

Prepared by: George Jett (Test Engineer),  
Approved by: Dr. Arif Rahman (Chief Technology Officer)

# **Design Qualification Report for the MaxOne Universal Blood Shipper – Summary of Pack-outs using Phase Change Coolants**



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# 1. Design Qualification for Transport of Warm Unprocessed Whole Blood Cooling Down Towards 20-24°C

## 1.1 Scope:

The scope of this section in the Design Qualification (DQ) report is to summarize the performance of MaxOne Universal Shipper (SKU#E17V48) for transporting warm unprocessed whole blood units. The report addresses basic shipper specifications, components breakdown, packing methods and temperature compliance data captured for the E17V48 to transport Warm Processed Whole Blood cooling towards 20-24°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 8 hours.

## 1.2 Product/payload Specifications:

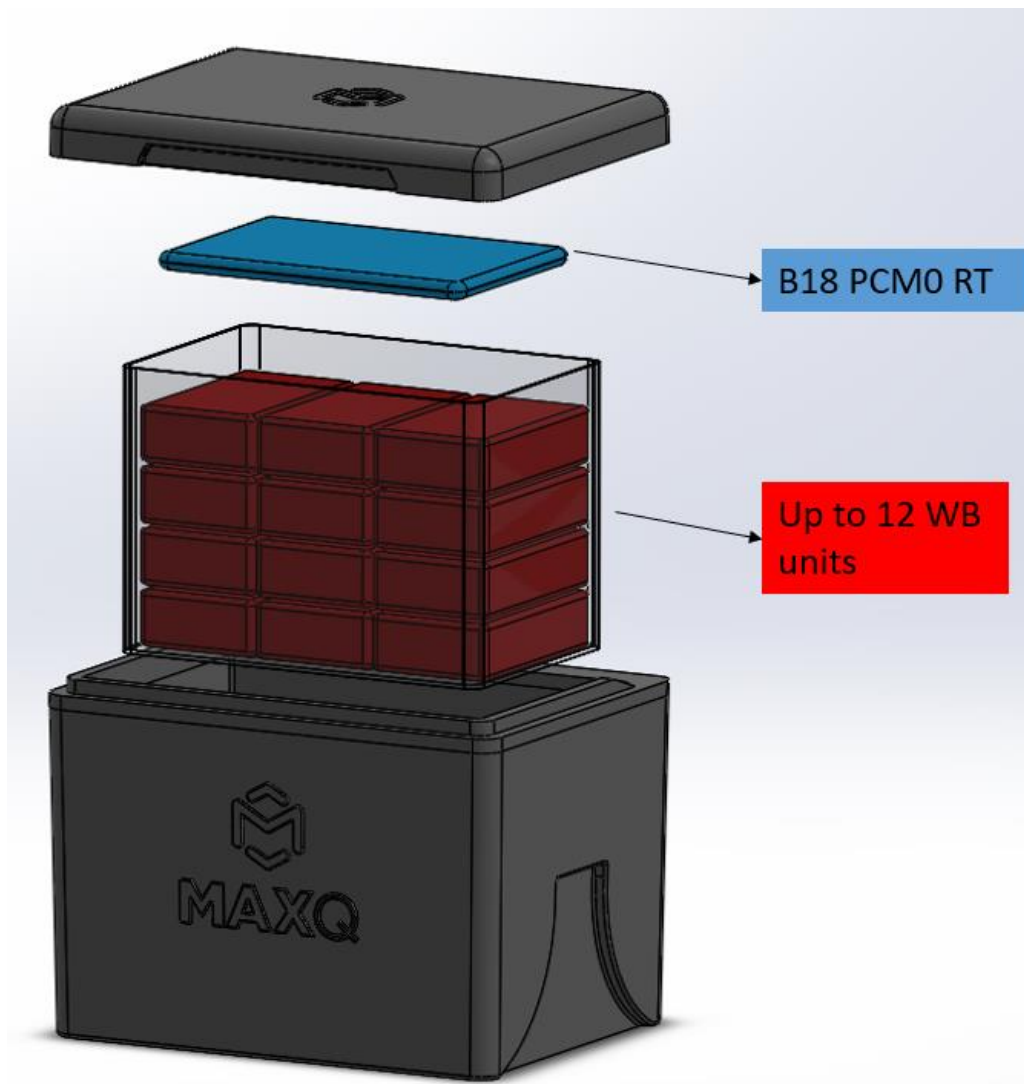
Type	Warm Processed Whole Blood
Form factor	Whole blood units
Volume	500mL per unit
Capacity	Up to 12x Unprocessed Whole Blood
Required Temperature	Cooling down towards 20-24°C
Validation Standard	8 hours against ISTA 7D standards

## 1.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.6 in x 13.4 in x 14 in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 in (LWH)
- System Weight (excluding payload): 16.3 lbs.
- Coolant: 1 x B18 PCM0 hard plastic bottle

## 1.4 Packing Methods

### 1.4.1 Packout Schematic:



### 1.4.2 Coolant Conditioning Procedure:

- 1 x B18 PCM0, Stored at Room Temperature

### 1.4.3 Packing Instructions:

- 1) Place up to 1-12 units of Unprocessed Whole Blood in the bottom of the container.
- 2) Place one room temperature B18 PCM0 on top of the units.
- 3) Place lid on top of box.

## 1.5 Test Methods and Results:

### 1.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) is designed to transport Unprocessed Whole Blood units cooling down to 20-24°C ( $\pm 0.5^{\circ}\text{C}$ ) for a minimum of 8 hours. Four different test cases were conducted to demonstrate the shipper's ability to maintain required temperature under the extreme ambient conditions following ISTA standards (GMP/GDP). Thermal chambers with NIST traceable calibration were programmed with 24-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 1.4 and placed inside a chamber for 8 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

### 1.5.2 Pass/Fail Criteria:

The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria:** Payload temperature was cooling towards 20-24°C ( $\pm 0.5^{\circ}\text{C}$ ) for the first 8 hours of the total test duration.

**Fail Criteria:** Payload temperature went below 20°C ( $\pm 0.5^{\circ}\text{C}$ ) during the first 8 hours of the total test duration.

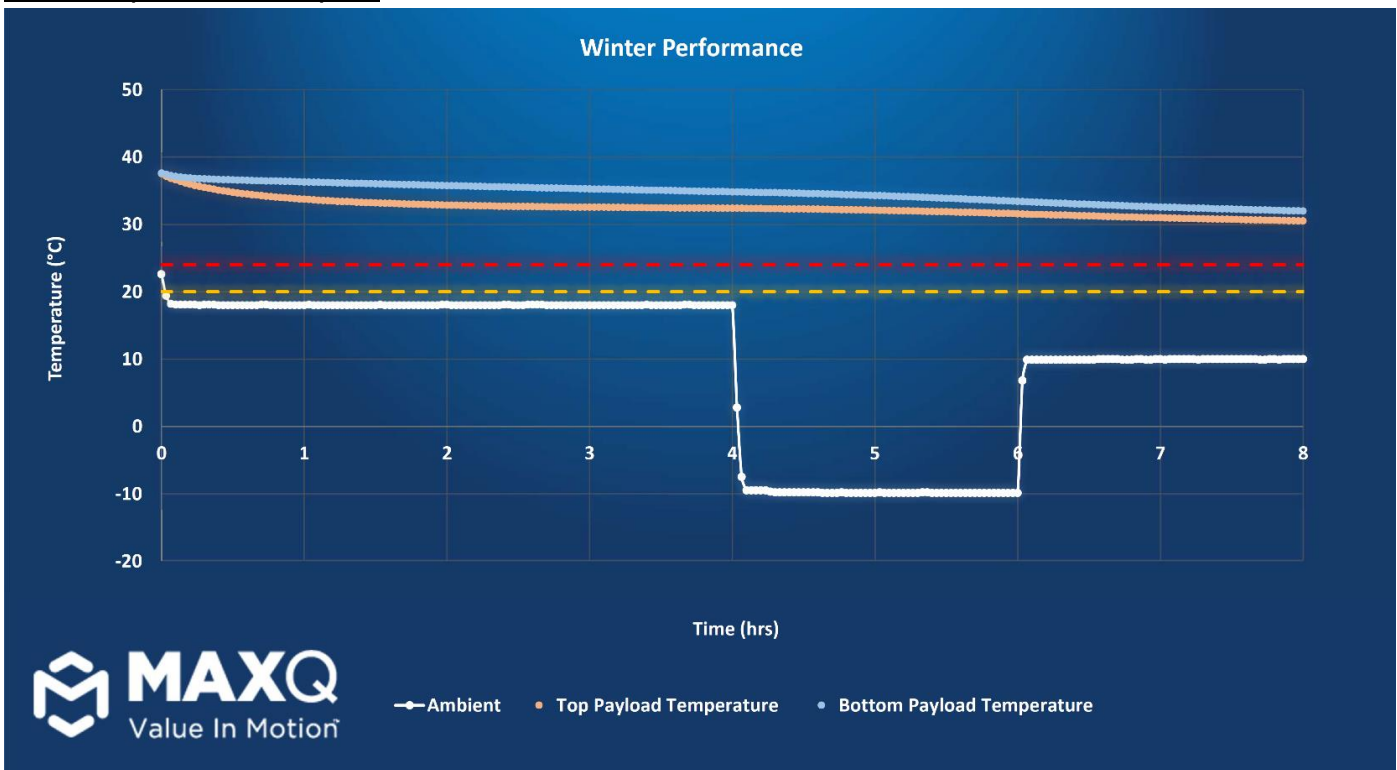
### 1.5.3 Test Results:

#### 1.5.3.1 Warm Unprocessed Whole Blood | Winter Ambient | Maximum Payload

Test setup:

Test payload	12 x 500mL mock Whole Blood units kept at 35-37 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	8 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

