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Validation Guide for the MaxPlus MTP Cooler® 3.0

Intended for bedside storage of Red Blood Cells (1 – 6 °C), Thawed Plasma (1 – 6 °C, cooling down to 1 – 6 °C), Platelets (20 – 24 °C), and Chilled Platelets (1 – 6 °C) in a single cooler



Contents

1.	System Overview:	4
2.	System Components:	4
3.	Cooler Specifications:	5
4.	Durability qualification:	5
5.	Packaging assembly illustration:	6
6.	Pack-out instructions:	8
7.	Cooler Validation:	9
7.1	Validation Plan	9
A.	Validation test case # 1 – Maximum warm payload bedside storage testing	9
B.	Validation test case # 2 – Maximum cold payload bedside storage testing	9
C.	Validation test case # 3 – Minimum cold payload bedside storage testing	9
D.	Validation test case # 4 – Warm payload depletion testing	9
E.	Validation test case # 5 – Cold payload depletion testing	9
F.	Validation test case # 6 – Platelet testing	10
7.2	Gel pack preparation	10
7.3	Payload preparation	10
7.4	Data Logger preparation	11
7.5	Pre-conditioning the data logger	11
8.	Pack-out variations	12
9.	Other use considerations	12
10.	Cooler Validation Results	13
A.	Validation Test Case # 1, Max Warm Payload Testing	13
B.	Validation Test Case # 2, Max Cold Payload Testing	14
C.	Validation Test Case # 3, Min Cold Payload Testing	15
D.	Validation Test Case # 4, Warm Payload Depletion Testing	16
E.	Validation Test Case # 5, Cold Payload Depletion Testing	18
F.	Validation Test Case # 6, Platelet Testing	20
11.	Chilled Platelets	21
11.1	Packaging assembly illustration	21
11.2	Pack-out instructions	21
11.2.1	Coolant conditioning	21
11.2.2	Packing steps	21

11.3 Validation Test Case # 7, Chilled Platelet Testing 22
Revision History: 23


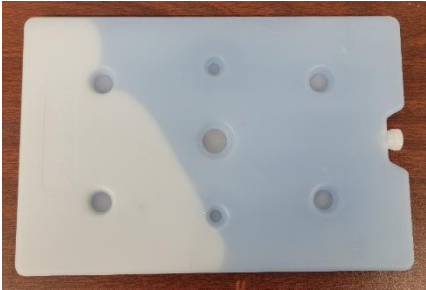



NOTE: If you need any help in executing the test cases listed in this guide, please contact your MaxQ sales representative for help. You may also contact the technical support line – 405-466-5629 or sales@packmaxq.com – Please list “Validation guidance for MTP Cooler” in the subject line.

1. System Overview:

The MaxPlus MTP Cooler® 3.0 is exclusively designed and validated for hospital transfusion services for bedside storage of Red Blood Cells (1 – 6 °C), Thawed Plasma (cooling down to 1 – 6 °C), and Platelets (20 – 24 °C) in a single cooler. The following report includes system components, pack-out instructions, cooler validation plan, and test results.

2. System Components:

- MaxPlus MTP Cooler®
- Payload tray
- Gel packs

<p>Name: B18 PCM5 Color: Yellow, Size: Large</p> 	<p>B18 PCM0 Color: Blue, Size: Large</p> 
<p>B18 PCM22 (for Platelets ONLY) Color: White/clear, Size: Large</p> 	
<p>B22 PCM5 Color: Yellow, Size: Small</p> 	<p>B22 PCM0 Color: Blue, Size: Small</p> 

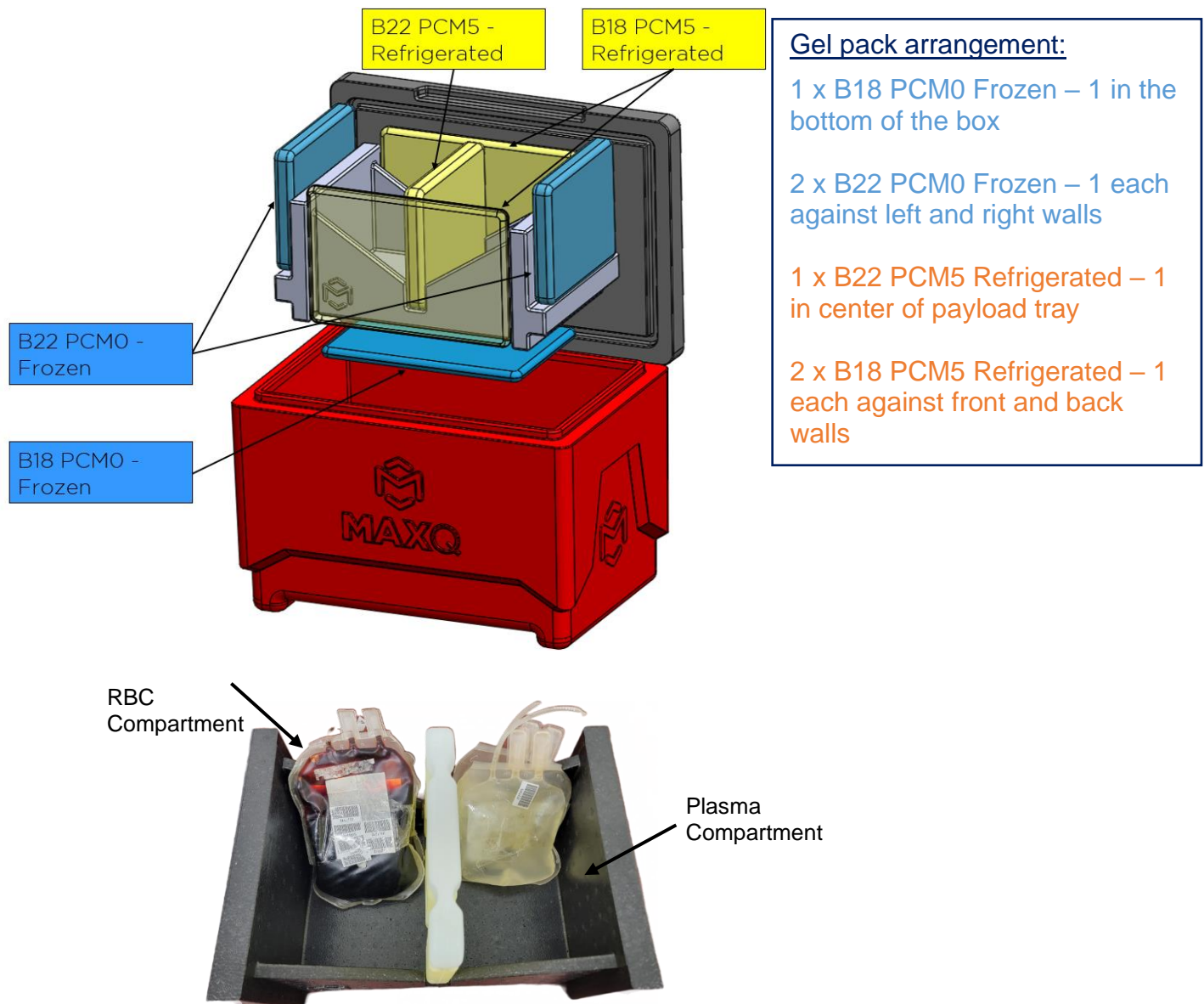
3. Cooler Specifications:

