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Validation Guide for the MaxPlus Transfusion Cooler™

SKU # MTC13

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



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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 Transfusion Cooler” in the subject line.

1. System Overview:

The MaxPlus Transfusion Cooler™ is exclusively designed and validated for hospital transfusion services for bedside storage of Red Blood Cells or Thawed Plasma (1 – 6 °C).



2. System Components:

- MaxPlus Transfusion Cooler™
- Gel Packs

Name: S6 (3x units)

Color: Blue

Size: 8.75" x 7" x 0.75"



Name: BP0P (2x units)

Color: White

Size: 8.5" x 7.5" x 0.875"



3. MaxPlus Transfusion Cooler™ Specifications:

Outer dimensions: 13.75" x 12.75" x 12"

Inner dimensions: 10.6" x 9.5" x 8.25"

Payload dimensions: 6.575" x 8" x 7.625"

System Weight: 9.7 lbs. (Excluding payload)

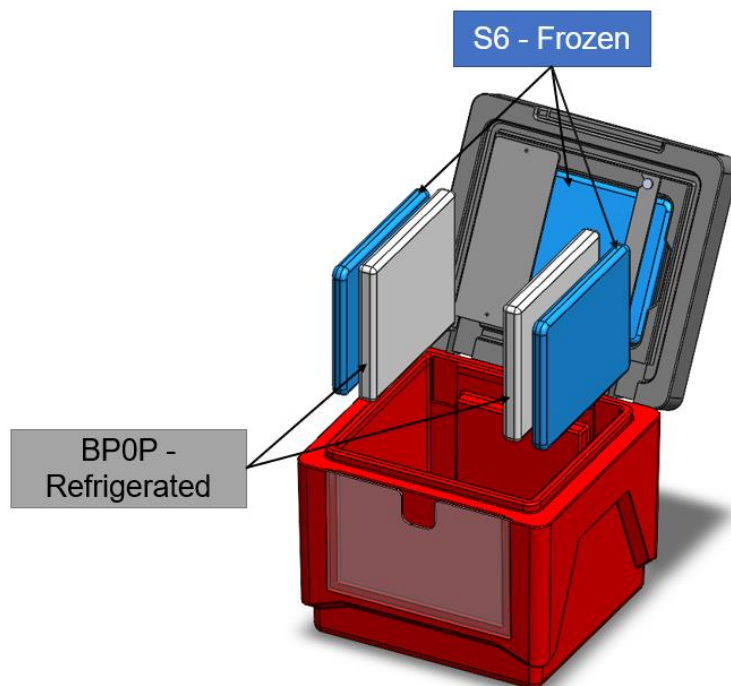
Payload:

- Type: Red Blood Cells (RBC) / Liquid Plasma
- Capacity: 1 to 10 units of RBC / Liquid Plasma
- Storage / Transport Temperature: 1 – 6 °C
- Validated Storage / Transport duration: up to 24 hours

4. Durability qualification:

The new MaxPlus Transfusion Cooler, MTC13, is built using Expanded Polypropylene (EPP) foam. EPP is highly impact resistant and very durable under heavy use. It is used to ship sensitive equipment all over the world. The material is highly resistant to chemicals and can be cleaned using organic solvents, standard lab / OR cleaning agents and wipes.

5. Packaging assembly illustration:



Gel Pack Arrangement:

3x S6 Frozen – 1 each against left and right walls, 1 in the lid pocket

2x BP0P Refrigerated – 1 each against Frozen S6 PCM0 on left and right walls

6. Pack-out instructions (All test cases):

Pack-out Procedure:

Step 1: Place two units of frozen S6 gel packs against the container walls.

Step 2: Place two refrigerated BP0P gel packs against the frozen S6 gel packs.

Step 3: Insert the last frozen S6 gel pack into the lid slot and latch the lid bar in place.

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 Transfusion Cooler, MTC13, packed with three frozen S6 gel packs and two refrigerated BP0P gel packs has been qualified for **24+ hours (1 to 6°C) for internal facility usage** (ambient between 18 to 24°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.

7. Cooler Validation:

7.1 Validation test cases:

The MaxPlus Transfusion Cooler is validated for three different operational test cases. The test cases are listed below:

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

This test validates the MaxPlus Transfusion 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.

B. 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.

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

This test validates the MaxPlus Transfusion 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 the minimum number of units and can maintain required temperature for a minimum of 24 hours.