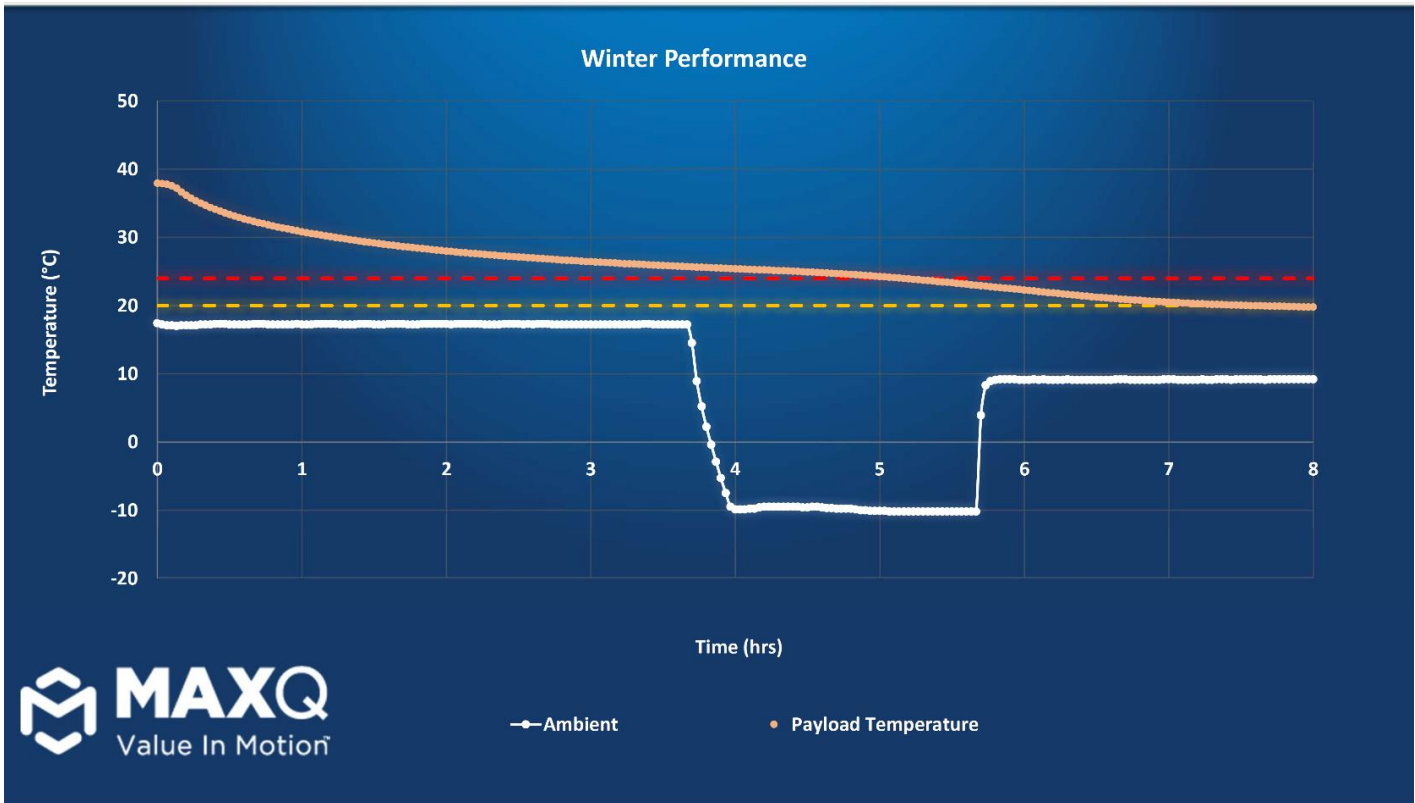
Total time (hours) payload-cooling towards 20-24°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
8	8	30.5	31.9

### 1.5.3.2 Warm Unprocessed Whole Blood | Winter Ambient | Minimum Payload

Test setup:

Test payload	1 x 500mL mock Whole Blood units kept at 35-37 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	8 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 20-24°C	Minimum payload temperature during tested duration (°C)
8	19.8

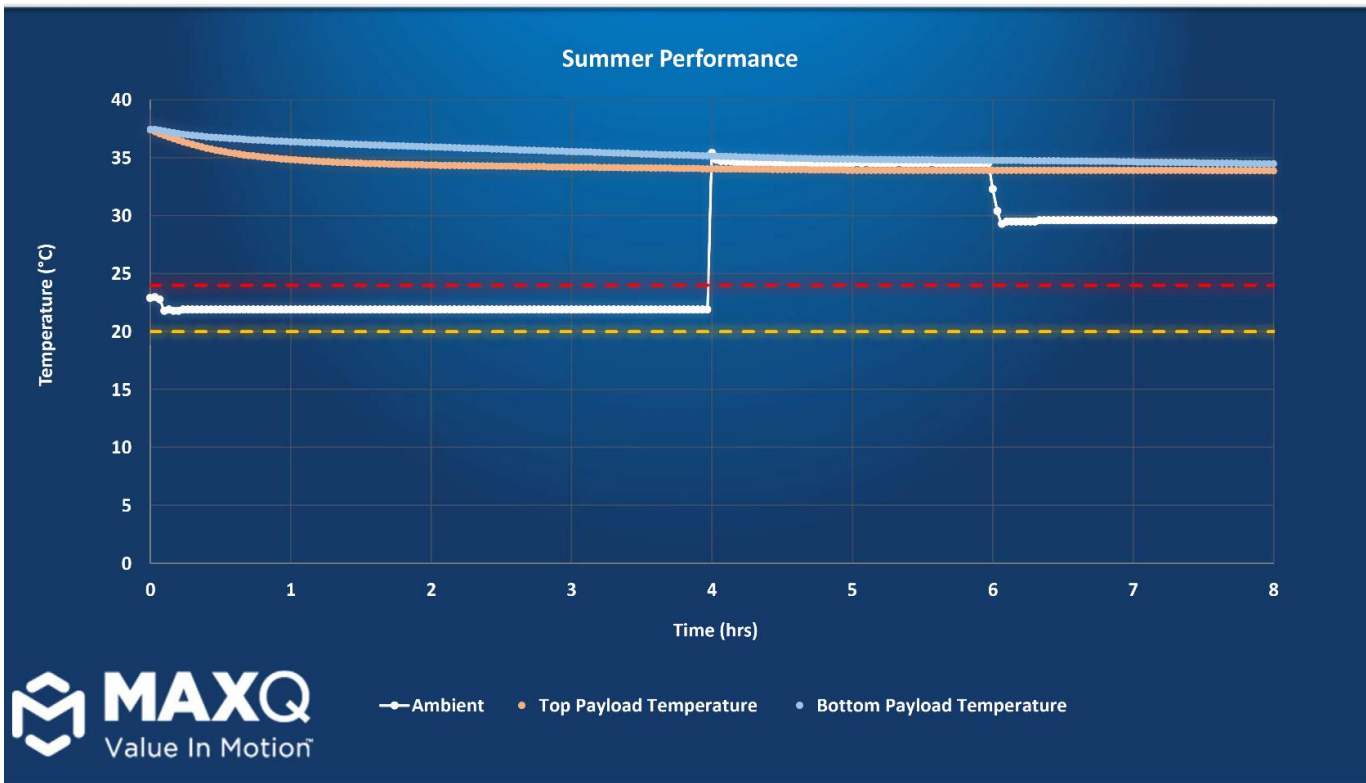


### 1.5.3.3 Warm Unprocessed Whole Blood | Summer Ambient | Maximum Payload

Test setup:

Test payload	12 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	Summer Ambient
Test duration	8 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 20-24°C		Maximum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
8	8	33.9	34.5

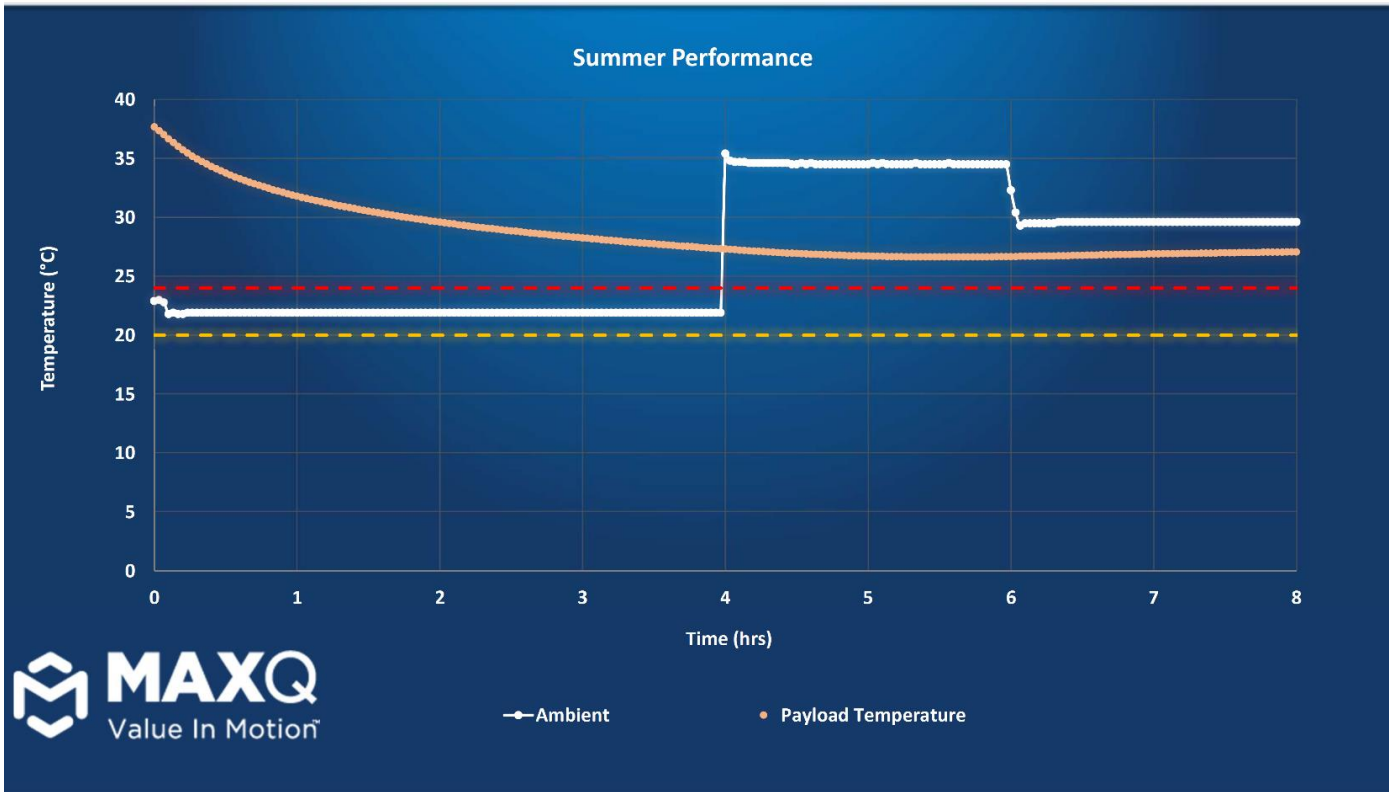


### 1.5.3.4 Warm Unprocessed Whole Blood | Summer Ambient | Minimum Payload

Test setup:

Test payload	1 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	Summer Ambient
Test duration	8 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 20-24°C	Maximum payload temperature during tested duration (°C)
8	27.1

## 2. Design Qualification for Transport of Warm Unprocessed Whole Blood Cooling Down towards 1-10°C using Phase Change Material

### 2.1 Scope:

The scope of this section in the Design Qualification (DQ) report is to summarize the performance of MaxOne Universal Shipper (SKU#E17V48) for transporting warm unprocessed whole blood. The report addresses basic shipper specifications, components breakdown, packing methods and temperature compliance data captured for the E17V48 to transport Warm Unprocessed Whole Blood cooling towards 1-10°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 24 hours.

