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# Design Qualification Report for the MaxOne Universal Blood Shipper



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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:

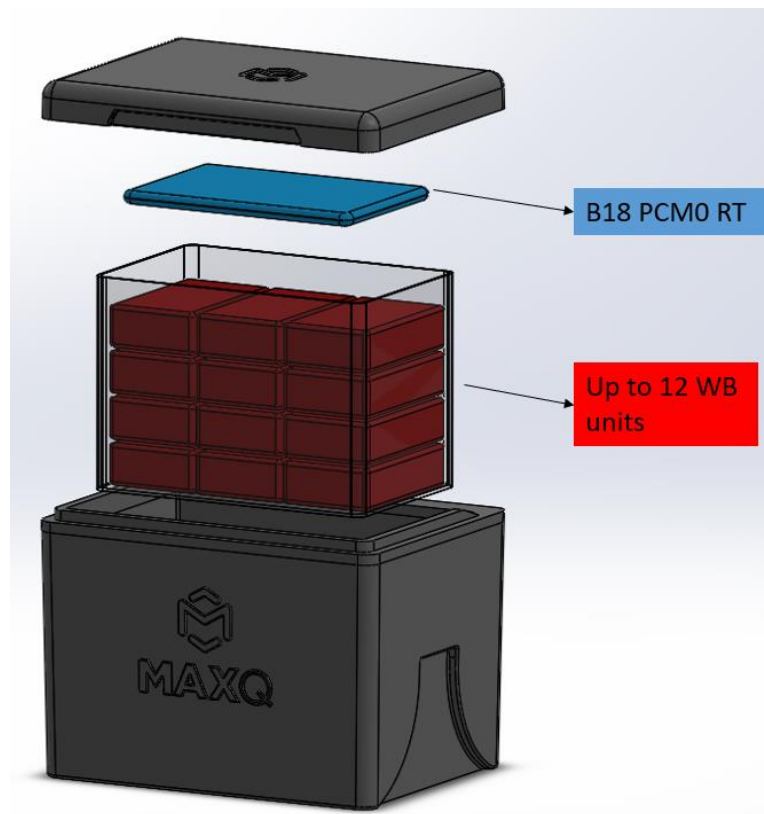
Type	Warm Processed Whole Blood
Form factor	Whole blood units
Volume	500mL per unit
Capacity	Up to 12x Unprocessed Whole Blood
Required Temperature	Cooling down towards 20-24°C
Validation Standard	8 hours against ISTA 7D standards

### 2.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.25 x 13 x 13.25in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 (LWH)
- System Weight (excluding payload): 16.3 lbs.
- Coolant: 1 x B18 PCM0

## 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 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.

### 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.

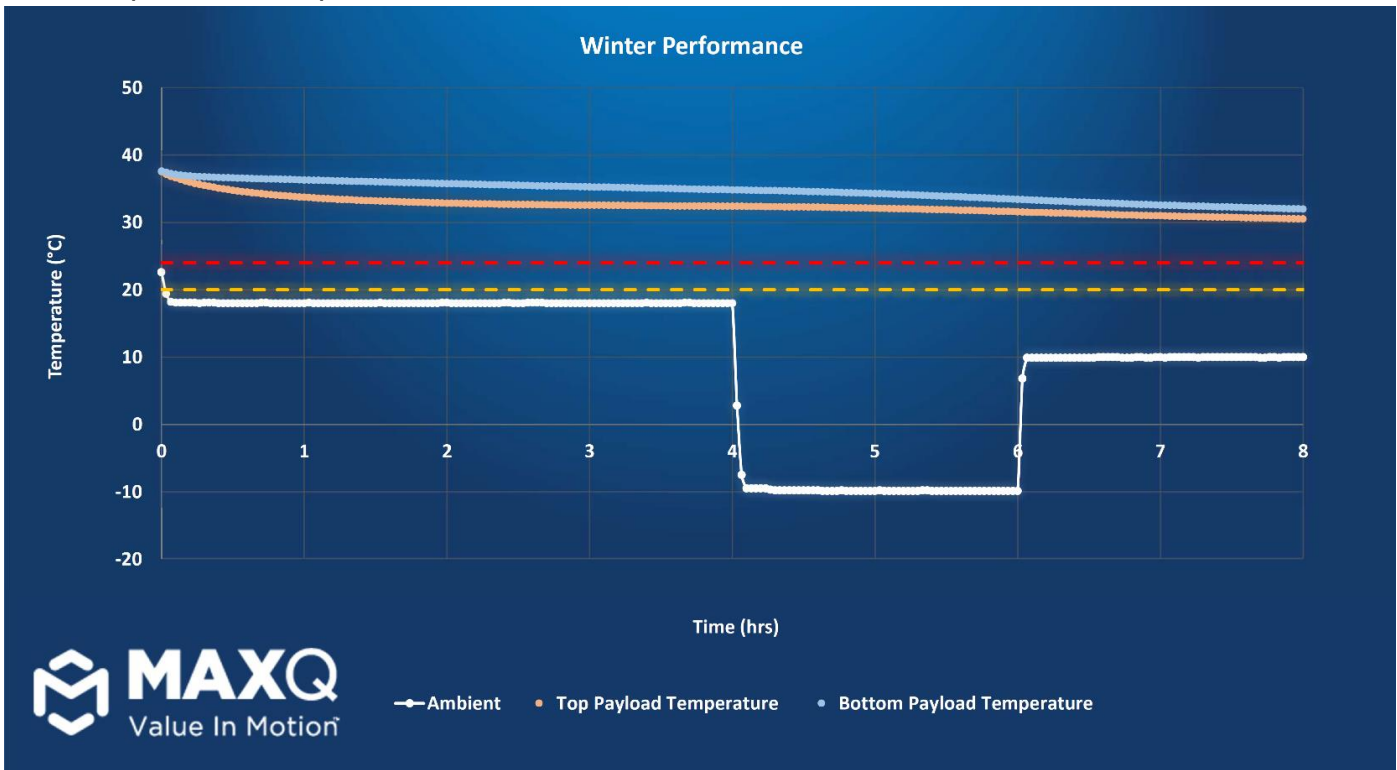
### 1.5.3 Test Results:

#### 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.

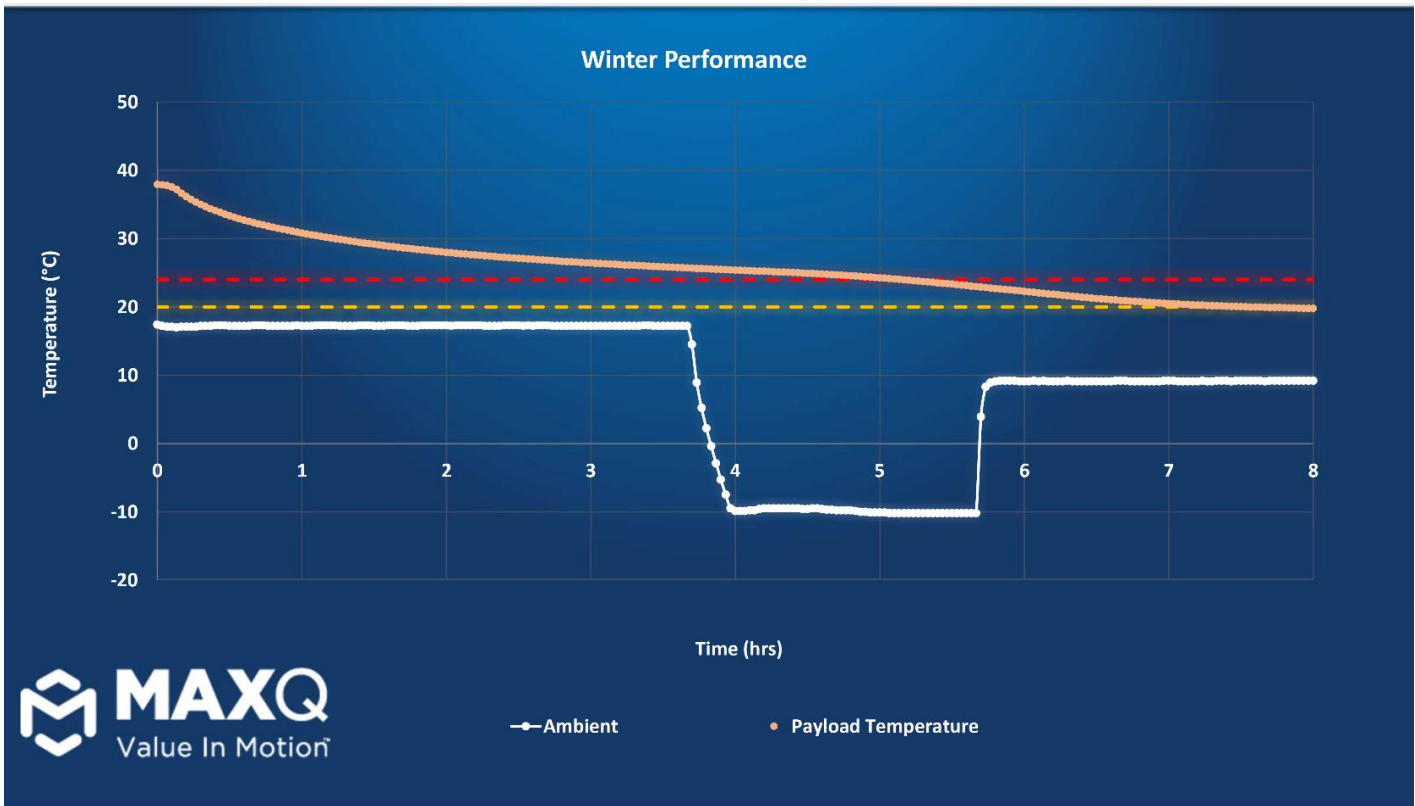
Total time (hours) payload-cooling towards 20-24°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
8	8	30.5	31.9