- **Outer dimensions:** 20.1"x13.8"x16.3"
- **Inner dimensions:** 17"x10.8"x10"
- **System Weight:** 21 lbs. (Excluding payload)
- **Payload:**
 - **Type:** Red Blood Cells, Plasma (Cold or Warm), and Platelets
 - **Capacity:** 2 to 6 units of RBC, 2 to 6 units of Plasma, 1 to 2 units of Platelets
 - **Temperature for cold RBC/Plasma:** 1 – 6 °C
 - **Temperature for thawed Plasma (warm):** Cooling down towards 1-6°C
 - **Temperature for Platelets:** 20-24°C
- **Validated storage duration:** 12 hours

4. Durability qualification:

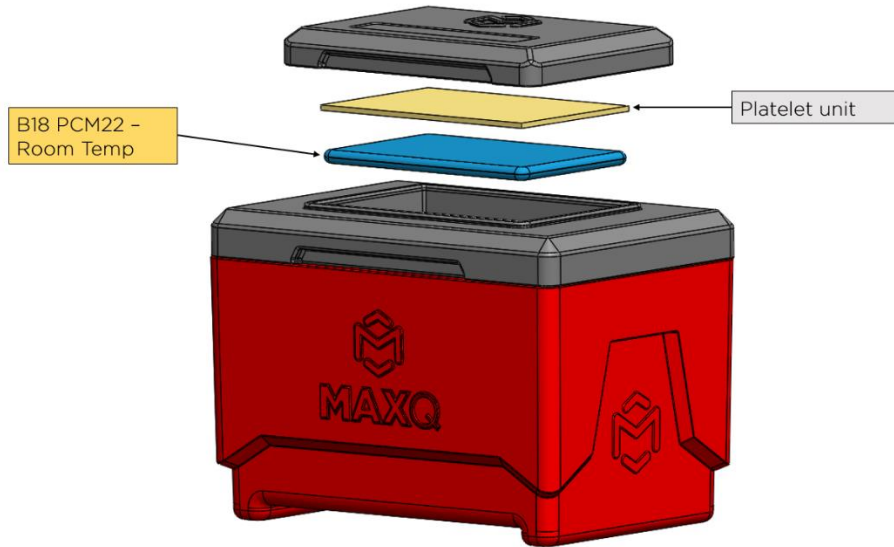
Expanded Polypropylene foam is highly impact resistant and very durable under heavy use. It is used to ship sensitive equipment all over the world. The material is highly resistant to chemicals and can be cleaned using organic solvents, standard lab / OR cleaning agents and wipes.

5. Packaging assembly illustration:



***Red blood cells (RBC) compartment:** The payload tray is designed to hold 2 to 6 refrigerated red blood cell units.

***Plasma (PL) compartment:** The payload tray is designed to hold 2 to 6 units of either liquid plasma from refrigerator between 1 to 6 °C or warm plasma directly from the thawing equipment.



Gel pack arrangement:

1 x B18 PCM22 room temperature on the bottom

*Platelet (PLT) compartment: The Platelet compartment on the lid is designed to hold 1-2 platelet units between 20 to 24 °C.

6. Pack-out instructions:

6.1 Coolant conditioning

- Charge two B22 PCM0 (Small, blue color) and one B18 PCM0 (Large, blue color) gel packs in the freezer (below -20°C) for a minimum of 12 hours
- Charge two B18 PCM5 (Large, yellow color) and one B22 PCM5 (Small, yellow color) gel packs in the refrigerator (1 – 6 C) for a minimum of 12 hours
- Charge one B18 PCM22 (Large, white color) gel pack in the platelet incubator (22C) for a minimum of 12 hours.

Note: Depending on the freezer used for conditioning any freezer temperature below -15°C will be sufficient to condition the coolants within the recommended period.

6.2 Packing steps

Step 1: Place one frozen B18 PCM0 (Large, blue color) gel packs on the bottom of the cooler inside the dedicated pocket. (Refer to packaging assembly illustration on page 5)

Step 2: Place payload tray into box on top of the B18 PCM0.

Step 3: Place Two frozen B22 PCM0 (Small, blue color) gel packs, one on the left and one on the right of your payload tray.

Step 4: Place one refrigerated B22 PCM5 (small, yellow color) gel pack in the center of your payload tray.

Step 5: Place RBC and Plasma units inside the tray and close the cooler lid, ensuring that it is sealed properly. *For validation of the cooler please refer to 'Data logger preparation' and 'Payload preparation' for detailed instruction.*

Note: RBC units from the refrigerator and warm Plasma units from the thawing equipment (or refrigerator) should be placed in separate specifically labeled compartments each.

Step 6: Take the B18 PCM22 (Large, white color) gel pack from the platelet incubator and place it inside of the platelet compartment.

Step 7: Place 1-2 units of Platelet units inside the platelet pouch on top of the coolant bottle.

Step 8: Close the platelet compartment lid making sure the lid is completely closed.

Disclaimer: The MaxPlus MTP Cooler® (SKU # MTP18E12) has been qualified for up to **12 hours to hold RBC units (1 to 6°C) and Plasma units (1 to 6°C or cooling down towards 1 to 6°C for warm Plasma units), and Platelet unit (20 to 24°C)** at ambient between 18 to 25°C in the described laboratory cooler validation tests. The ambient temperature profile for a specific location may vary. MaxQ cannot guarantee that the payload can maintain required temperature range without any excursions if the ambient temperature exposure of the packed system is not within the tested temperature range.