### 2.2 Product/Payload Specifications:

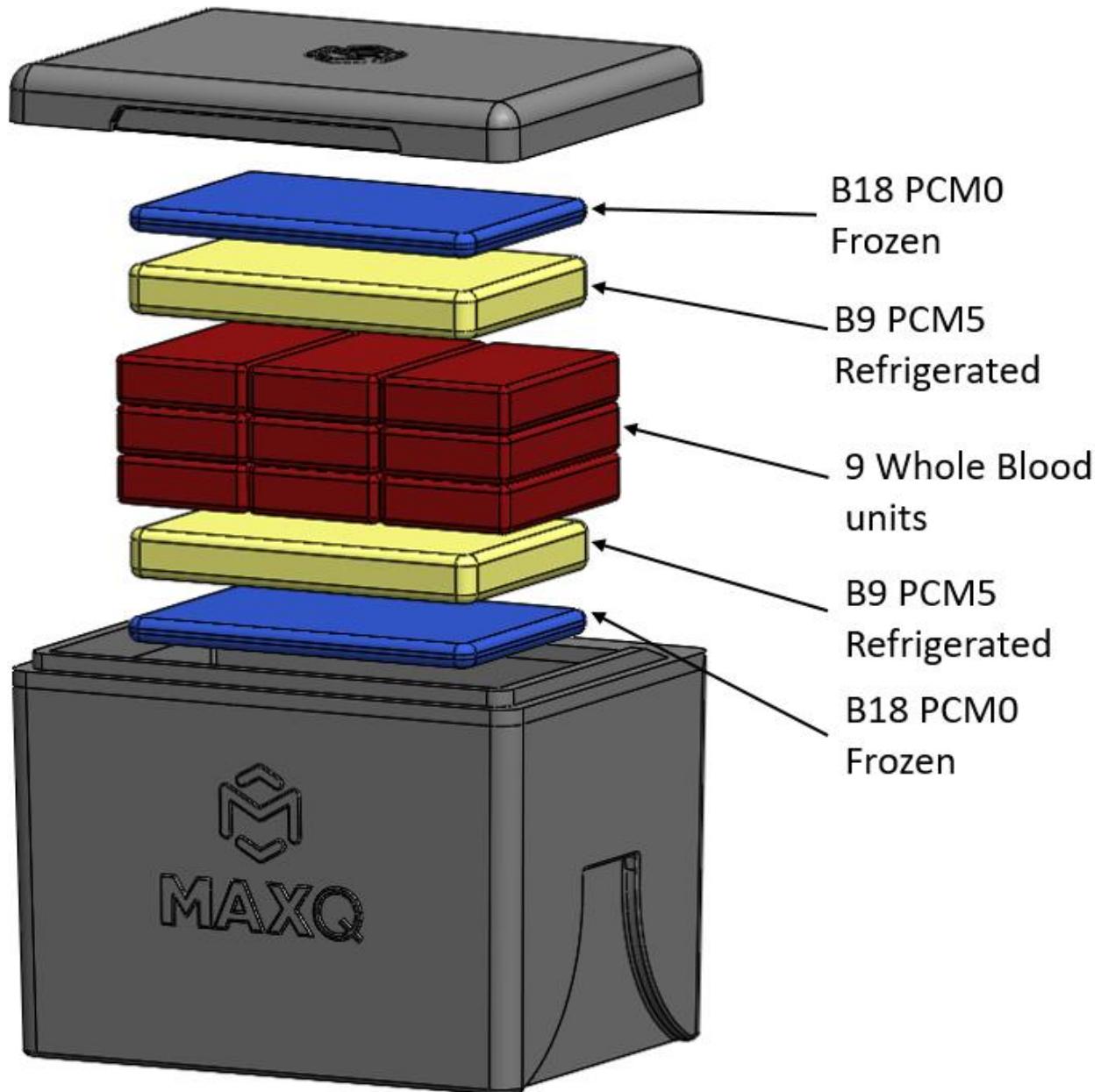
Type	Warm Unprocessed Whole Blood
Form factor	Whole Blood Unit
Volume	~500mL per unit
Capacity	Up to 9x Unprocessed Whole Blood units
Required Temperature	Cooling down towards 1-10°C ( $\pm 0.5^\circ\text{C}$ )
Validation Standard	24 hours against ISTA 7D standards

### 2.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.6 in x 13.35 in x 14 in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 in (LWH)
- System Weight (excluding payload): 19.7 lbs.
- Coolant: 2 x B18 PCM0 bottles (blue) and 2 x B9 PCM5 bottles (yellow)

## 2.4 Packing Methods

### 2.4.1 Packout Schematic:



### 2.4.2 Coolant Conditioning Procedure:

- 2 x B18 PCM0 (blue) frozen below  $-20^{\circ}\text{C}$  for a minimum of 24 hours
- 2 x B9 PCM5 (yellow) refrigerated between  $1 - 6^{\circ}\text{C}$  for a minimum of 24 hours

### 2.4.3 Packing Instructions:

- 1) Place one frozen B18 PCM0 (blue) in the bottom of the box.
- 2) Place one Refrigerated B9 PCM5 (yellow) on top of the B18 PCM0.
- 3) Place up to 9 units of Unprocessed Whole Blood units on top of the coolant bottles.
- 4) Place one Refrigerated B9 PCM5 (yellow) on top of the payloads.
- 5) Place the Final Frozen B18 PCM0 (blue) on top of the B9 PCM5.
- 6) Place lid on top of box.

## **2.5 Test Methods and Results:**

### 2.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) with two B18 PCM0's frozen and two B9 PCM5's refrigerated is designed to transport warm unprocessed whole blood cooling down towards 1-10°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 24 hours. Four different test cases were conducted to demonstrate the shipper's ability to maintain required temperature under the extreme ambient conditions following ISTA standards (GMP/GDP). Thermal chambers with NIST traceable calibration were programmed with 24-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 2.4 and placed inside a chamber for 24 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

### 2.5.2 Pass/Fail Criteria:

The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria:** Payload temperature was cooling towards 1-10°C ( $\pm 0.5^\circ\text{C}$ ) during the 24 hours of test duration.

**Fail Criteria:** Payload temperature went below 1°C ( $\pm 0.5^\circ\text{C}$ ) during the 24 hours of test duration.

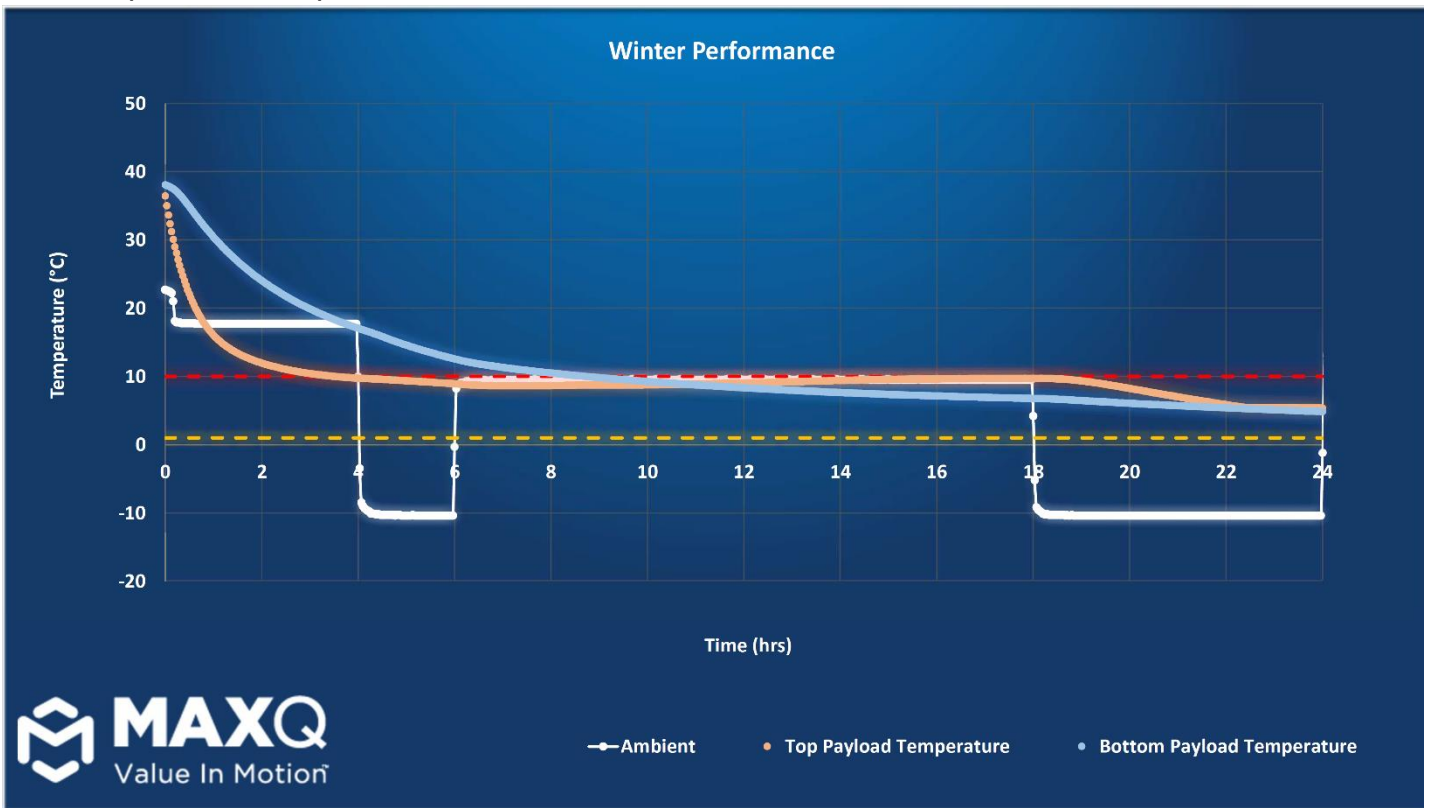
### 2.5.3 Test Results:

#### 2.5.3.1 Warm Unprocessed Whole Blood | Winter Ambient | Maximum Payload

Test setup:

Test payload	9 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	24 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

