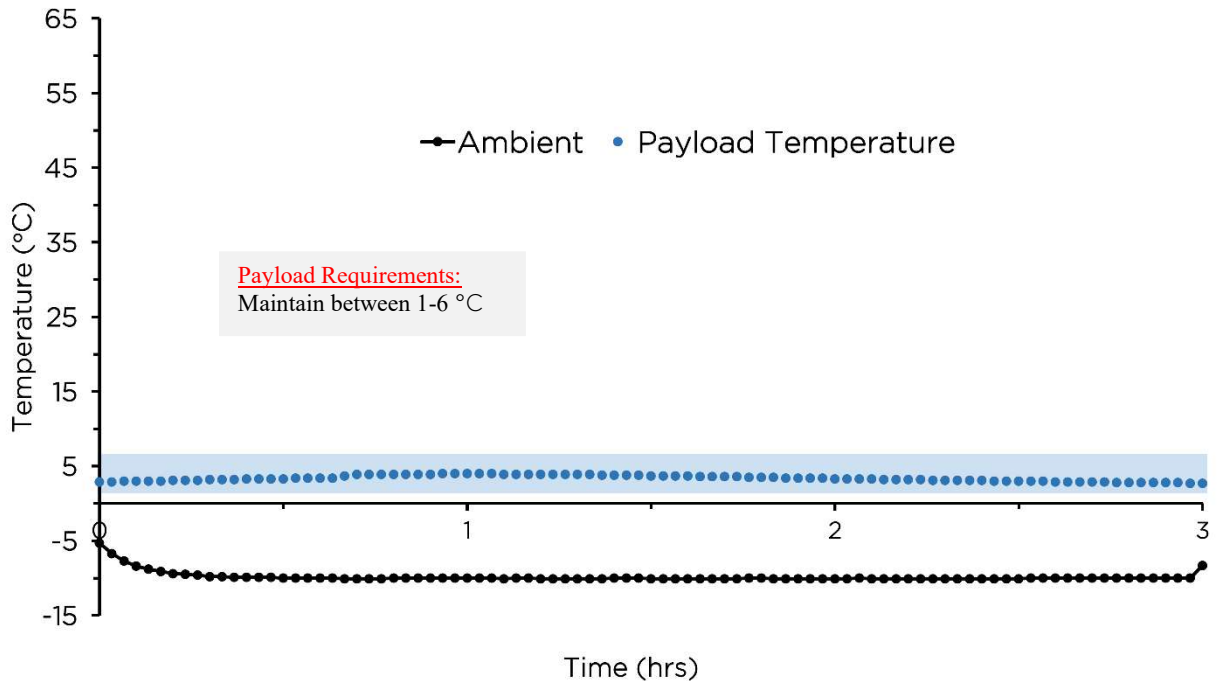
Test duration	Time = 0 hours	Time = 3 hours
Simulated product Temperature (°C)	4.7	2.2

Validation Case # 4: Immediate Winter ambient

Test setup:

Container	EMT10V24
Gel packs	PCM5 Cassette (2 units) PCM0 brick (1 unit)
Preconditioning	Two PCM5 cassettes stored in the refrigerator at 1-6°C for 24 hours and one PCM0 brick stored in the freezer (< -18°C) for 24 hours
Test payload	Four 300-350mL mock blood units from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature - MaxQ Logger * Ambient temperature - MaxQ Logger *
Ambient temperature	-10°C
Test duration	3 hours

Thermal performance



Analysis: Temperature of simulated products (maximum payload: 4 units) inside the cooler stayed within the required 1-6°C temperature range for a total of 3 hours.

Test duration	Time = 0 hours	Time = 3 hours
Simulated product Temperature (°C)	3.3	2.3