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# Validation Guide for the MaxPlus Alpha Cooler®

Intended for bedside storage of Red Blood Cells/Cold Plasma (1 – 6 °C) with integrated temperature monitoring capabilities



Website: <https://www.packmaxq.com/maxplus-alpha2>

Reference Materials: <https://www.packmaxq.com/alpha2-reference>

Brochure: [Alpha Cooler brochure](#)

# Table of Contents

System Overview: .....	3
System Components: .....	3
Accessories: .....	3
Cooler Specifications: .....	3
Durability qualification: .....	3
Packaging assembly illustration: .....	4
Pack-out instructions :.....	4
Cooler Validation: .....	5
1. Validation test case # 1 - Maximum payload bedside storage testing .....	5
2. Validation test case # 2 - Payload depletion testing .....	5
Gel pack preparation .....	5
Payload preparation .....	6
Glycol Buffered Wireless Sensor preparation .....	6
Other use considerations .....	6
Cooler Validation Results .....	7
Validation Case # 1: Maximum Payload (1 to 6°C) .....	7
Validation Case # 2: Payload Depletion Testing (1 to 6°C) .....	8

**NOTE:** If you need any help in executing the validation test cases listed in this guide, please contact your MaxQ sales representative for help. You may also contact the technical support at (405)-466-5629 or [sales@packmaxq.com](mailto:sales@packmaxq.com) - Please list "Validation guidance for Alpha Cooler" in the subject line.

## System Overview:

The MaxPlus Alpha Cooler is exclusively designed for hospital transfusion services with MaxQ's proprietary Integrated Monitoring System for logging blood product temperature inside the cooler and providing comprehensive status report through a mobile application.



## System Components:

- MaxPlus Alpha Cooler (1)
- Main Controller (1)
- Glycol Buffered Wireless Payload sensor (1)
- S6 blue gel packs (2 units), BPOP white gel packs (3 units)

## Accessories:

- Micro-USB charging cable with power adapter
- SD card reader
- Spare battery for the buffered wireless payload sensor
- USB Bluetooth adapter for communicating with Desktop computer

## Cooler Specifications:

- Outer dimensions : 13.25"x13.25"x13.25"
- Inner dimensions : 10"x10"x10"
- Payload dimensions : 6"x10"x8" (LxWxH)
- System Weight : 13.7 lbs. (Excluding payload)
- Payload:
  - Type: Red blood cells or Thawed Plasma
  - Capacity: 2 to 10 units
  - Temperature: 1 - 6 °C
  - Validated storage duration : up to 24 hours for maximum payload

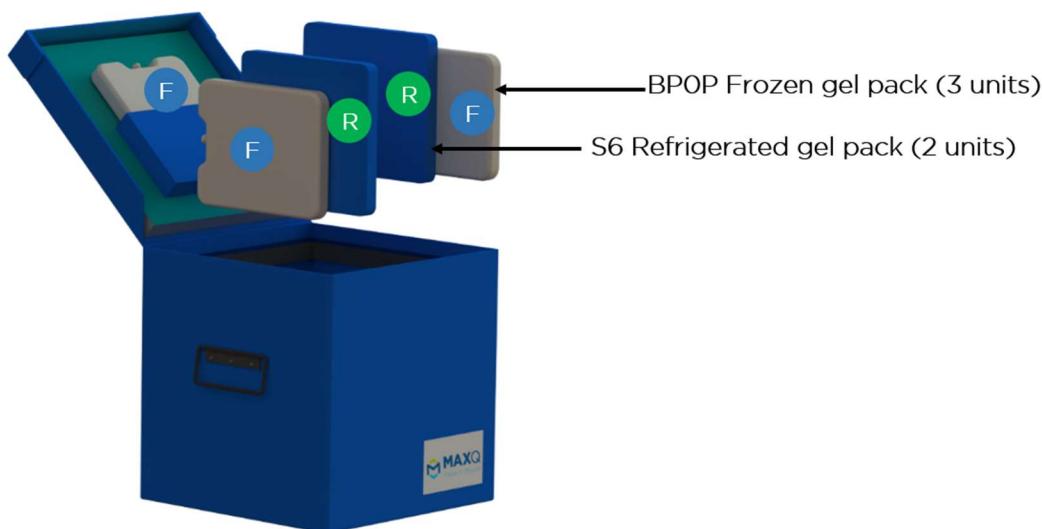
## Durability qualification:

Polypropylene corrugated plastic used for the MaxPlus Alpha 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 hinges<sup>1</sup>. The

material is highly resistant to chemicals and can be cleaned using organic solvents, standard lab / OR cleaning agents and wipes.