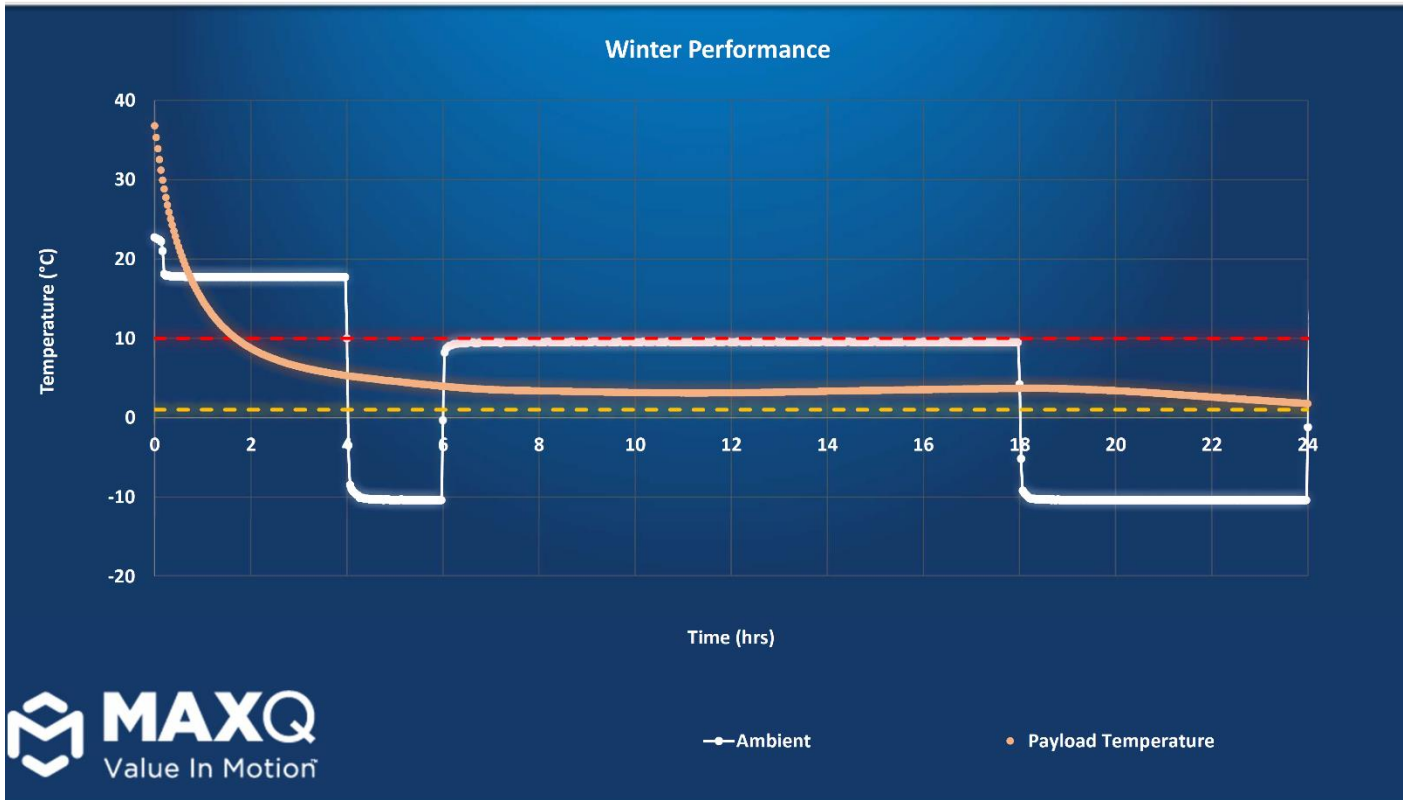
Total time (hours) payload-cooling towards 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
24	24	5.3	4.8

### 2.5.3.2 Warm Unprocessed Whole Blood | Winter Ambient | Minimum Payload

Test setup:

Test payload	1 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	24 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 1-10°C	Minimum payload temperature during tested duration (°C)
24	1.7

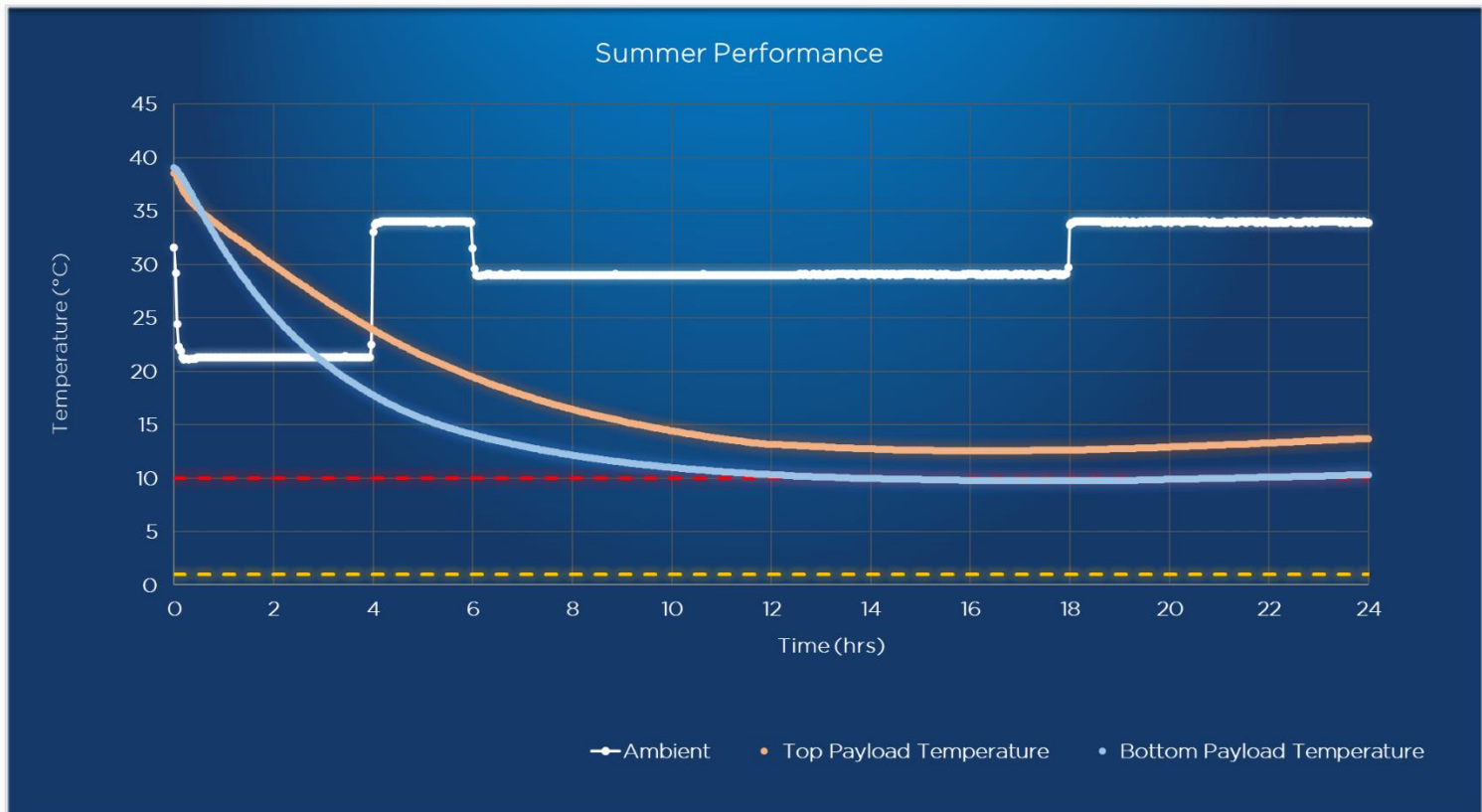


### 2.5.3.3 Warm Processed Whole Blood | Summer Ambient | Maximum Payload

Test setup:

Test payload	9 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	Summer Ambient
Test duration	24 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
24	24	12.5	9.7

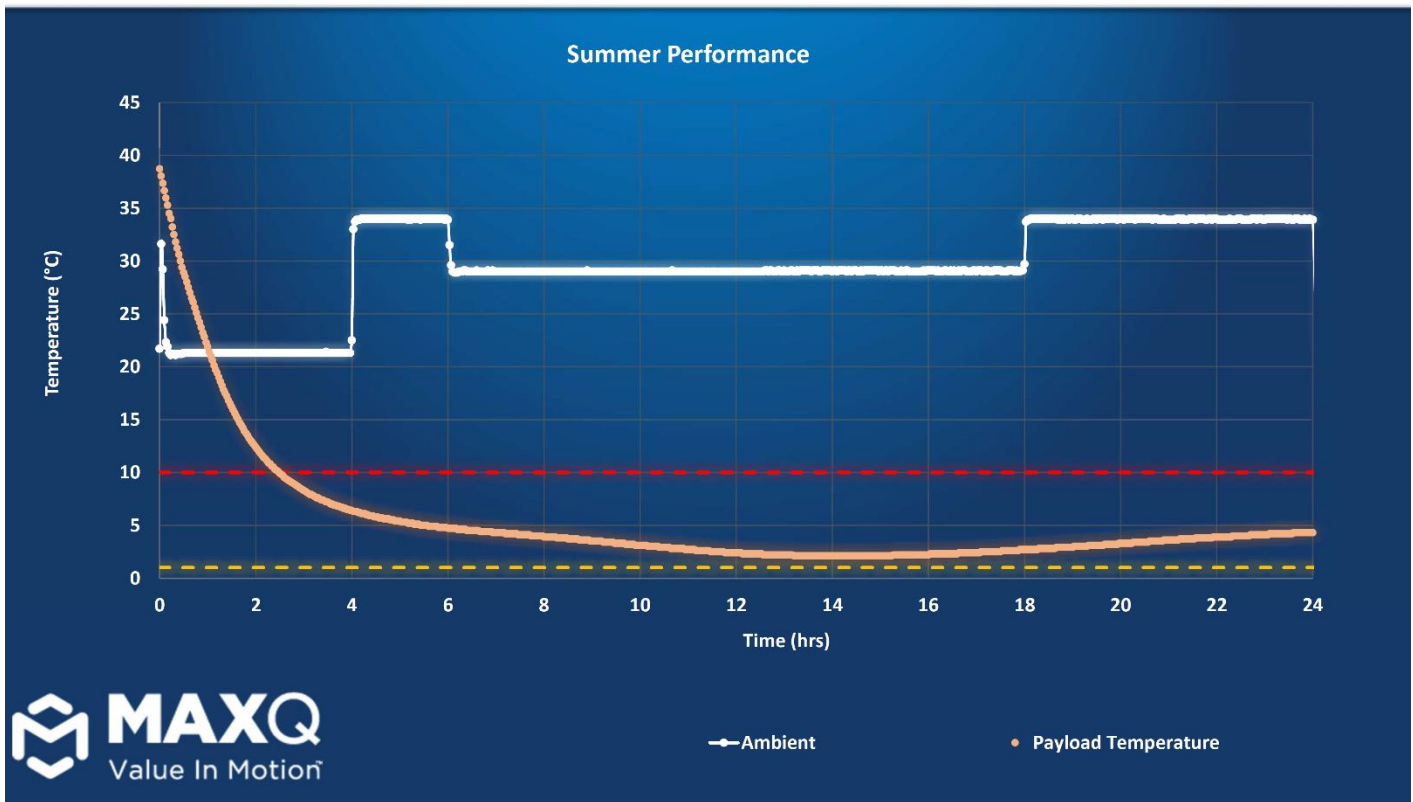


2.5.3.4 Warm Processed Whole Blood | **Summer Ambient** | **Minimum Payload**

Test setup:

Test payload	1 x 500mL mock Whole Blood units kept at 36-38 °C for 12 hours
Ambient temperature	<b>Summer Ambient</b>
Test duration	24 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-cooling towards 1-10°C	Minimum payload temperature during tested duration (°C)
24	2.1

### 3. Design Qualification for transport of refrigerated RBC units between 1-10°C using Phase Change Material

#### 3.1 Scope:

The scope of this section in the Design Qualification (DQ) report is to summarize the performance of MaxOne Universal Shipper (SKU#E17V48) for transporting refrigerated Red Blood Cell units. The report addresses basic shipper specifications, components breakdown, packing methods and thermal performance data captured for the E17V48 to transport refrigerated Red Blood Cells at 1-10°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 48 hours.