### 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

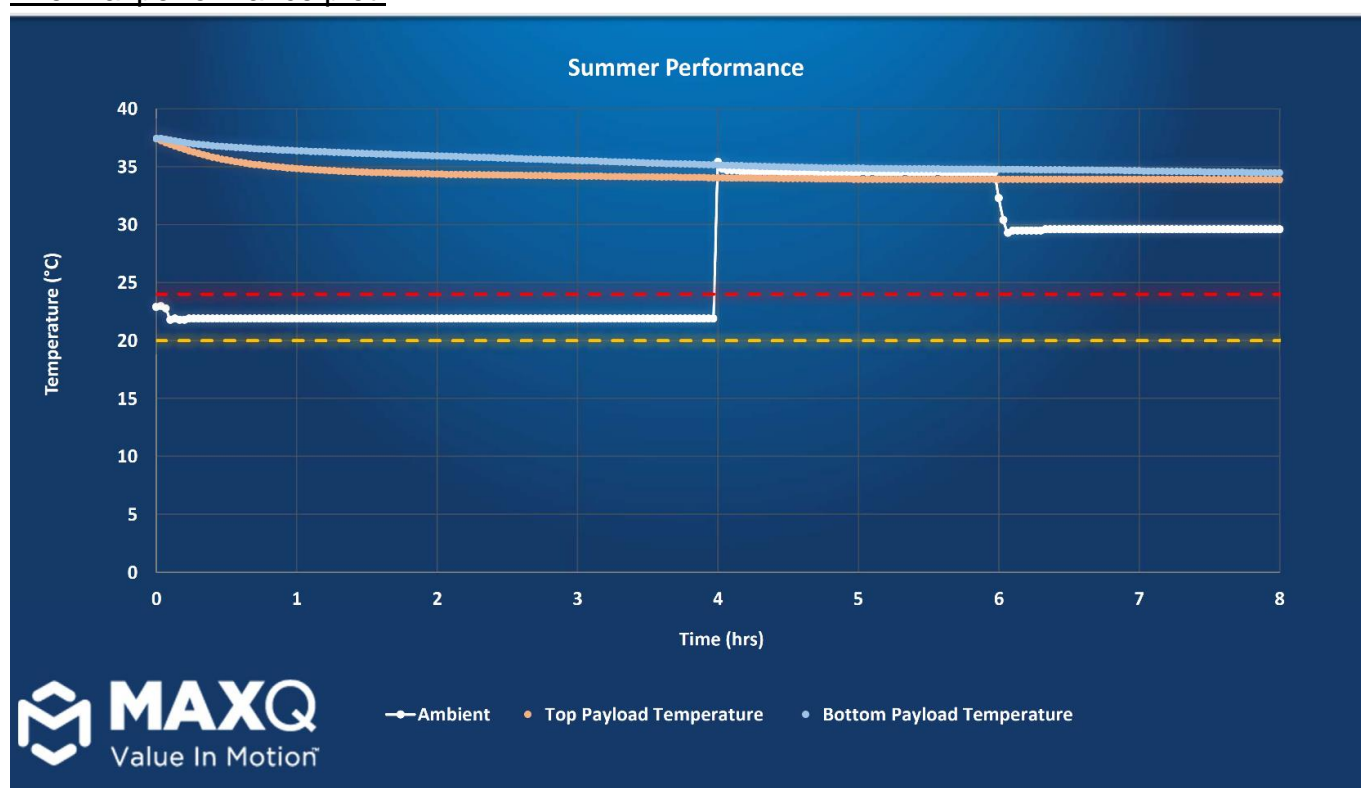


### 1.5.3.3 Warm Unprocessed Whole Blood | Summer Ambient | Maximum Payload

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

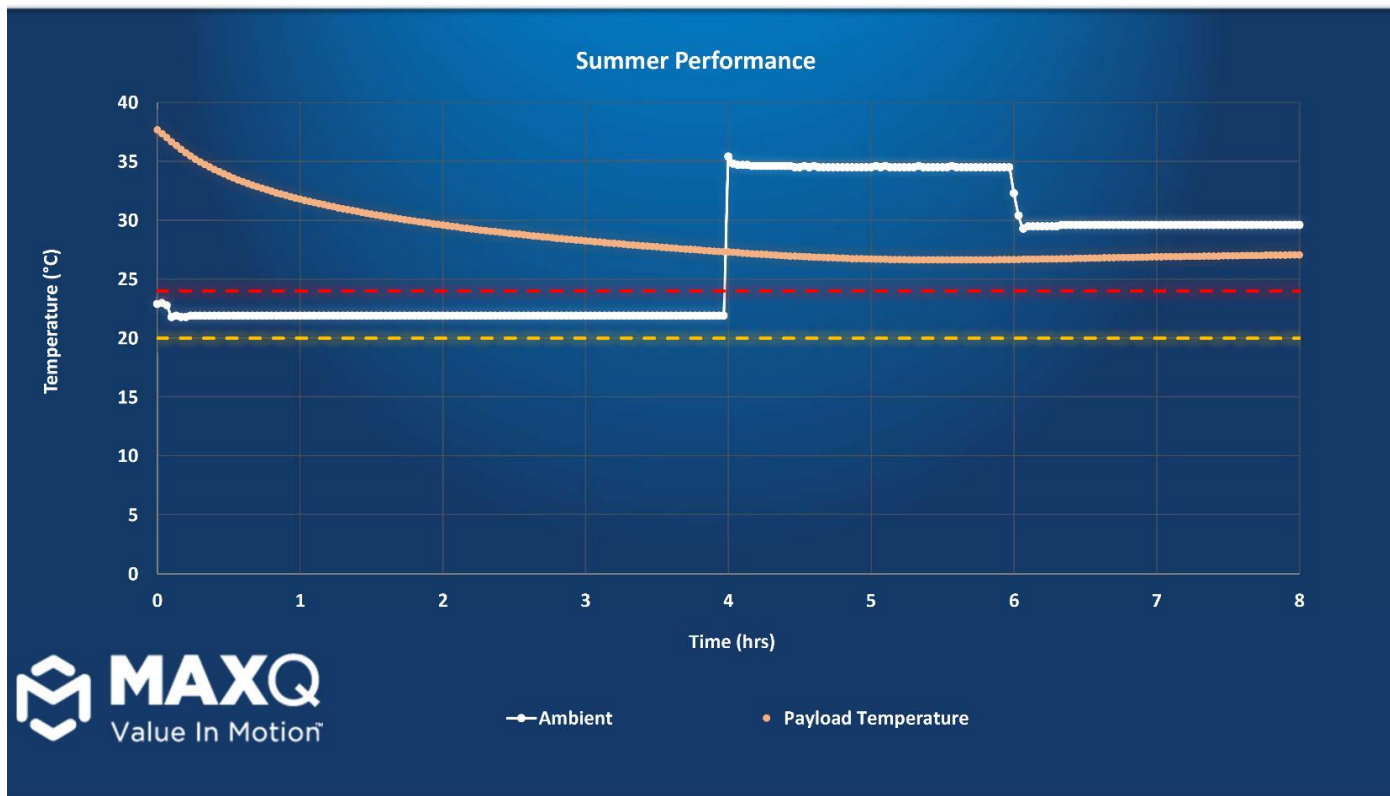


### 1.5.3.4 Warm Unprocessed Whole Blood | Summer Ambient | Minimum Payload

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 wet ice

### 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:

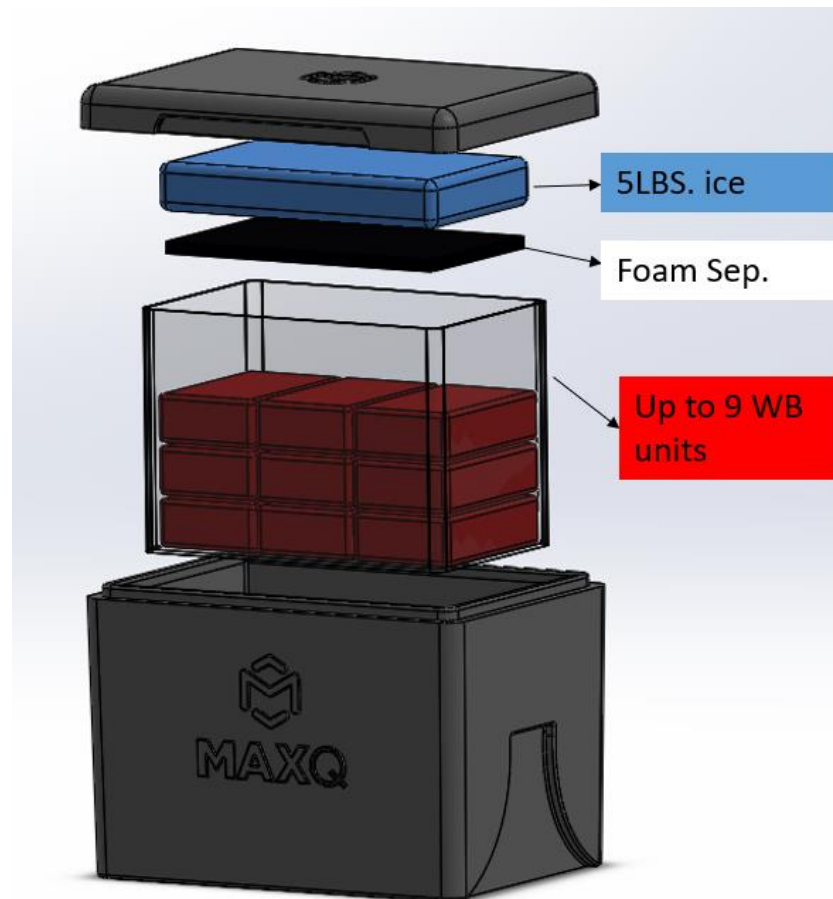
Type	Warm Unprocessed Whole Blood
Form factor	Whole Blood Unit
Volume	~500mL per unit
Capacity	Up to 9x Processed Red Blood Cell units
Required Temperature	Cooling down towards 1-10°C ( $\pm 0.5^\circ\text{C}$ )
Validation Standard	24 hours against ISTA 7D standards

### 2.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.25 x 13 x 13.25in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 (LWH)
- System Weight (excluding payload): 14.5 lbs.
- Coolant: 5 lbs. wet ice

## 2.4 Packing Methods

### 2.4.1 Packout Schematic:



### 2.4.2 Coolant Conditioning Procedure:

- Wet ice in a plastic bag

### 2.4.3 Packing Instructions:

- 1) Place Up to 9 units of Unprocessed Whole Blood Units in the bottom of the container.
- 2) Put 0.5 separator on top of the units.
- 3) Place one bag of wet ice (approx. 5lbs.) on top of the separator.
- 4) Close the lid.

## 2.5 Test Methods and Results:

### 2.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) 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 3.4 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.