7. Cooler Validation:

7.1 Validation Plan

MaxQ conducted laboratory validation of the MaxPlus MTP Cooler 3.0 under the following test cases. The test cases were developed to simulate various payload compositions that may be applicable to transfusion services in general. The system components and pack-out instructions are kept the same for all these test cases.

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

This test validates the MaxPlus MTP Cooler® for storing maximum number of **cold RBC units (6 units)** between 1 to 6°C and storing maximum number of **warm PL (6 units)** cooling down towards 1 to 6°C. This test case simulates operational scenario where the MTP cooler is issued with warm plasma products and can maintain required temperature for up to 12 hours.

B. Validation test case # 2 – Maximum cold payload bedside storage testing

This test validates the MaxPlus MTP Cooler® for storing maximum number of **cold RBC units (6 units)** and **maximum number of cold PL units (6 units)** between 1 to 6°C. This test case simulates operational scenario where the MaxPlus MTP cooler is issued with refrigerated products only (both RBC and PL) and can maintain required temperature for up to 12 hours.

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

This test validates the MaxPlus MTP Cooler® for storing minimum number of **cold RBC units (2 units)** and minimum number of **cold PL units (2 units)** between 1 to 6°C. This test case simulates operational scenario where the MTP cooler is issued with just two refrigerated products (RBC and PL) for patients and can maintain required temperature for up to 12 hours.

D. Validation test case # 4 – Warm payload depletion testing

This test case simulates operational scenario where the MaxPlus MTP Cooler® is issued with maximum **warm plasma (6 units)** cooling down towards 1 to 6°C and maximum **cold RBC units (6 units)** between 1 to 6°C. Subsequently, 1 unit of cold RBC and 1 unit of warm PL were removed from the cooler every 15 minutes until only 1 unit of cold RBC and 1 unit of warm PL are left in the cooler. This simulates operational scenario where the patient is being infused with the blood products every 15 minutes. The cooler is tested to maintain required temperature for up to 12 hours.

E. Validation test case # 5 – Cold payload depletion testing

This test case simulates operational scenario where the MaxPlus MTP Cooler® is issued with maximum number of **cold plasma (6 units)** and maximum number of **cold RBC (6 units)**. Subsequently, 1 unit of cold RBC and 1 unit of cold PL were removed from the cooler every 15 minutes until only 1 unit of

cold RBC and 1 unit of cold PL are left in the cooler. This simulates operational scenario where the patient is being infused with the blood products. The cooler is tested to maintain required temperature (1-6°C) for a total of 12 hours.

F. Validation test case # 6 – Platelet testing

This test case simulates operational scenario where the MaxPlus MTP Cooler® is issued with maximum number of **cold RBC units (6)** and maximum number of **cold PL units (6)**, and 1 unit of Platelet placed inside the Platelet compartment. The cooler is placed inside a NIST traceable calibrated environmental chamber maintaining a constant ambient of 18°C (64.4°F, to simulate a colder OR) and the platelet simulant inside the Platelet compartment maintained between 20 to 24°C for up to 12 hours. This test case simulates the maximum hold time scenario for the platelet product.

7.2 Gel pack preparation

During cooler validation, the following steps were followed to pre-condition the gel packs for testing.

1. Two B22 PCM0 (Small, blue color) and one B18 PCM0 (Large, blue colored) gel pack bottles was pre-conditioned inside a freezer (below -20°C) for a minimum of 12 hours. The gel pack bottles was placed lying flat inside the freezer to avoid non-uniform freezing of the coolant.
2. Two B18 PCM5 (Large, yellow color) and one B22 PCM5 (Small, yellow color) gel pack bottles was pre-conditioned inside a refrigerator (1-6°C) for a minimum of 12 hours.
3. B18 PCM22 gel pack bottle (Large, white bottle) was kept inside the Platelet incubator at 22°C for a minimum of 12 hours prior to use.

Note: The B18 PCM22 platelet coolant can be stored between 21 – 24°C controlled room temperature without affecting the performance of the cooler. However, storing the coolant at 20°C can affect the performance of the cooler.

7.3 Payload preparation

It is recommended to use appropriate payload simulant units to conduct cooler validation. All payload simulants used for validation test should be pre-conditioned at appropriate temperature for at least 12 hours prior to start of the test. Please see below for list of simulants and preparation methods used during MaxQ's cooler validation.

- 350mL water filled bags were used as payload simulant for RBC/Plasma units. 400mL water filled bags were used as payload simulant for Platelet units.
- To prepare Cold RBC/Plasma simulant units for testing, 350mL water bags were stored inside refrigerator (1-6°C) for at least 12 hours before testing.
- To prepare warm Plasma simulant units for testing, 350mL water bags were stored in an NIST traceable calibrated environmental chamber to condition the simulated warm plasma units at 37°C for at least 12 hours before testing.
- Platelet simulant units used for testing were stored in an NIST traceable calibrated environmental chamber to condition the units to 22°C for at least 12 hours before testing.

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 bag*. Packaging tape can be used to affix the external probe to one of the payload units (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).

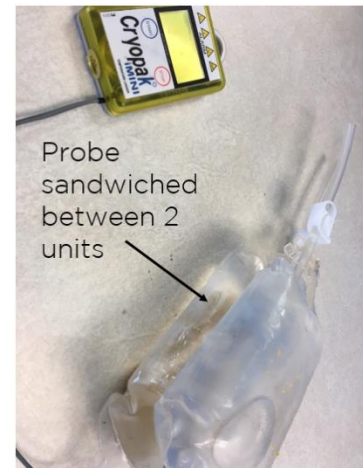
*Please note that measuring the core temperature by inserting the metal probe inside the blood bag is also possible and will be considered a valid test.



Figure 1. Temperature probe taped outside a payload simulant bag.



Figure 2. Temperature probe sandwiched between two payload units.



7.5 Pre-conditioning the data logger

- For cold products testing: Store the data logger and simulant units with the probe inside the refrigerator between 1 to 6°C for at least 2 hours to eliminate any chance of temperature spike.
- For room temperature products testing: Store the data logger and simulant unit with probe inside the platelet incubator at 22°C for at least 2 hours

Please note that for warm products the payload can be used right away from the thawing equipment at or below 37°C. However, the probe shall be affixed to the bag after the simulant is taken out from the thawing equipment as shown above.