#### 3.2 Product/Payload Specifications:

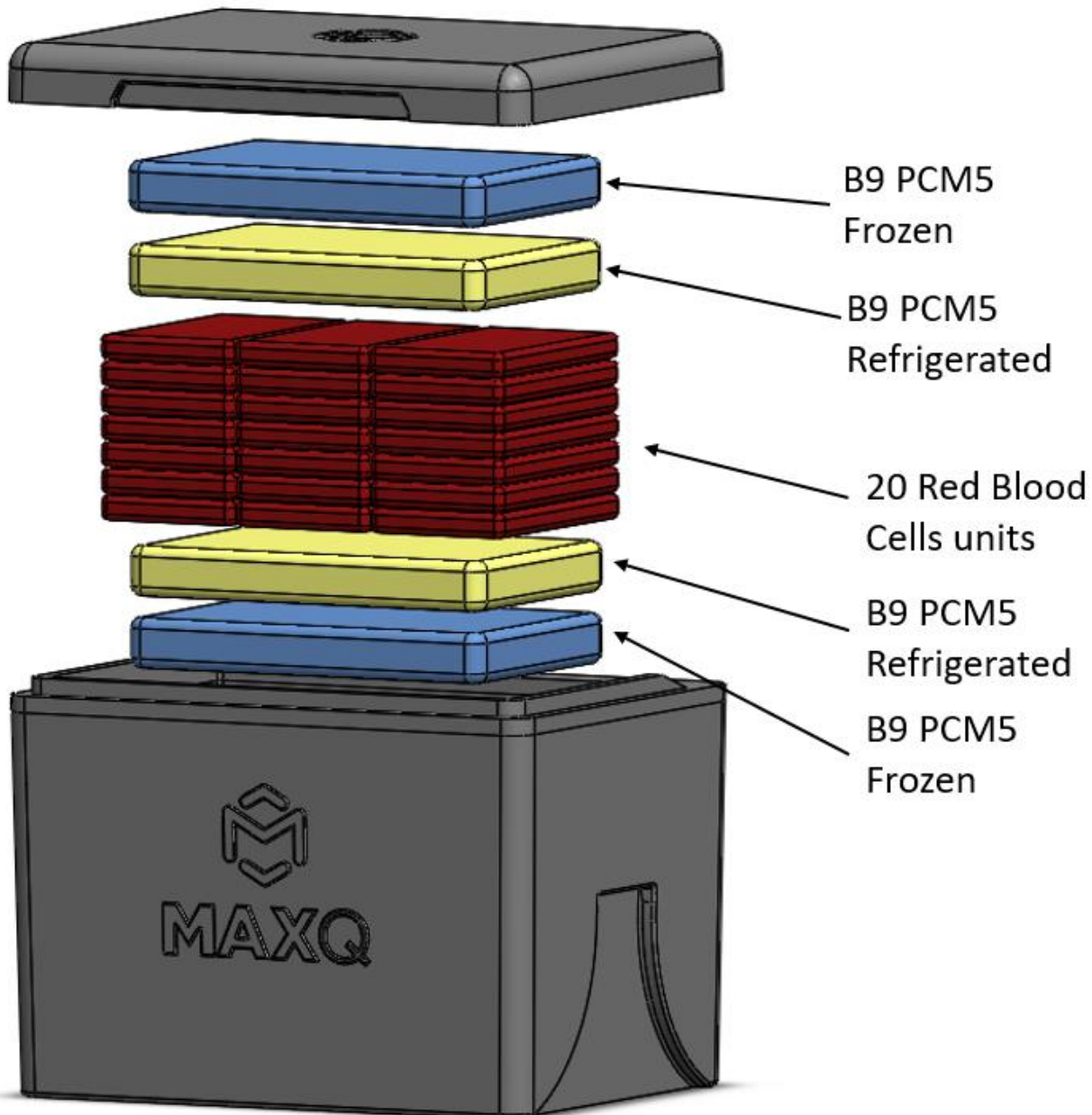
Type	Refrigerated Red Blood Cells / Plasma
Volume	300-350mL per unit
Capacity	Up to 20x Processed Red Blood Cell units
Required Temperature	1-10°C ( $\pm 0.5^\circ\text{C}$ )
Validation Standard	48 hours against ISTA 7D ambient conditions

#### 3.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable, and highly reusable
- Outer Dimensions: 17.6 x 13.4 in x 14 in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.4 in (LWH)
- System Weight (excluding payload): 21.1 lbs.
- Coolant: 4 x B9 PCM5 bottles (Yellow)

### 3.4 Packing Methods

#### 3.4.1 Packout Schematic (1-10°C):



#### 3.4.2 Coolant Conditioning Procedure:

- Two B9's (yellow) PCM5 Bottles in a Refrigerator
- Two B9's (yellow) PCM5 Bottles in a Freezer

### 3.4.3 Packing Instructions:

- 1) Place one frozen B9 PCM5 (yellow) bottle in the bottom of the box.
- 2) Place one refrigerated B9 PCM5 (yellow) bottle on top of the Frozen PCM5 (blue) bottle.
- 3) Place up to 20 refrigerated Red Blood Cell units on top of the coolants.
- 4) Place one refrigerated B9 PCM5 (yellow) bottle on top of the units.
- 5) Place the final frozen B9 PCM5 (yellow) bottle on top.
- 6) Close the lid.

## **3.5 Test Methods and Results:**

### 3.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) with two B9 PCM5's frozen and Two B9 PCM5's refrigerated is designed to maintain Red Blood Cell units between 1-10°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 48 hours. Four different test cases were conducted to demonstrate the shipper's ability to maintain required temperature under the extreme ambient conditions following ISTA standards (GMP/GDP). Thermal chambers with NIST traceable calibration were programmed with 48-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 3.4 and placed inside a chamber for 48 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

### 3.5.2 Pass/Fail Criteria:

The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria:** Payload temperature was maintained between 1-10°C ( $\pm 0.5^\circ\text{C}$ ) during the first 48 hours of the total test duration.

**Fail Criteria:** Payload temperature went above 10°C ( $\pm 0.5^\circ\text{C}$ ) or below 1°C ( $\pm 0.5^\circ\text{C}$ ) during the first 48 hours of the total test duration.

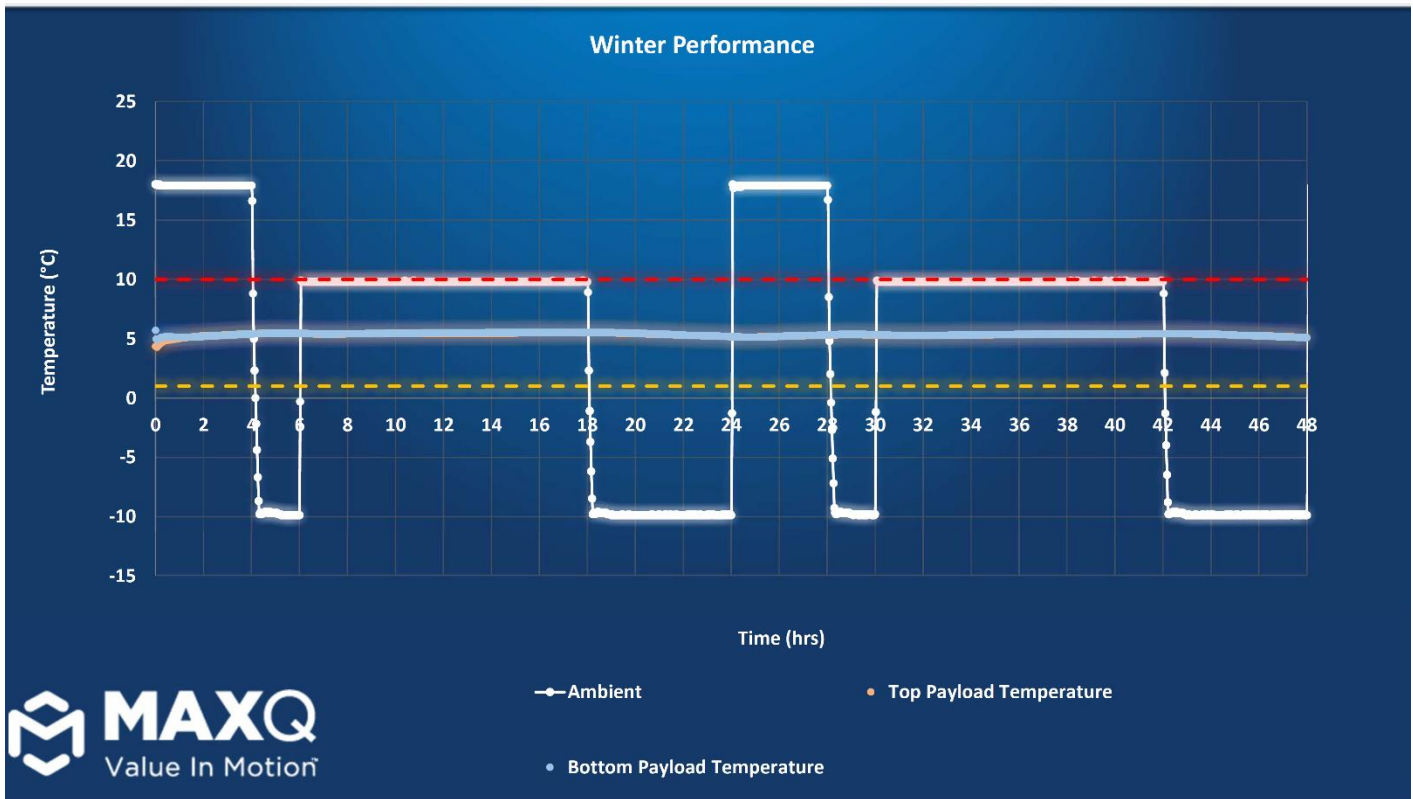
### 3.5.3 Test Results:

#### 3.5.3.1 Chilled Red blood Cells (1-10°C) | Winter Ambient | Maximum Payload

Test setup:

Test payload	20 x 300-350mL mock Red Blood Cell units kept at 1-6°C for 12 hrs.
Ambient temperature	Winter Ambient
Test duration	48 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