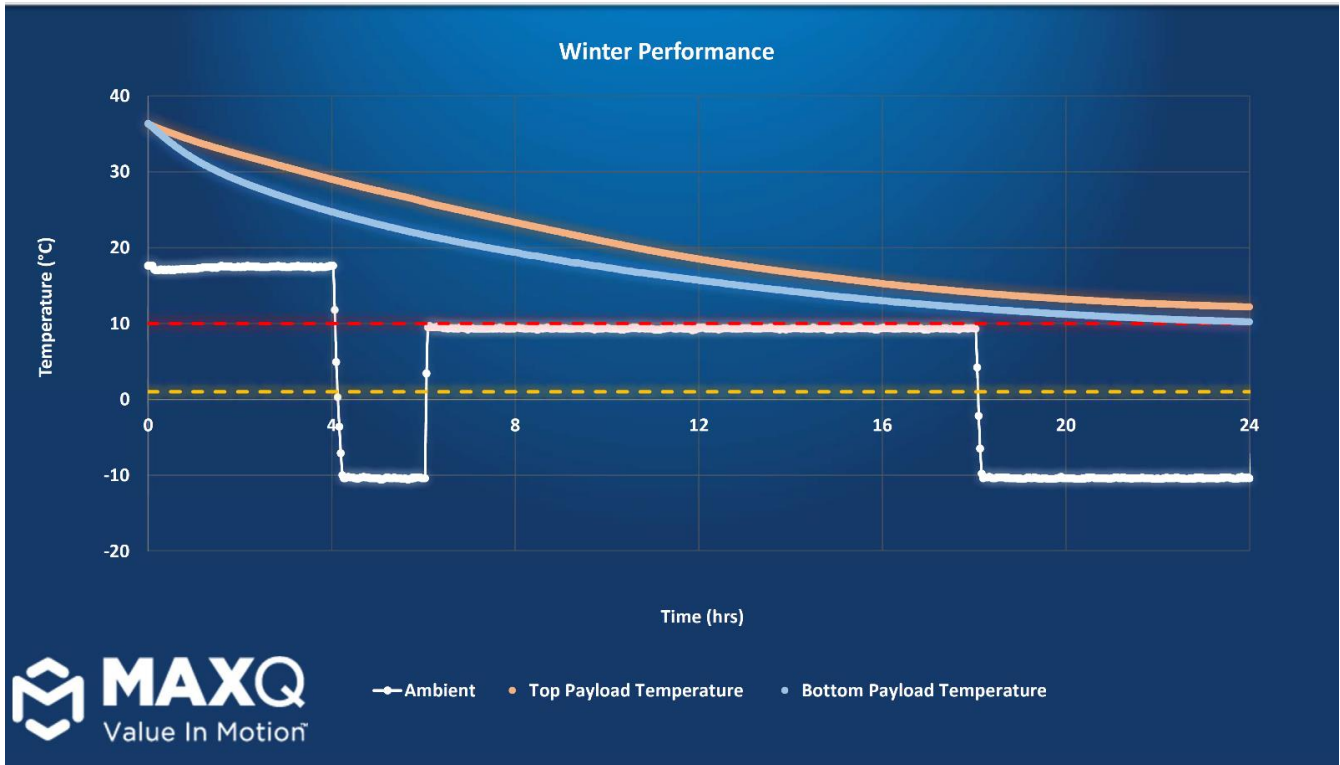
### 2.5.3 Test Results:

#### 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.

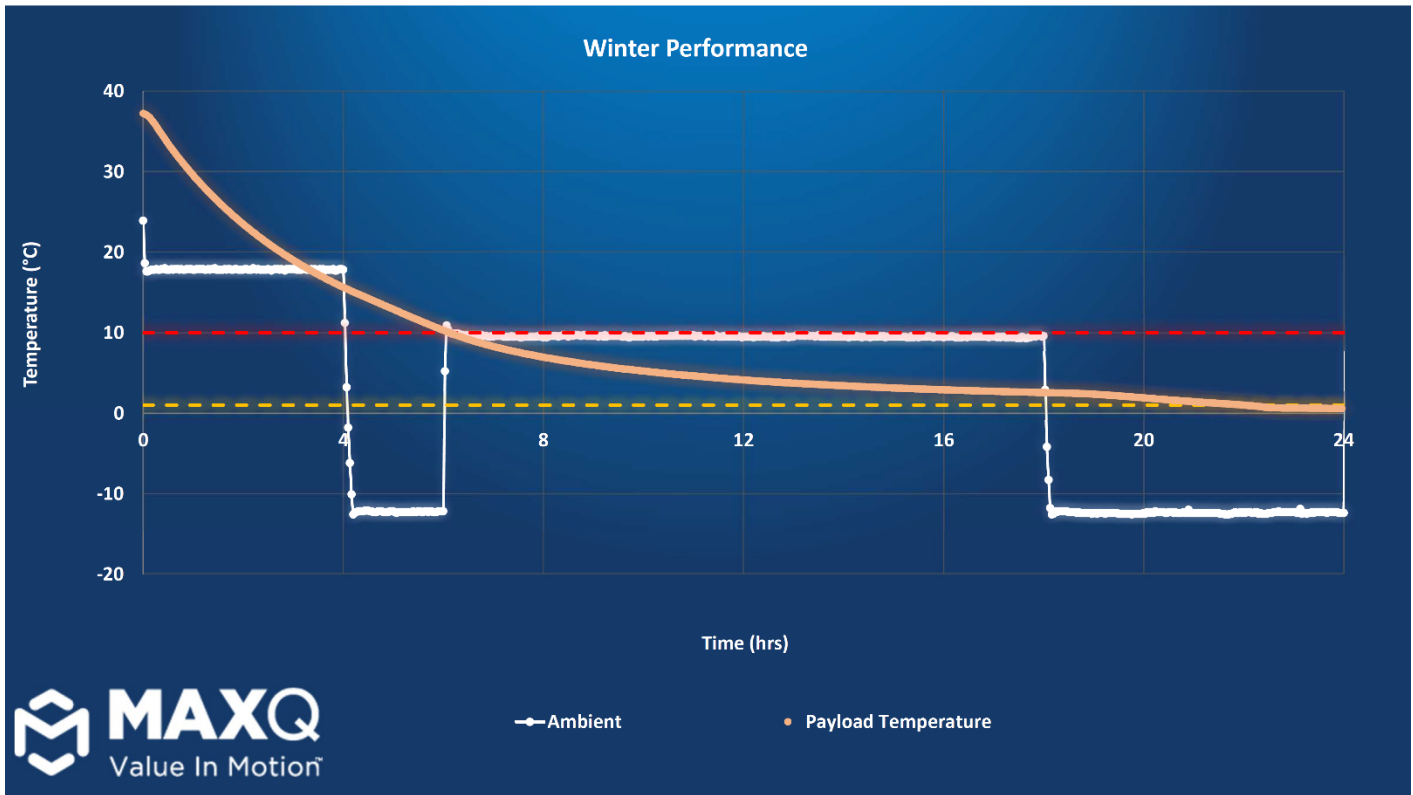
Total time (hours) payload-cooling towards 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
24	24	10.2	12.2