8. Pack-out variations

The MaxPlus MTP Cooler® 3.0 has been validated using B18 PCM0 and B22 PCM0 gel pack bottles (blue) pre-conditioned inside a commercial freezer that maintains temperature between -20°C to -30°C. Using a plasma freezer (< -26°C) to pre-condition the B18 PCM0 and B22 PCM0 gel pack bottles will not change the validation protocol or validation duration.

No other pack-out variations are recommended by the manufacturer.

9. Other use considerations

None listed.

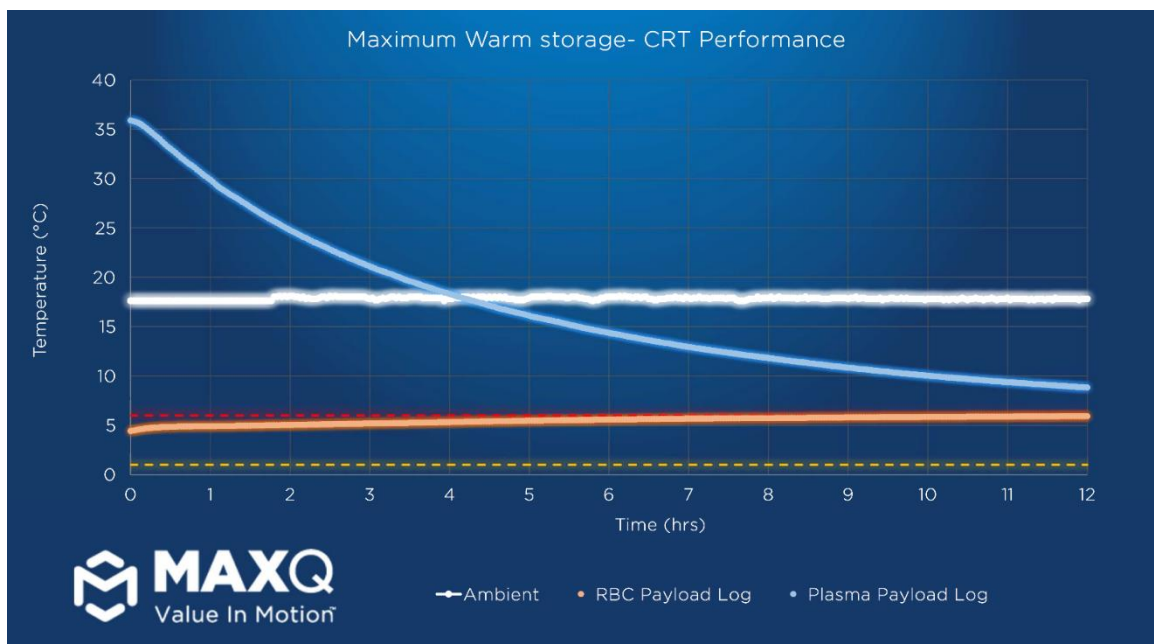
10. Cooler Validation Results

A. Validation Test Case # 1, Max Warm Payload Testing

Test setup:

Container	MaxPlus MTP cooler (MTP3.0)
Gel packs	B22 PCM5 (1 unit), B22 PCM0 (2 units), B18 PCM5 (2 units), B18 PCM0 (1 unit)
Preconditioning	Two B22 PCM0's and B18 PCM0 at -20°C for 12 hours and Two B18 PCM5's and one B22 PCM5 stored in the refrigerator (1-6°C) for 12 hours
Test payload	RBC: 6 units of 350mL water bags from refrigerator (1 – 6 °C) Warm plasma: 6 units of 350mL water bags from incubator (30-37 °C)
Temperature data loggers	RBC temperature – MaxQ Logger IT4* Plasma temperature – MaxQ Logger IT10* Ambient temperature – MaxQ Logger 30*
Ambient temperature	17-19°C
Test duration	12 hours

Performance graph



Thermal performance results

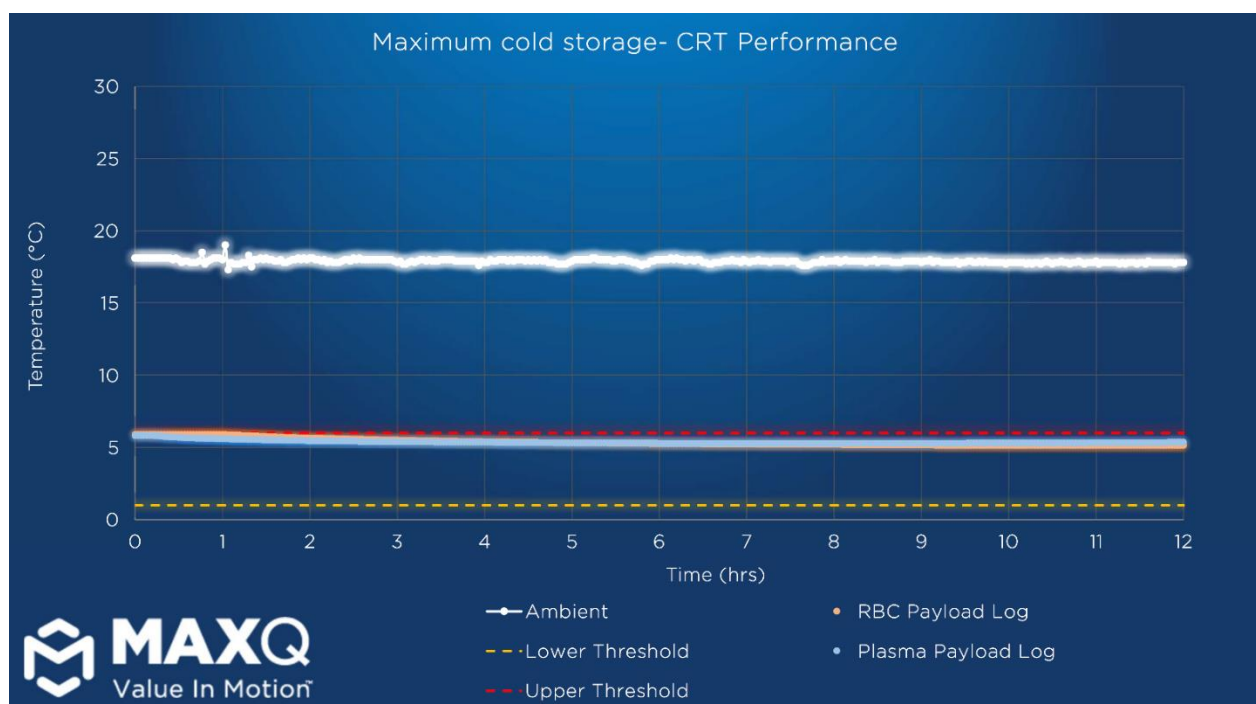
	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
RBC	4.4	5.9	Pass
Warm Plasma	35.9	8.8	Pass