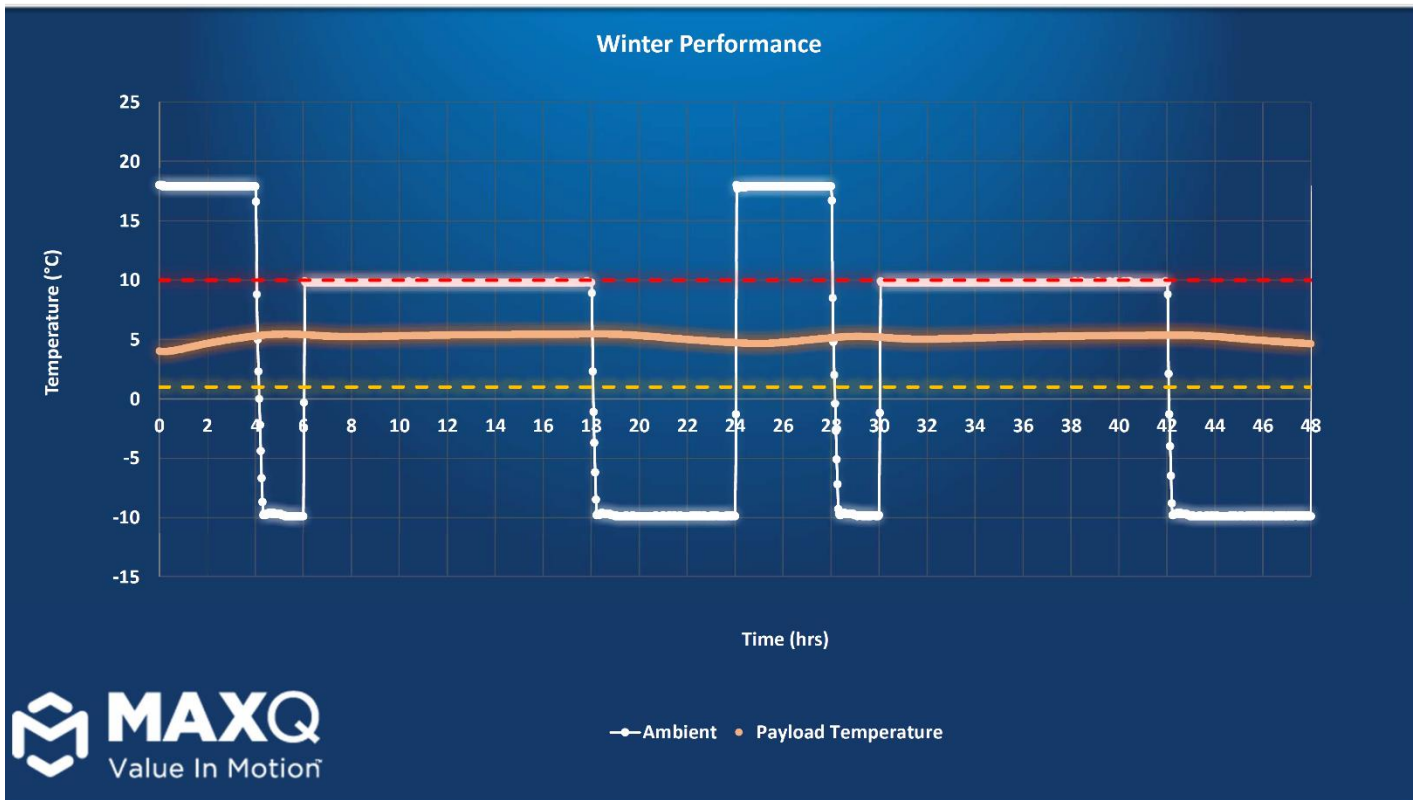
Total time (hours) payload-maintained 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
48	48	4.2	4.9

### 3.5.3.2 Chilled Red blood Cells (1-10°C) | Winter Ambient | Minimum Payload

Test setup:

Test payload	1 x 300-350mL mock Red Blood Cell units kept at 1-6°C for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 1-10°C	Minimum payload temperature during tested duration (°C)
48	4

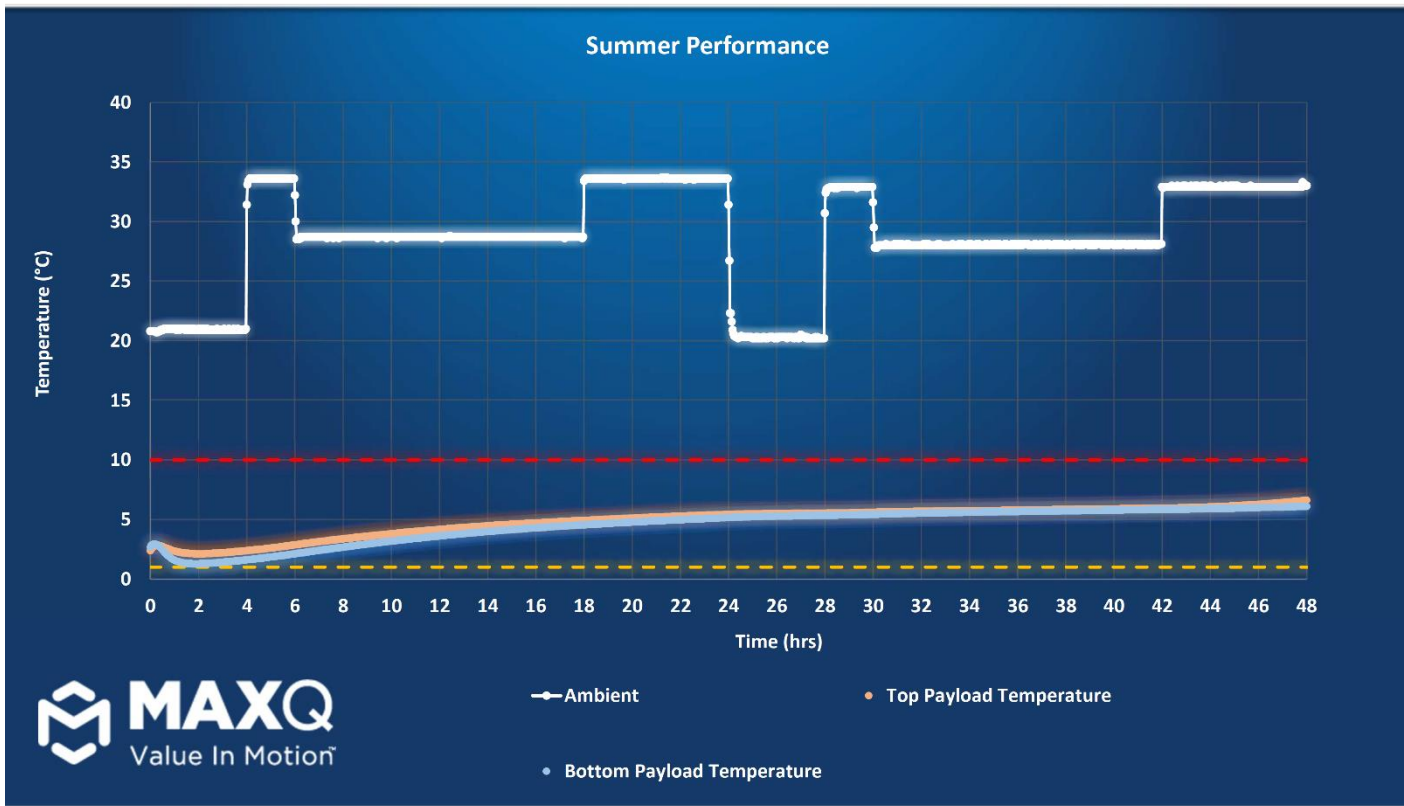


### 3.5.3.3 Chilled Red blood Cells (1-10°C) | Summer Ambient | Maximum Payload

**Test setup:**

Test payload	20 x 300-350mL mock Red Blood Cell units kept at 1-6°C for 12 hours
Ambient temperature	Summer Ambient
Test duration	48 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

**Thermal performance plot:**



**Observations:** The following table summarizes payload temperature data.

Total time (hours) payload-maintained 1-10°C		Maximum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
48	48	6.6	6.1

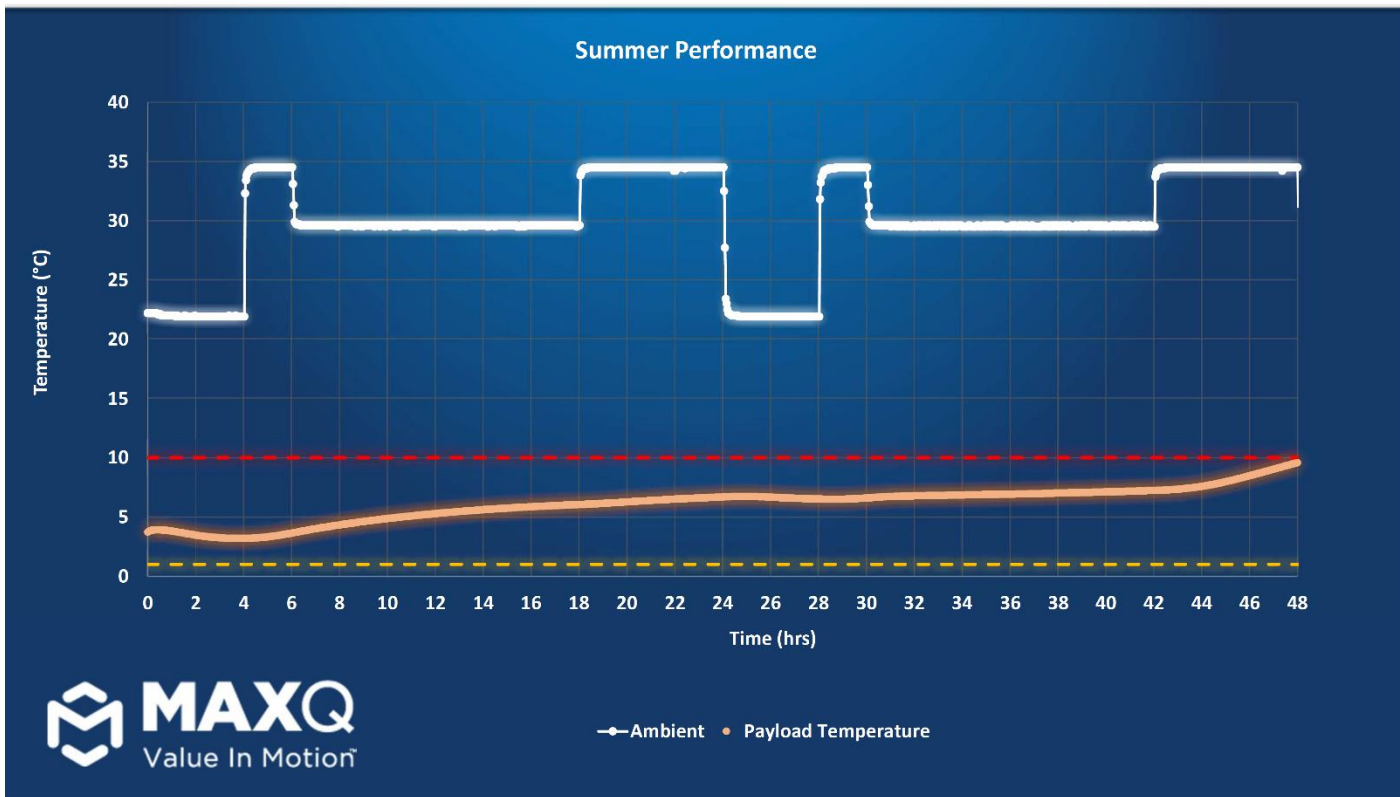


### 3.5.3.4 Chilled Red blood Cells (1-10°C) | Summer Ambient | Minimum Payload

**Test setup:**

Test payload	1 x 300-350mL mock Red Blood Cell units kept at 1-6°C for 12 hours
Ambient temperature	Summer Ambient
Test duration	48 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 1-10°C	Maximum payload temperature during tested duration (°C)
48	9.6

## 4. Design Qualification for Transport of Room Temperature Platelets using Phase Change Material

### 4.1 Scope:

The scope of this section in the Design Qualification (DQ) report is to summarize the performance of MaxOne Universal Shipper (SKU#E17V48) for transporting Controlled Room Temperature (CRT) Platelet units. The report addresses basic shipper specifications, components breakdown, packing methods and thermal performance data captured for the E17V48 to transport CRT Platelet units at 20-24°C ( $\pm 0.5^{\circ}\text{C}$ ) for a minimum of 40 hours.