### 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.

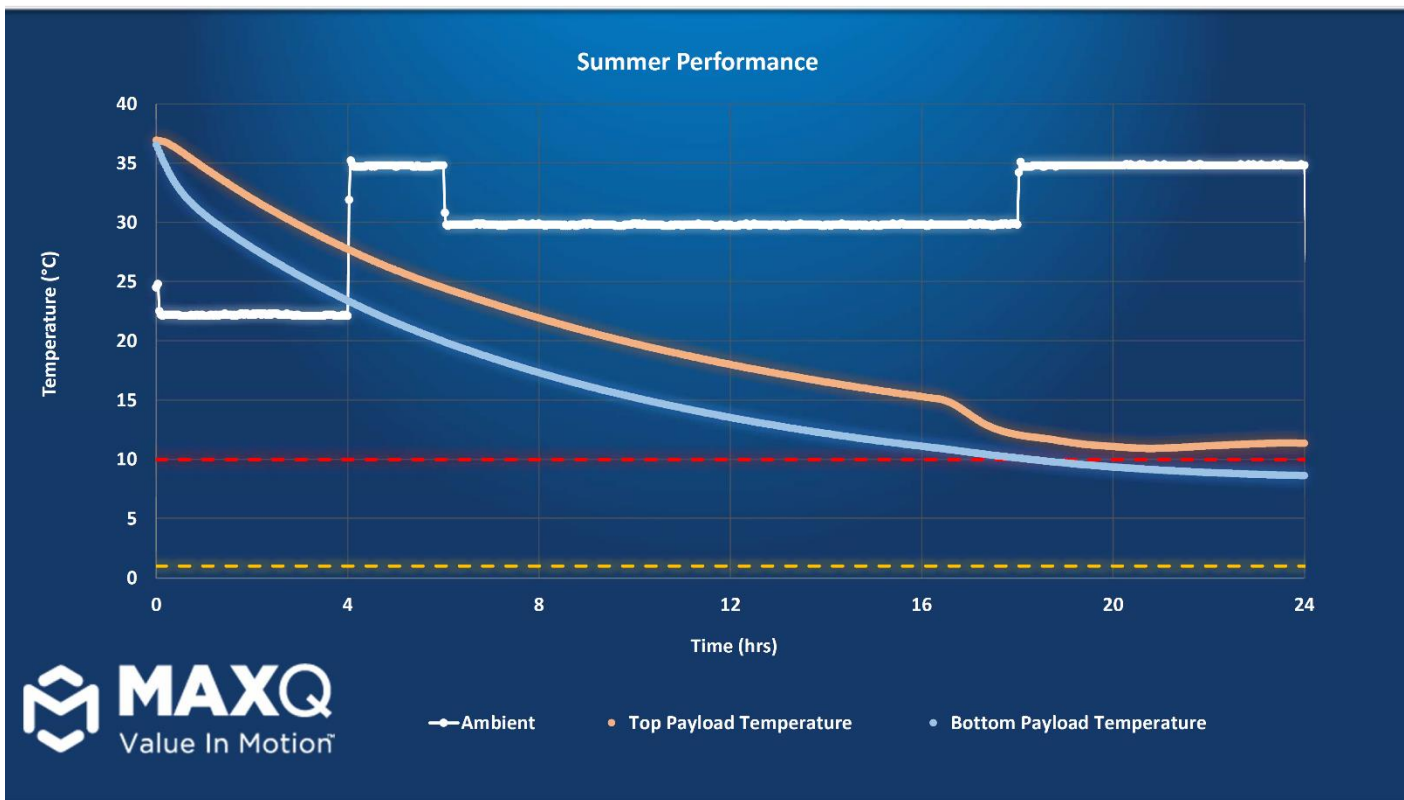
Total time (hours) payload-cooling towards 1-10°C	Minimum payload temperature during tested duration (°C)
24	0.6

### 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	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-cooling towards 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
24	24	11.4	8.6