B. Validation Test Case # 2, Max Cold Payload Testing

Test setup:

Container	MaxPlus MTP cooler (MTP 3.0)
Gel packs	B22 PCM5 (1 unit), B22 PCM0 (2 units), B18 PCM5 (2 units), B18 PCM 0 (1 unit)
Preconditioning	Two B22 PCM0's and B18 PCM0 at -20°C for 12 hours and Two B18 PCM5's and one B22 PCM5 stored in the refrigerator (1-6°C) for 12 hours
Test payload	RBC: 6 units of 350mL water bags from refrigerator (1 – 6 °C) Cold plasma: 6 units of 350mL water bags from refrigerator (1 - 6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger IT4* Plasma temperature – MaxQ Logger IT10* Ambient temperature – MaxQ Logger 39 body*
Ambient temperature	17 to 19°C
Test duration	12 hours

Performance graph



Thermal performance results

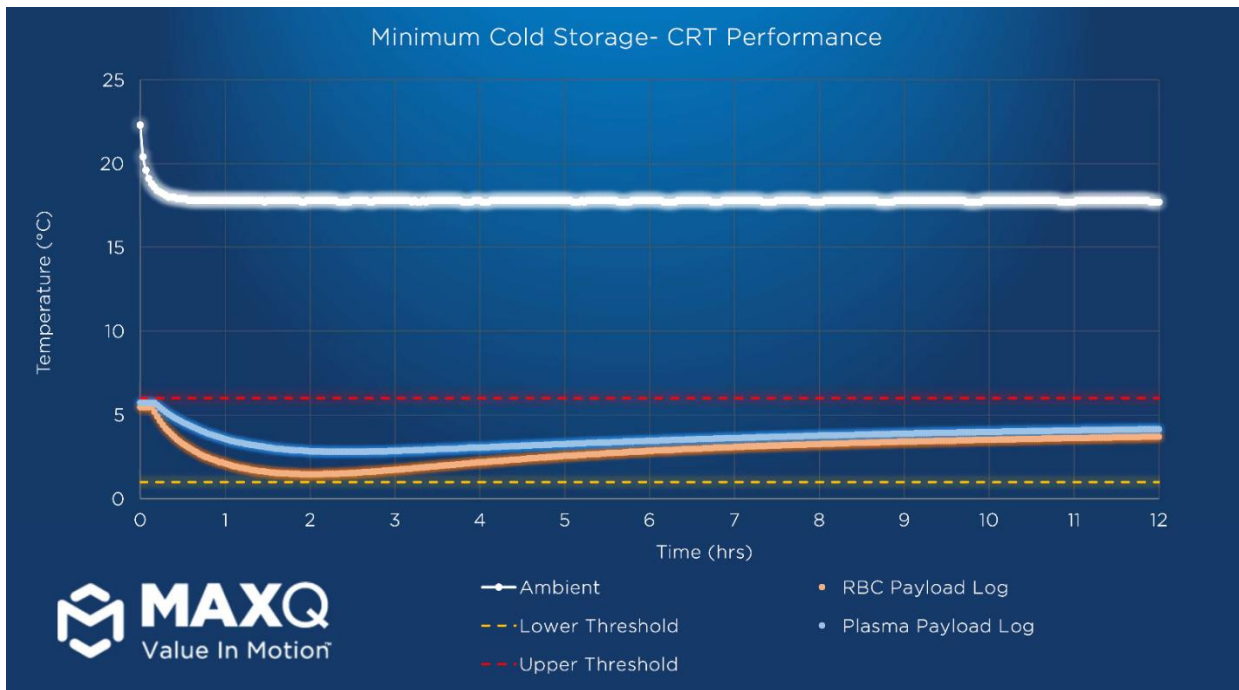
	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
RBC	5.9	5.2	Pass
Cold Plasma	5.8	5.4	Pass

C. Validation Test Case # 3, Min Cold Payload Testing

Test setup:

Container	MaxPlus container (MTP 3.0)
Gel packs	B22 PCM5 (1 unit), B22 PCM0 (2 units), B18 PCM5 (2 units), B18 PCM 0 (1 unit)
Preconditioning	Two B22 PCM0's and B18 PCM0 at -20°C for 12 hours and Two B18 PCM5's and one B22 PCM5 stored in the refrigerator (1-6°C) for 12 hours
Test payload	RBC: 2 units of 350mL water bags from refrigerator (1 – 6 °C) Cold plasma: 2 units of 350mL water bags from refrigerator (1-6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger IT4* Plasma temperature – MaxQ Logger IT10* Ambient temperature – MaxQ Logger 37 body*
Ambient temperature	17 to 23°C
Test duration	12 hours

Performance graph



Thermal performance results

	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
RBC	5.5	3.7	Pass
Cold Plasma	5.7	4.1	Pass