<sup>1</sup> 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

## Pack-out instructions :

**Step 1:** Charge three BPOP gel packs in freezer (below -20°C), and two S6 gel packs in the refrigerator (1-6 °C) for a minimum of 12 hours.

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

**Step 2:** Place two frozen BPOP gel packs against the two opposite walls of the container and one in the designated lid pouch.

**Step 3:** Place two refrigerated S6 gel packs against the two opposite walls of the container making sure to place them on the inside face of the frozen gel packs to avoid putting blood components in close contact with frozen coolant.

**Step 4:** Place the Main Controller into the dedicated slot on top of the cooler lid.

**Note:** Do not turn ON the Main Controller device before placing it inside the dedicated slot. The wireless sensor pairing will not work if the main controller device is not placed properly on the cooler lid. In case the Main Controller is turned on before placing it inside

the dedicated slot, please turn off the controller. Place it inside the slot and then turn it on.

**Step 5:** Turn ON the Main Controller and follow on-screen instructions.

**Step 6:** Wait till you see the first temperature reading on the display and then place glycol buffered wireless sensor inside the container.

**Note:** Glycol submerged wireless sensor should be conditioned inside the refrigerator for at least 2 hours before usage. The objective is to acclimatize the sensor to refrigerated temperature. The sensor can be kept inside the refrigerator for anytime more than 2 hours without any adverse effect.

**Step 7:** Place your payload (blood units) inside the container and close the cooler lid, ensuring that it is sealed properly.

**Note:** For changing sample rate or time on the system please refer to the training manual provided with the system.

**Disclaimer:** The MaxPlus Alpha 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 18 to 30°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.

## Cooler Validation:

MaxQ conducted validation of the MaxPlus Alpha Cooler under the following test cases.

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

This test validates the MaxPlus Alpha Cooler for storing maximum number of cold RBC or PL units (10 units) between 1 to 6°C. This test case simulates operational scenario where the Alpha 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 MaxPlus Alpha Cooler is issued with maximum number of cold RBC or PL (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 transfused products periodically. The cooler is tested to maintain required temperature (1-6°C) for a total of 24 hours.

## Gel pack preparation

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

- 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

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.
- To prepare cold RBC/PL payload simulant units, 350mL water bags were stored inside refrigerator (1-6°C) for at least 12 hours prior to start of the test.

## Glycol Buffered Wireless Sensor preparation

It is strongly recommended to pre-condition the glycol buffered wireless sensor inside the refrigerator between 1 to 6°C for at least 2 hours to reduce initial temperature spike.

- The glycol submerged wireless sensor should only be taken out of the refrigerator after all the coolants have been placed inside the cooler and the on-screen instruction has requested to 'turn on the wireless sensor'.
- After the glycol submerged wireless sensor has been turned ON, the user is requested to allow the sensor to establish secure communication with the display (15-20 seconds) before opening the lid of the cooler to place the sensor inside the cooler. The user can confirm established connection between the wireless sensor and the display by verifying temperature data that will be displayed on the screen. After verifying the temperature data is displayed on the screen, the user may open the cooler to place the wireless sensor.

## Other use considerations

Validation of MaxPlus Alpha cooler for any other payload configuration other than the recommended one will result in shorter validation duration. MaxPlus Alpha 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](mailto:sales@packmaxq.com) if your validation test criteria are different than what is listed in this validation guide.