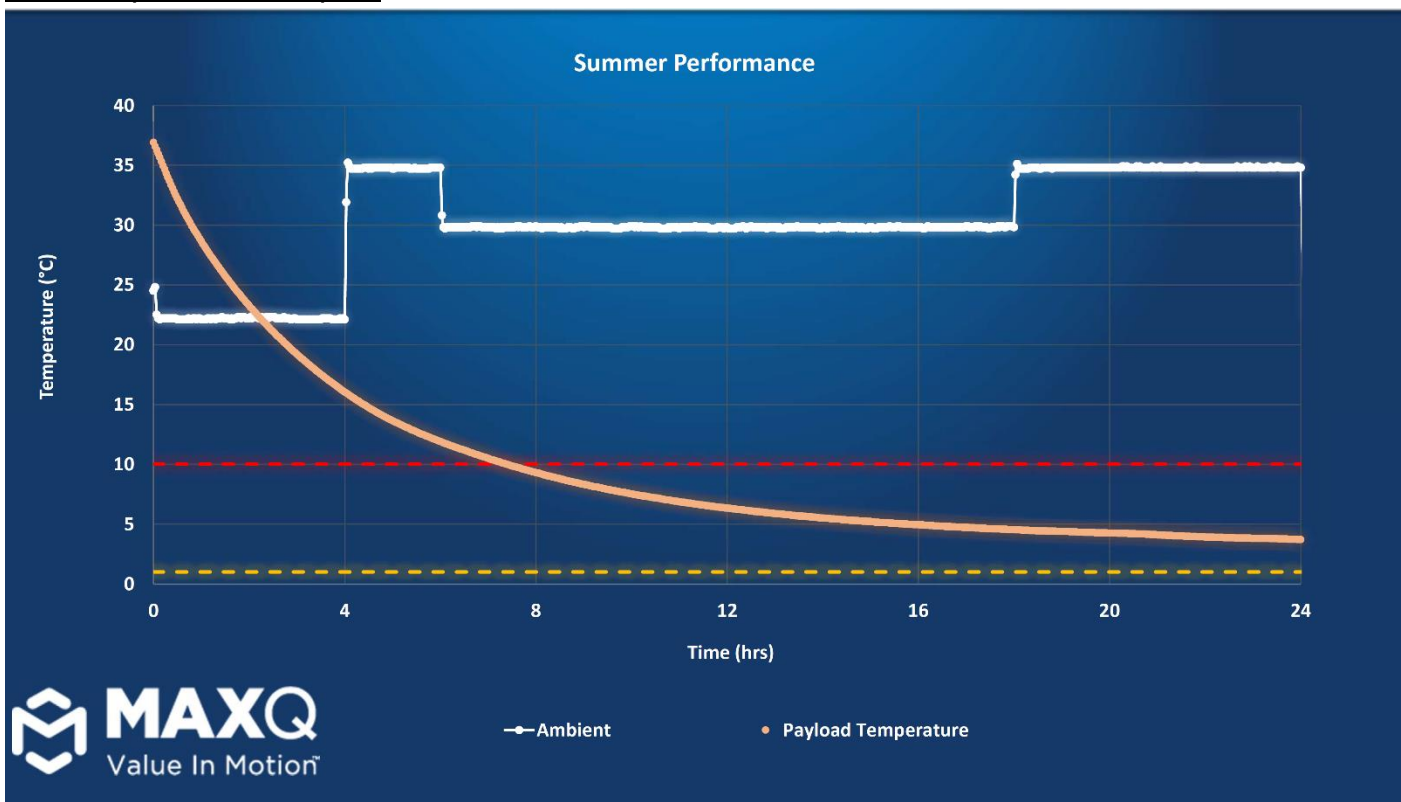


2.5.3.4 Warm Processed Whole Blood | **Summer Ambient** | **Minimum Payload**

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	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-cooling towards 1-10°C	Minimum payload temperature during tested duration (°C)
24	3.7

### 3. Design Qualification for transport of refrigerated RBC units between 1-10°C using wet ice

#### 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 44 hours.

#### 3.2 Product/Payload Specifications:

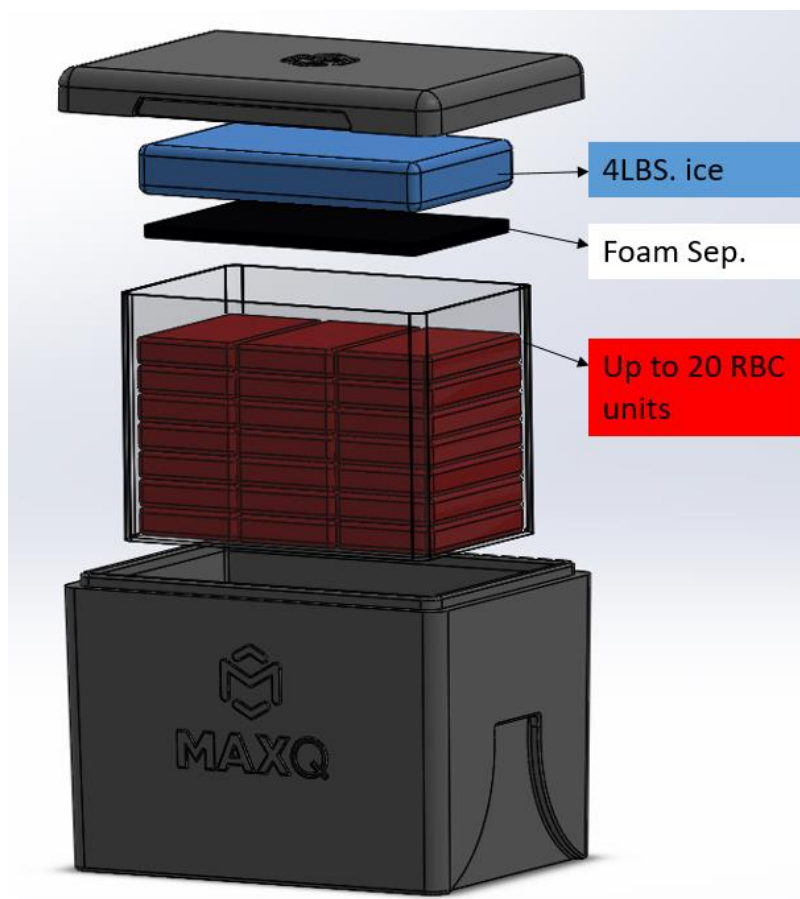
Type	Refrigerated Red Blood Cells / Plasma
Volume	300-350mL per unit
Capacity	Up to 20x Processed Red Blood Cell units
Required Temperature	1-10°C ( $\pm 0.5^\circ\text{C}$ )
Validation Standard	48 hours against ISTA 7D ambient conditions