### 4.2 Product/Payload Specifications:

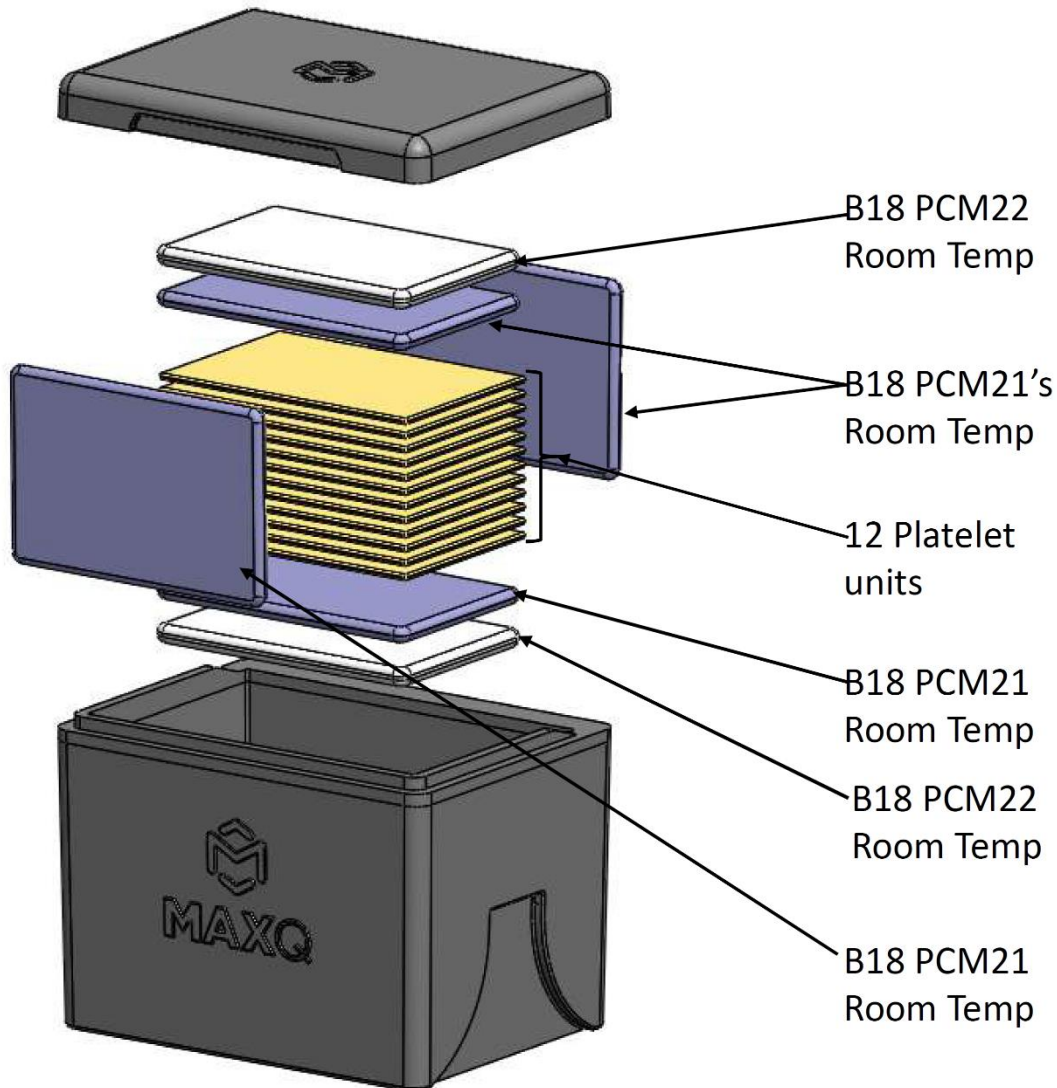
Type	Room Temperature Platelet
Form factor	Cerus Pathogen Reduced Platelet bags
Volume	350-400mL per unit
Capacity	Up to 12x Room Temperature Platelet units
Required Temperature	Between 20-24°C ( $\pm 0.5^{\circ}\text{C}$ )
Validation Standards	48 hours against ISTA 7D standards

### 4.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.6 in x 13.4 in x 14 in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 in (LWH)
- System Weight (excluding payload): 14.5 lbs.
- Coolant: 2 x B18 PCM22 (clear/off white) bottles and 4 x B18 PCM21 (purple/blue) bottles

## 4.4 Packing Methods

### 3.4.1 Packout Schematic:



### 4.4.2 Coolant Conditioning Procedure:

- All bottles come from Room Temperature.

#### 4.4.3 Packing Instructions:

1. Place one Room temperature PCM22 B18 (clear/off white) in the very bottom of the box
2. Place one PCM21 B18 (purple/blue) bottle on top of the PCM22 B18 (clear/off white)
3. Place Up to 12 units of Room Temperature Platelet units on top of the bottles.
4. Place two PCM21 B18 bottles (purple/blue) on the front and back walls of the container.
5. Place one Room Temperature PCM21 B18 (purple/Blue) on top of Platelet units
6. Place one PCM22 B18 (clear/off white) on top.
7. Close the lid.

### **4.5 Test Methods and Results:**

#### 4.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) is designed to transport CRT Platelets between 20-24°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 48 hours. Four different test cases were conducted to demonstrate the shipper's ability to maintain required temperature under the extreme ambient conditions following ISTA standards (GMP/GDP). Thermal chambers with NIST traceable calibration were programmed with 48-hour summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 4.4 and placed inside a chamber for 48 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

#### 4.5.2 Pass/Fail Criteria:

The below criteria were used to determine the pass or failure of each test case.

**Pass Criteria:** Payload temperature was between 20-24°C ( $\pm 0.5^\circ\text{C}$ ) during the first 40 hours of the test duration.

**Fail Criteria:** Payload temperature went above 24°C ( $\pm 0.5^\circ\text{C}$ ) or below 20°C ( $\pm 0.5^\circ\text{C}$ ) during the first 40 hours of test duration.

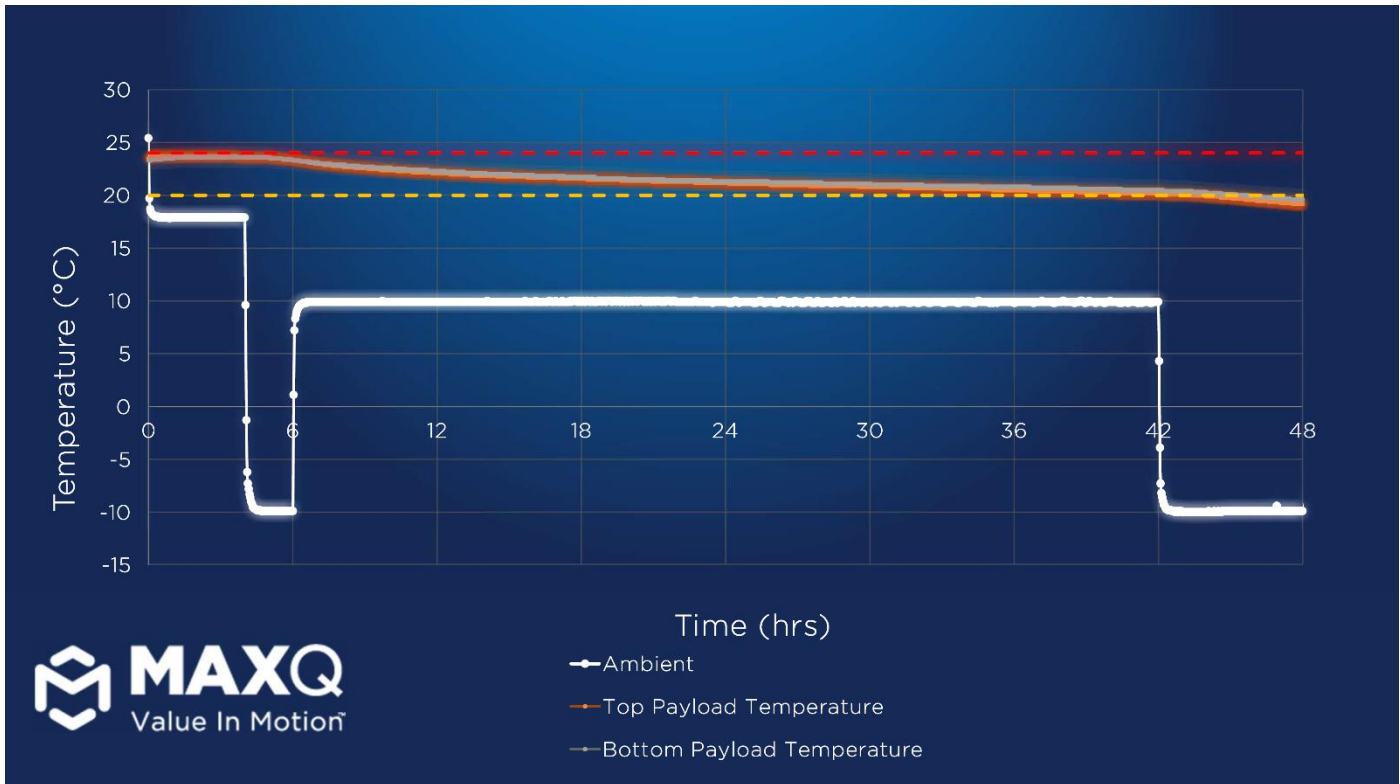
### 4.5.3 Test Results:

#### 4.5.3.1 Room Temperature Platelets (Between 20-24°C) | Winter Ambient | Maximum Payload

Test setup:

Test payload	12 x 350-400mL mock Platelet units kept at 20-24 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