7.2 Gel pack preparation

- Three S6 gel pack bottles (clear / blue bottle) should be pre-conditioned inside a freezer (at or below -18°C) for a minimum of 12 hours. The S6 gel pack bottles should be placed lying flat inside the freezer to avoid non-uniform freezing of the coolant.
- Two BP0P gel pack bottles (white bottle with white cap) should be pre-conditioned inside a refrigerator (1-6°C) for a minimum of 12 hours.

Note: If the S6 gel pack bottles (clear/blue) are conditioned in a freezer with a set point of **-30°C or lower**, the cooler must be **revalidated** to confirm that the payload temperature remains **above 1°C** during storage.

7.3 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 a refrigerator (1-6°C) for at least 12 hours

7.4 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 unit*. 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. Temperature probe taped outside a payload simulant bag.

- 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 air gap between the units and they stay together (Figure 2).



Figure 2. Temperature Probe sandwiched between two simulant units.

- If cooler validation is being conducted using a data logger without a probe, like a MaxConnect sensor, the logger can be affixed to the surface of the payload unit using rubber bands for performing validation.



Figure 3. MaxConnect sensor affixed outside a payload simulant bag with rubber band.

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

- For cold products: the data logger with the payload unit should be placed inside a refrigerator (1 to 6°C) for at least 2 hours to eliminate any chance of a temperature spike.

8. Pack-out variations

None listed.

9. Other use considerations

Validation of MaxPlus MTC13 cooler for any other payload configuration or use cases other than the recommended configuration listed could result in shorter validation duration. Please contact MaxQ Research at sales@flymaxq.com if your validation test criteria are different than what is listed in this validation guide.

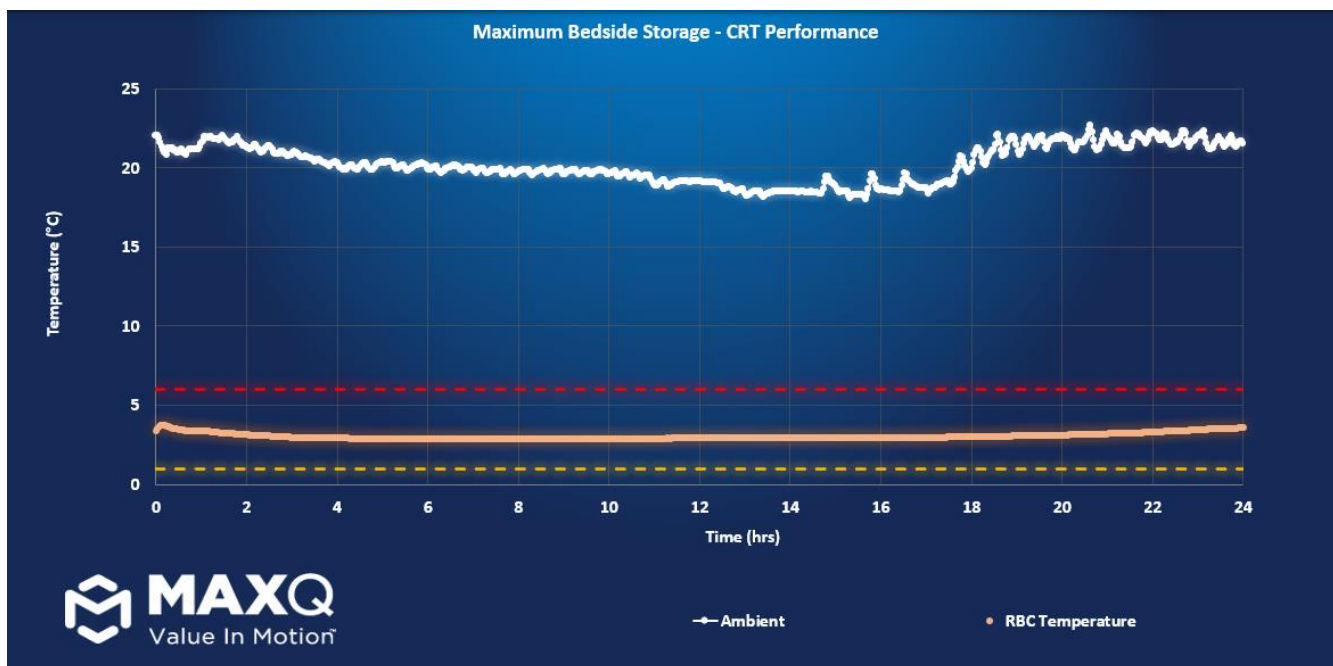
10. Cooler Validation Results

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

Test setup:

Container	MaxPlus Transfusion Cooler (MTC13)
Gel packs	S6 (3 units), BP0P (2 units)
Preconditioning	Three S6 PCM0's stored at / below -18°C for 12 hours and two BP0P PCM0's stored in the refrigerator (1-6°C) for 12 hours
Test payload	<u>Maximum:</u> 10 units of 300mL RBC simulant units from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature – MaxQ Logger IT20* Ambient temperature – MaxQ Logger IT13*
Ambient temperature	18 to 24°C
Test duration	24 hours

Performance Graph



Thermal Performance Results

	Payload temperature (°C)		Result
	Start (Time = 0 hours)	End (Time = 24 hours)	
Simulated RBC	3.4°C	3.6°C	Pass

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

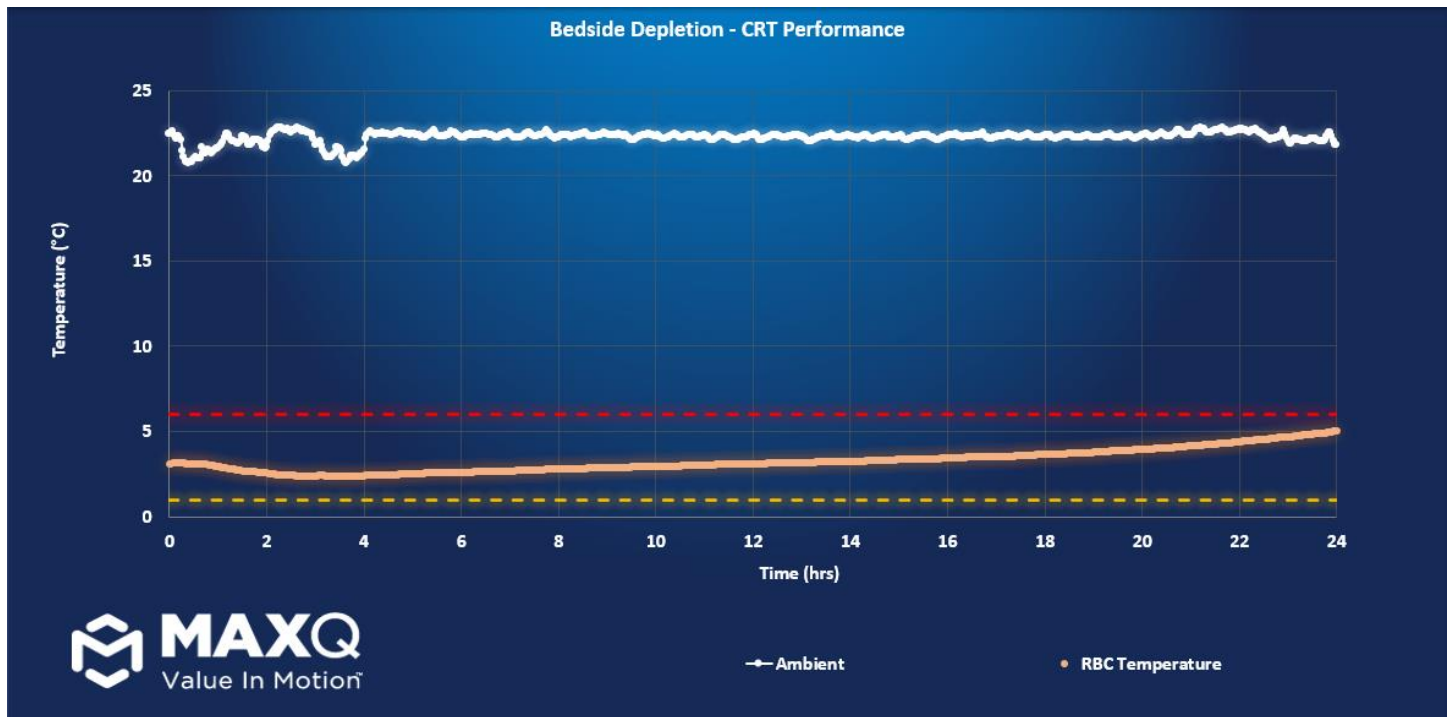
Test setup:

Container	MaxPlus Transfusion Cooler (MTC13)
Gel packs	S6 (3 units), BP0P (2 units)
Preconditioning	Three S6 PCMO's stored at / below -18°C for 12 hours and two BP0P PCMO's stored in the refrigerator (1-6°C) for 12 hours
Test payload	<u>Minimum*</u> : 2x 300mL RBC payload simulant units (See below)
Temperature data loggers	Payload temperature – MaxQ Logger IT20* Ambient temperature – MaxQ Logger IT13*
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 the 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.