D. Validation Test Case # 4, Warm Payload Depletion Testing

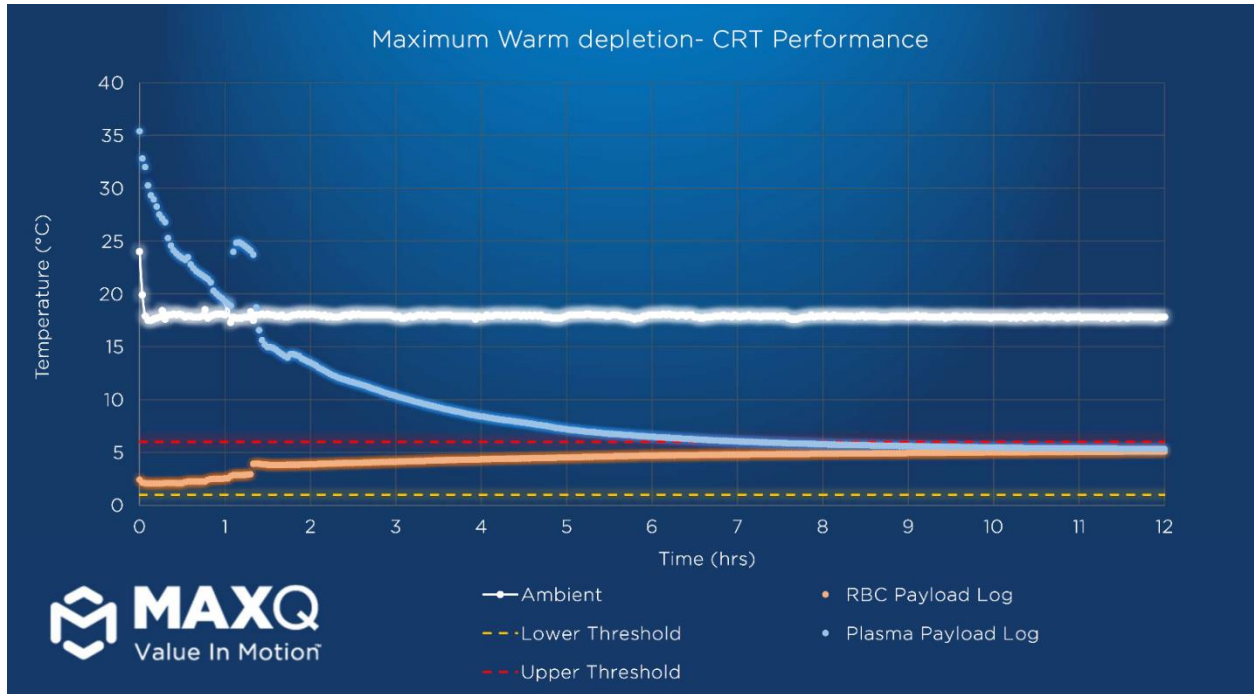
Test setup:

Container	MaxPlus MTP Cooler (MTP 3.0)
Gel packs	B22 PCM5 (1 unit), B22 PCM0 (2 units), B18 PCM5 (2 units), B18 PCM 0 (1 unit)
Preconditioning	Two B22 PCM0's and B18 PCM0 at -20°C for 12 hours and Two B18 PCM5's and one B22 PCM5 stored in the refrigerator (1-6°C) for 12 hours
Test payload	RBC: 6 units of 350mL water bags from refrigerator (1 – 6 °C) Warm plasma: 6 units of 350mL water bags from incubator (30-37 °C)
Temperature data loggers	RBC temperature – MaxQ Logger IT10* Plasma temperature – MaxQ Logger IT4* Ambient temperature – MaxQ Logger 22*
Ambient temperature	17 to 25°C
Test duration	12 hours

Product depletion test protocol:

- The cooler was packed with maximum payload (6 x 300mL RBC simulant units and 6 x 300mL Plasma simulant units) following instructions provided above.
- After every 15 minutes, the cooler was opened and 1 unit of RBC simulant and 1 unit of Plasma simulant were taken out to simulate real world usage of the cooler.
- The process was repeated for a total of 1 hour and 15 minutes
- After 1 hour and 15 minutes, only 1 unit of RBC simulant and 1 unit of plasma simulant remained and were left inside the cooler for the next 10 hours and 45 minutes (Total test duration: 12 hours).
- Temperature of the last unit was recorded and presented in the graph below.

Performance graph:



Thermal performance results:

	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
RBC	2.4	5.1	Pass
Warm Plasma	35.4	5.3	Pass

E. Validation Test Case # 5, Cold Payload Depletion Testing

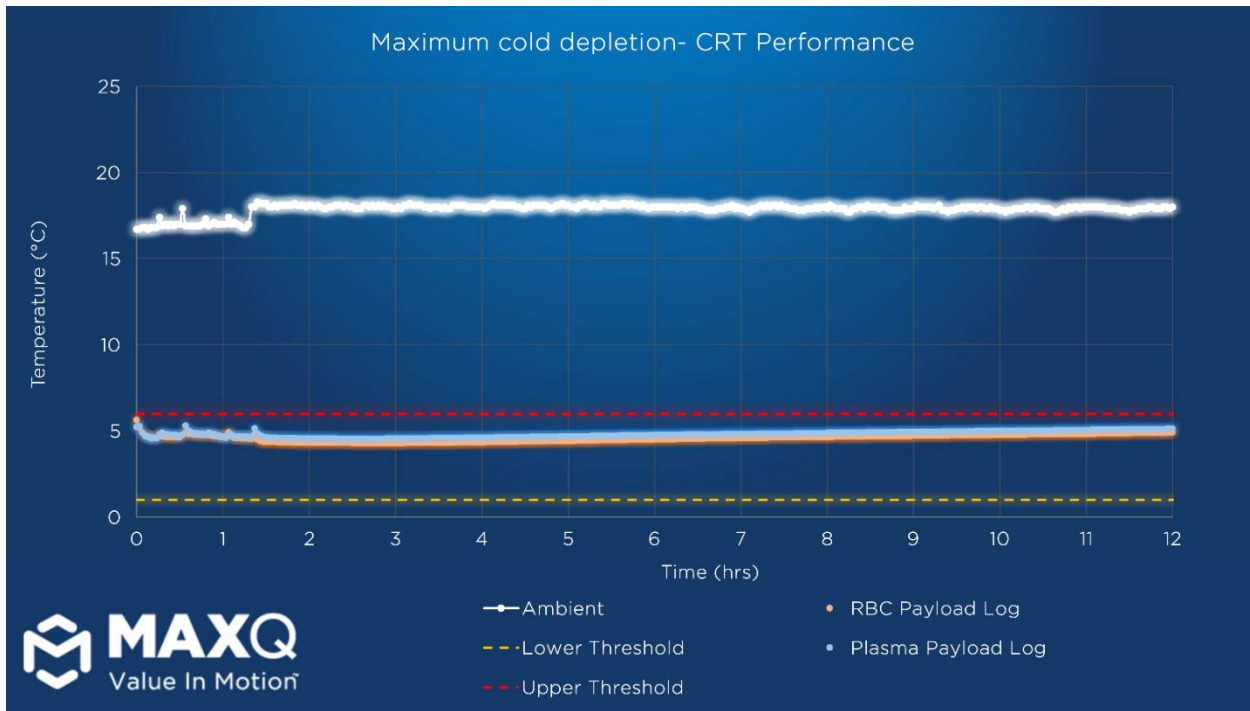
Test setup:

Container	MaxPlus MTP Cooler (MTP 3.0)
Gel packs	B22 PCM5 (1 unit), B22 PCM0 (2 units), B18 PCM5 (2 units), B18 PCM 0 (1 unit)
Preconditioning	Two B22 PCM0's and B18 PCM0 at -20°C for 12 hours and Two B18 PCM5's and one B22 PCM5 stored in the refrigerator (1-6°C) for 12 hours
Test payload	RBC: 6 units of 350mL water bags from refrigerator (1 – 6 °C) Cold plasma: 6 units of 350mL water bags from refrigerator (1-6 °C)
Temperature data loggers	RBC temperature – MaxQ Logger IT4* Plasma temperature – MaxQ Logger IT10* Ambient temperature – MaxQ Logger 30*
Ambient temperature	17 to 20°C
Test duration	12 hours

Product depletion test protocol:

- The cooler was packed with maximum payload (6 x 300mL RBC simulant units and 6 x 300mL Plasma simulant units) following instructions provided above.
- After every 15 minutes, the cooler was opened and 1 unit of RBC simulant and 1 unit of Plasma simulant were taken out to simulate real world usage of the cooler.
- The process was repeated for a total of 1 hour and 15 minutes (removing 2 units / 15 minutes)
- After 1 hour and 15 minutes only 1 unit of RBC simulant and 1 unit of plasma simulant remained and were left inside the cooler for the next 10 hours and 45 minutes (Total test duration: 12 hours).
- Temperature of the last unit was recorded and presented in the graph below.

Performance graph:



Thermal performance results:

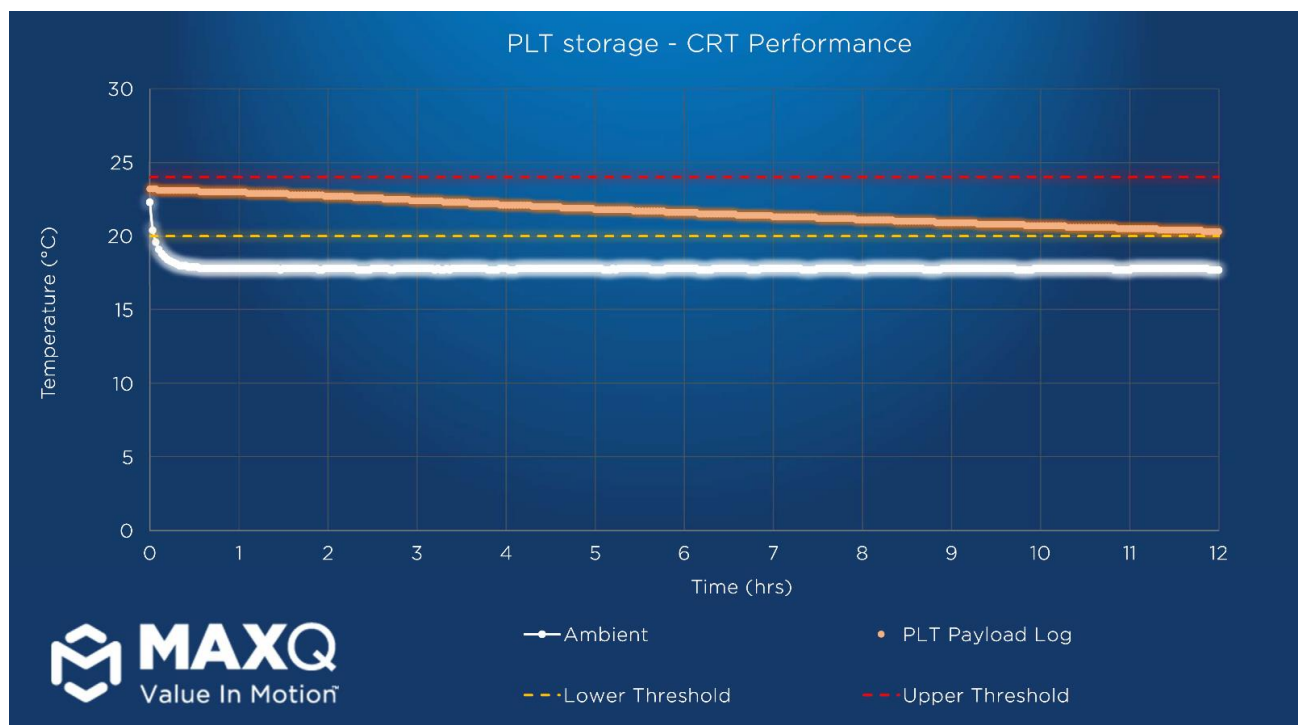
	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
RBC	5.6	4.9	Pass
Warm Plasma	5.2	5.1	Pass

F. Validation Test Case # 6, Platelet Testing

Test setup:

Container	MaxPlus MTP Cooler (MTP3.0)
Test payload	PLT: 1 unit of 400mL water bags from incubator (22 °C)
Temperature data loggers	PLT temperature – MaxQ Logger 37* Ambient temperature – MaxQ logger 37 body*
Ambient temperature	18°C
Test duration	12 hours