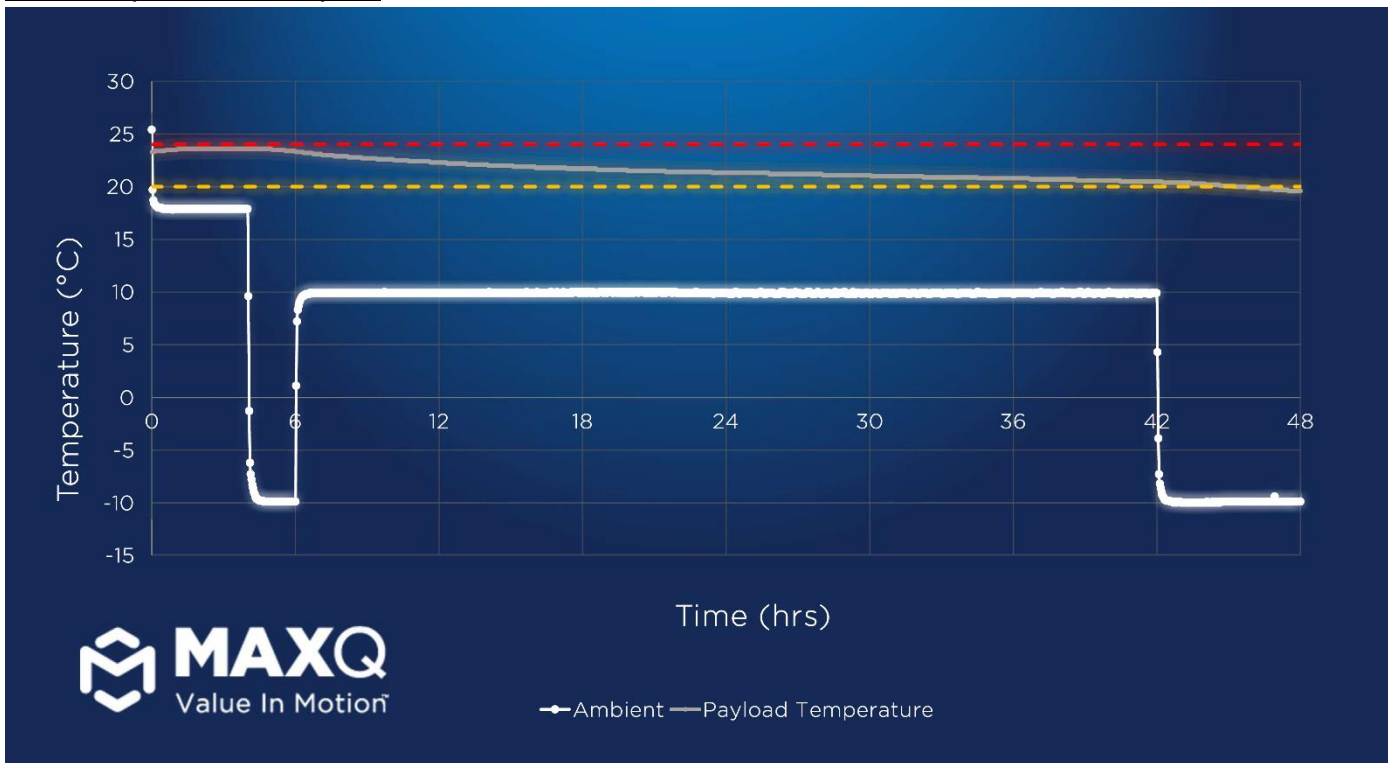
Total time (hours) payload-maintained between 20-24°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
46	48	19.2	19.6

### 4.5.3.2 Room Temperature Platelets (Between 20-24°C) | Winter Ambient | Minimum Payload

**Test setup:**

Test payload	1 x 350-400mL mock Platelet units kept at 20-24 °C for 12 hours
Ambient temperature	Winter Ambient
Test duration	48 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

**Thermal performance plot:**



**Observations:** The following table summarizes payload temperature data.

Total time (hours) payload-maintained 20-24°C	Minimum payload temperature during tested duration (°C)
48	19.6

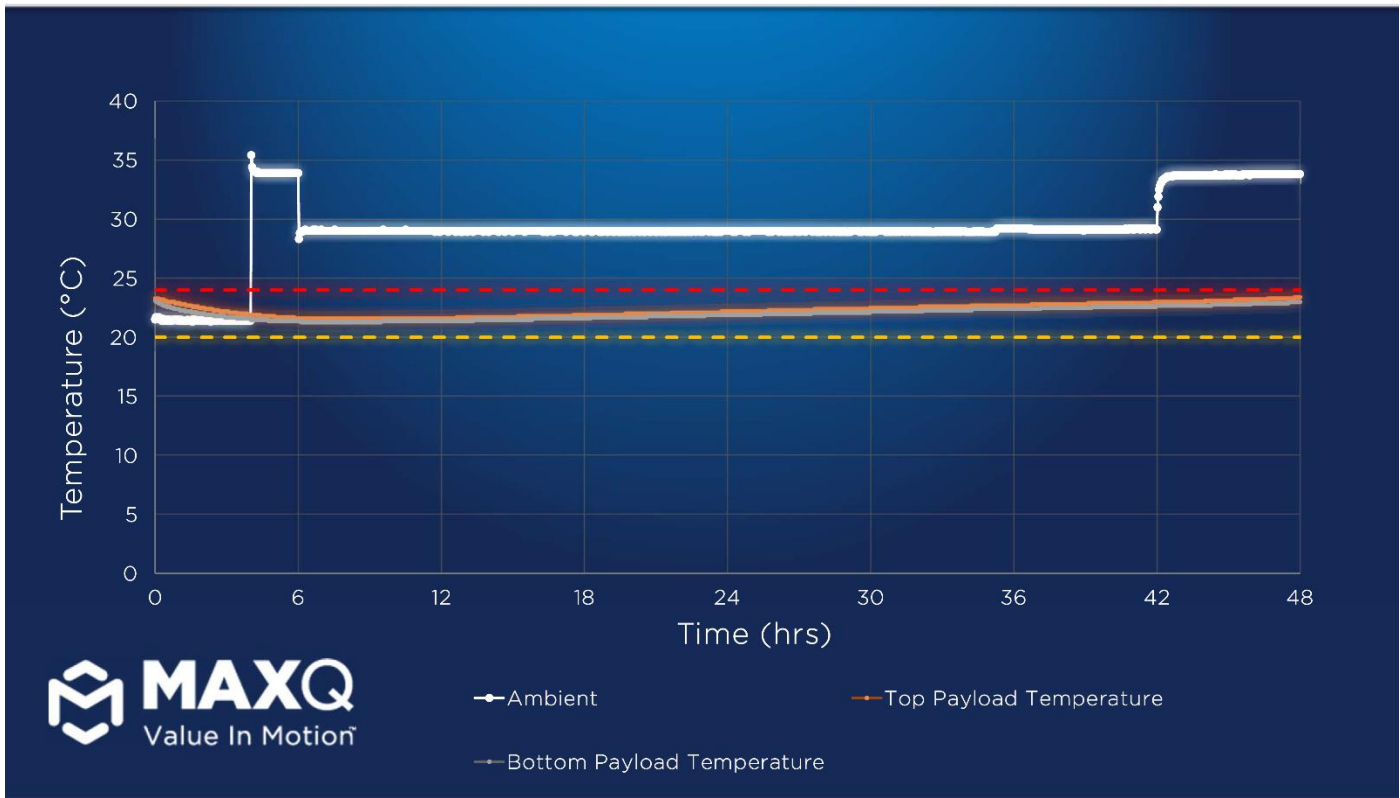


4.5.3.3 Room Temperature Platelets (Between 20-24°C) | **Summer Ambient** | **Maximum Payload**

Test setup:

Test payload	12 x 350-400mL mock Platelet units kept at 20-24 °C for 12 hours
Ambient temperature	<b>Summer Ambient</b>
Test duration	48 hours
Payload temp. measurement	Two NIST calibrated temperature probes were used. One attached to a simulant unit near top of the shipper, and other attached to a unit placed near the bottom of the shipper.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained between 20-24°C		Maximum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
48	48	23.4	23

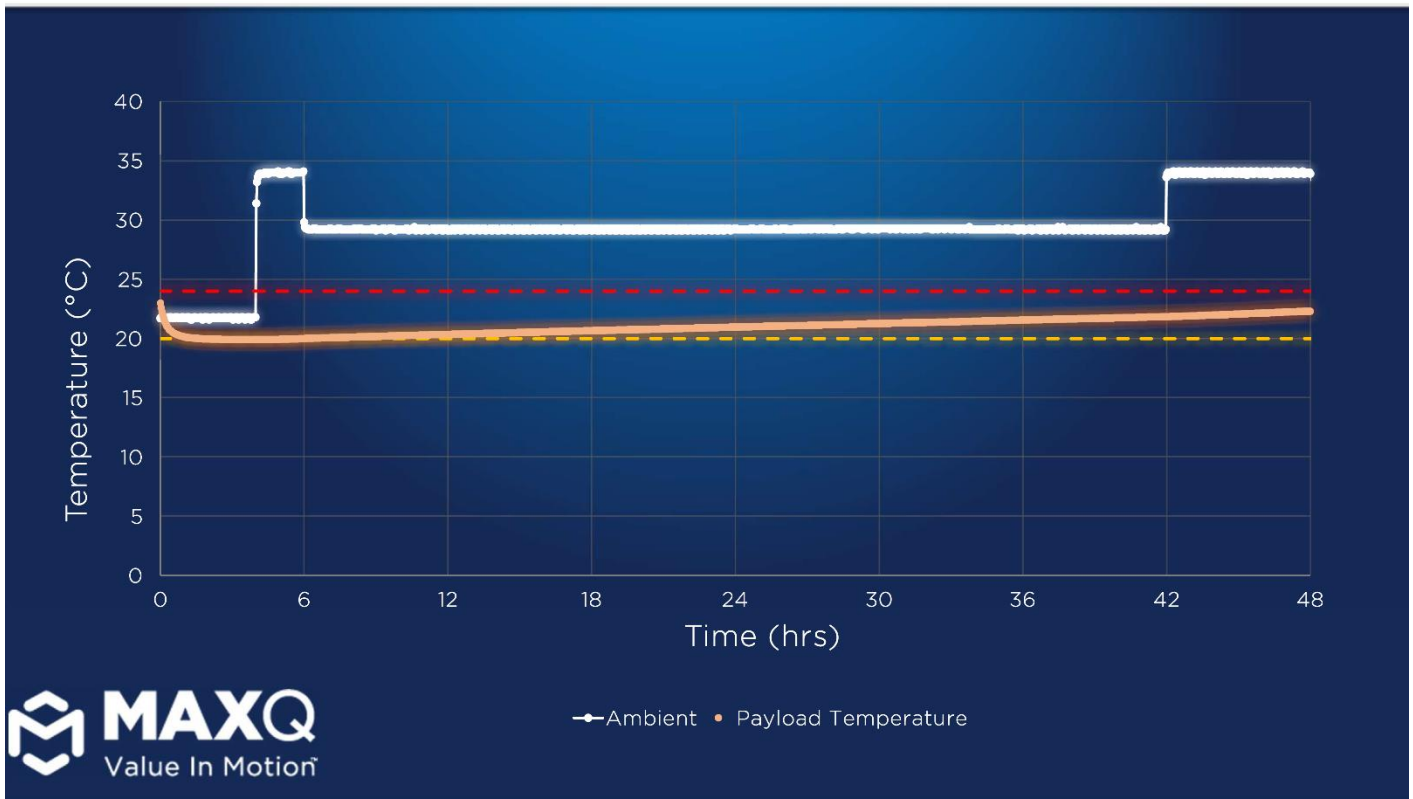


4.5.3.4 Room Temperature Platelets (Between 20-24°C) | **Summer Ambient** | **Minimum Payload**

Test setup:

Test payload	1 x 300-350mL mock Platelet units kept at 20-24 °C for 12 hours
Ambient temperature	<b>Summer Ambient</b>
Test duration	48 hours
Payload temp. measurement	One NIST calibrated temperature probe was attached to the simulant unit.

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 20-24°C	Maximum payload temperature during tested duration (°C)
48	22.3

## Revision History:

Revision Number	Revision Date	Revision Description	Revised by	Approved by
V1.0	6-14-23	Original document	George Jett	Dr. Arif Rahman