Performance Graph



Thermal Performance Results

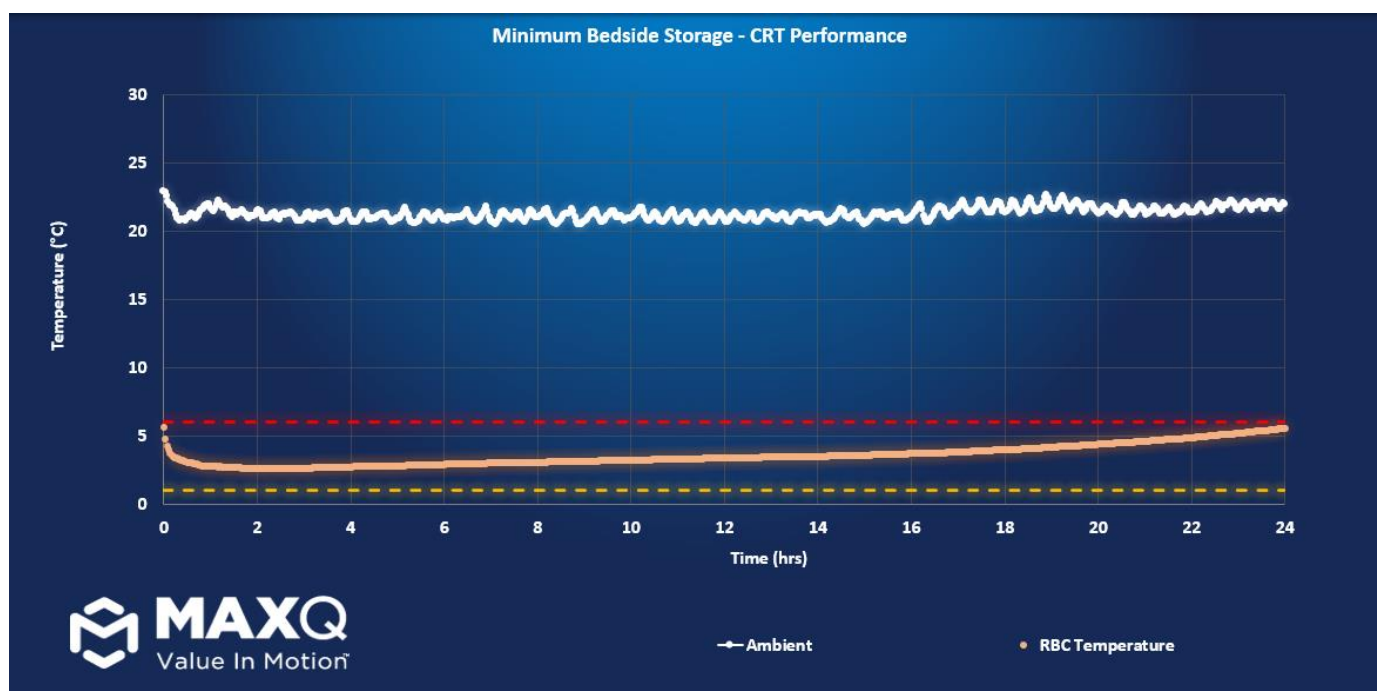
	Payload temperature (°C)		Result
	Start (Time = 0 hours)	End (Time = 24 hours)	
Simulated RBC	3.1°C	5.0°C	Pass

C. Validation Case # 3: Minimum Payload Bedside (1 to 6°C)

Test setup:

Container	MaxPlus Tranfusion Cooler (MTC13)
Gel packs	S6 (3 units), BP0P (2 units)
Preconditioning	Three S6 PCM0's stored at / below -18°C for 12 hours and two BP0P PCM0's stored in the refrigerator (1-6°C) for 12 hours
Test payload	<u>Minimum:</u> 1x 300mL RBC payload simulant unit from refrigerator (1-6°C)
Temperature data loggers	Payload Temperature – MaxQ Logger IT20* Ambient temperature – MaxQ Logger IT13*
Ambient temperature	18 to 24°C
Test duration	24 hours

Performance Graph



Thermal Performance Results

	Payload temperature (°C)		Result
	Start (Time = 0 hours)	End (Time = 24 hours)	
Simulated RBC	3.6°C	5.3°C	Pass