Performance graph

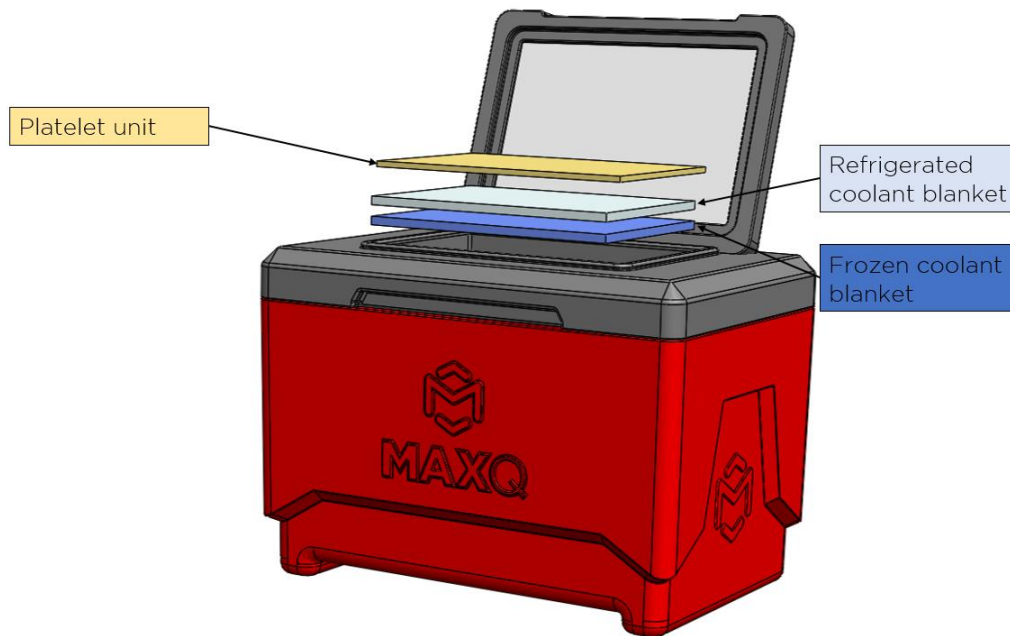


Thermal performance results

	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
PLT	23.2	20.3	Pass

11. Chilled Platelets

11.1 Packaging assembly illustration



Gel pack arrangement:

1 x Coolant Blanket
frozen on bottom

1 x Coolant blanket
refrigerated on top of
frozen coolant blanket

11.2 Pack-out instructions

11.2.1 Coolant conditioning

- Charge one Coolant blanket in a refrigerator (1 – 6°C) for a minimum of 12 hours
- Charge one Coolant blanket in a freezer (below -20°C) for a minimum of 12 hours

Note: Depending on the freezer used for conditioning any freezer temperature below -15°C will be sufficient to condition the coolants within the recommended period.

11.2.2 Packing steps

Step 1: Place one frozen Coolant blanket on the bottom of the PLT compartment.

Step 2: Place one refrigerated Coolant blanket on top of the frozen Coolant blanket.

Step 3: Place one Platelet unit on top of the refrigerated Coolant blanket.

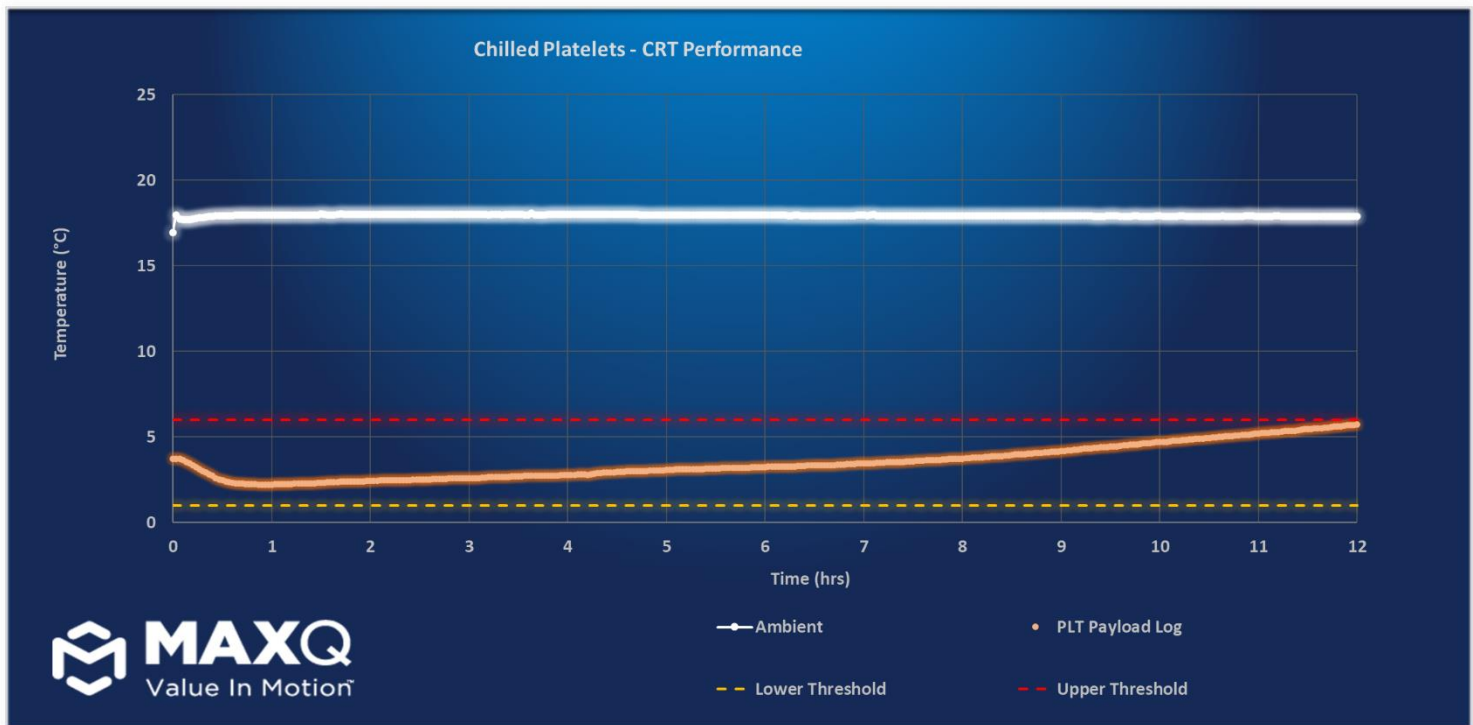
Step 4: Firmly close the Platelet compartment lid. *For validation of the cooler please refer to 'Data logger preparation' and 'Payload preparation' for detailed instruction.*

11.3 Validation Test Case # 7, Chilled Platelet Testing

Test setup:

Container	MaxPlus MTP Cooler (MTP3.0)
Test payload	PLT: 1 unit of 400mL payload simulant from refrigerator (1 - 6°C)
Temperature data loggers	PLT temperature – MaxQ Logger 21 & IT5* Ambient temperature – MaxQ logger IT15 body*
Ambient temperature	18°C
Test duration	12 hours

Performance graph



Thermal performance results

	Payload temperature (°C)		Result
	Start (Time: 0 hrs.)	End (Time: 12 hrs.)	
PLT	3.7	5.7	Pass

Revision History:

Revision Number	Date	Revision Description	Revised by	Approved by
V1.0	3/15/2023	Original document	George Jett	Dr. Arif Rahman
V2.0	11/10/2023	Chilled Platelets Validation Added	Murthy Doddasomayajula	Dr. Arif Rahman