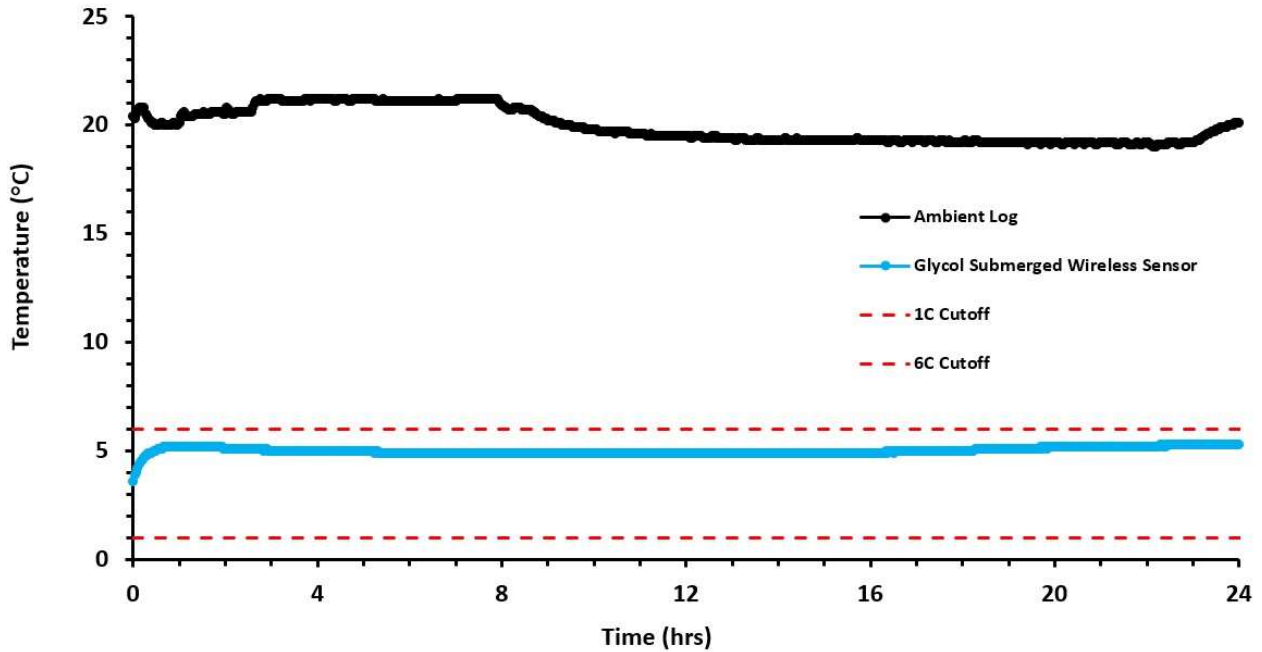
# Cooler Validation Results

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

### Test setup:

Container	MaxPlus Alpha Cooler (A12X24-PR)
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	Maximum: 10 units of 300mL water bags
Temperature data loggers	Payload - Wireless Sensor A340 Ambient temperature - MaxQ Logger 24*
	*Loggers were set to record temperature every 2 minutes
Ambient temperature	18 to 24°C
Test duration	24 hours

### Thermal performance:



### Thermal performance results

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)

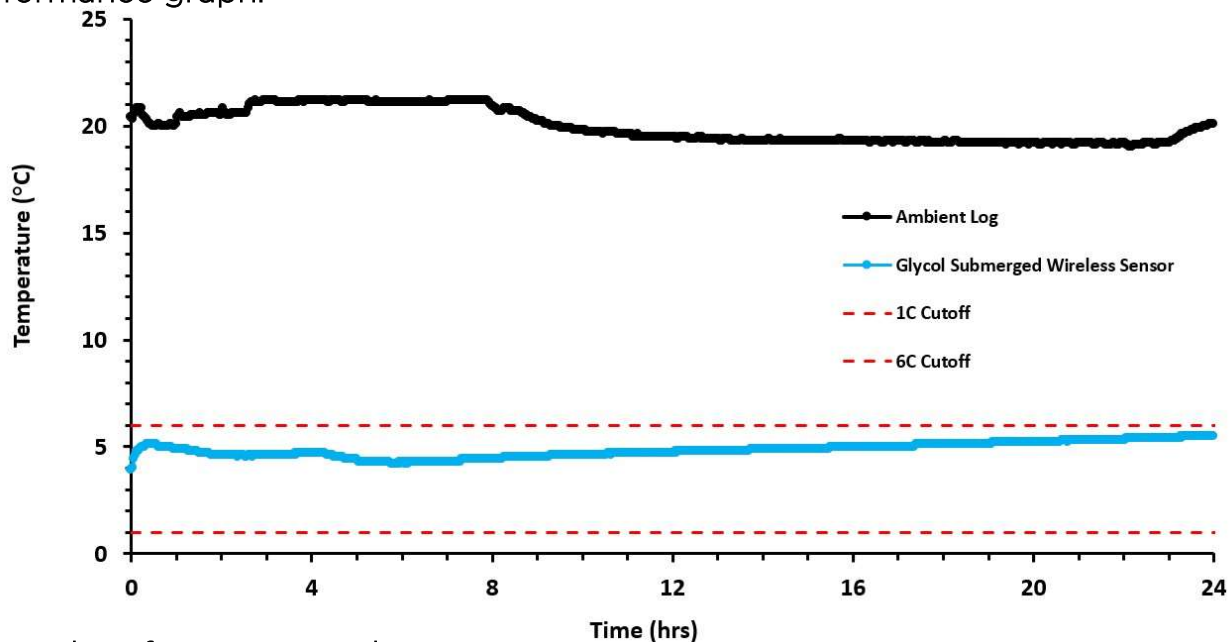
### Test setup:

Container	MaxPlus Alpha Cooler (A12X24-PR)
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	Minimum*: 2 units of 300mL water bags (See below)
Temperature data loggers	Payload -Wireless Sensor Ambient temperature - MaxQ Logger 23*  *Loggers were set to record temperature every 2 minutes
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).
- 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 inside the cooler was recorded and presented in the graph below.

### Performance graph:



### Thermal performance results:

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