#### 3.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable, and highly reusable
- Outer Dimensions: 17.25 x 13 x 13.25in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.4 (LWH)
- System Weight (excluding payload): 14.5 lbs.
- Coolant: 4 lbs. wet ice

## 3.4 Packing Methods

### 3.4.1 Packout Schematic (1-10°C):



### 3.4.2 Coolant Conditioning Procedure:

- Wet ice in a liner bag

### 3.4.3 Packing Instructions:

- 1) Place Up to 20 units of Processed Red blood Cells in the bottom of the container.
- 2) Put 0.5in separator on top of the units.
- 3) Place one bag of wet ice (approx. 4lbs.) on top of the separator.
- 4) Close the lid.

## 3.5 Test Methods and Results:

### 3.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) with 4 pounds of wet ice is designed to maintain Red Blood Cell units between 1-10°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 44 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 1.4 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 44 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 44 hours of the total test duration.

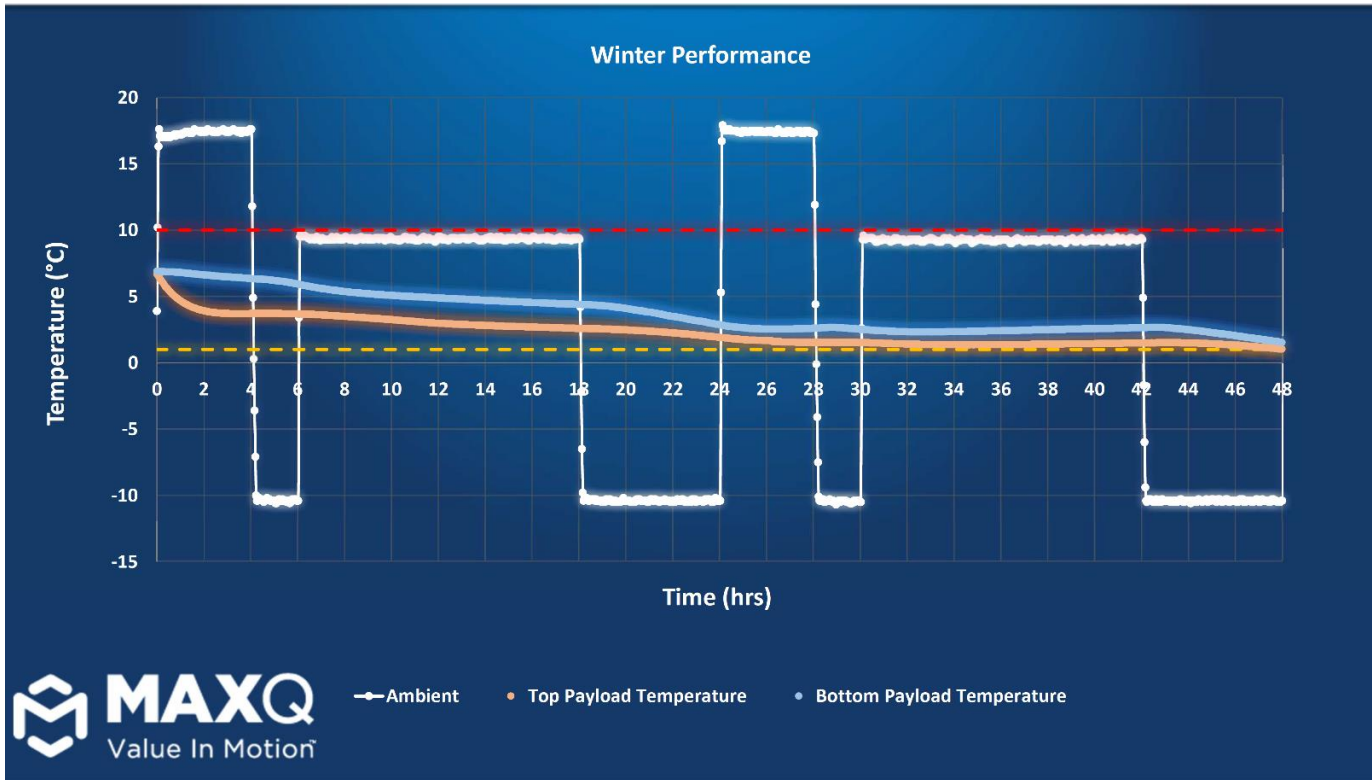
### 3.5.3 Test Results:

#### 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.

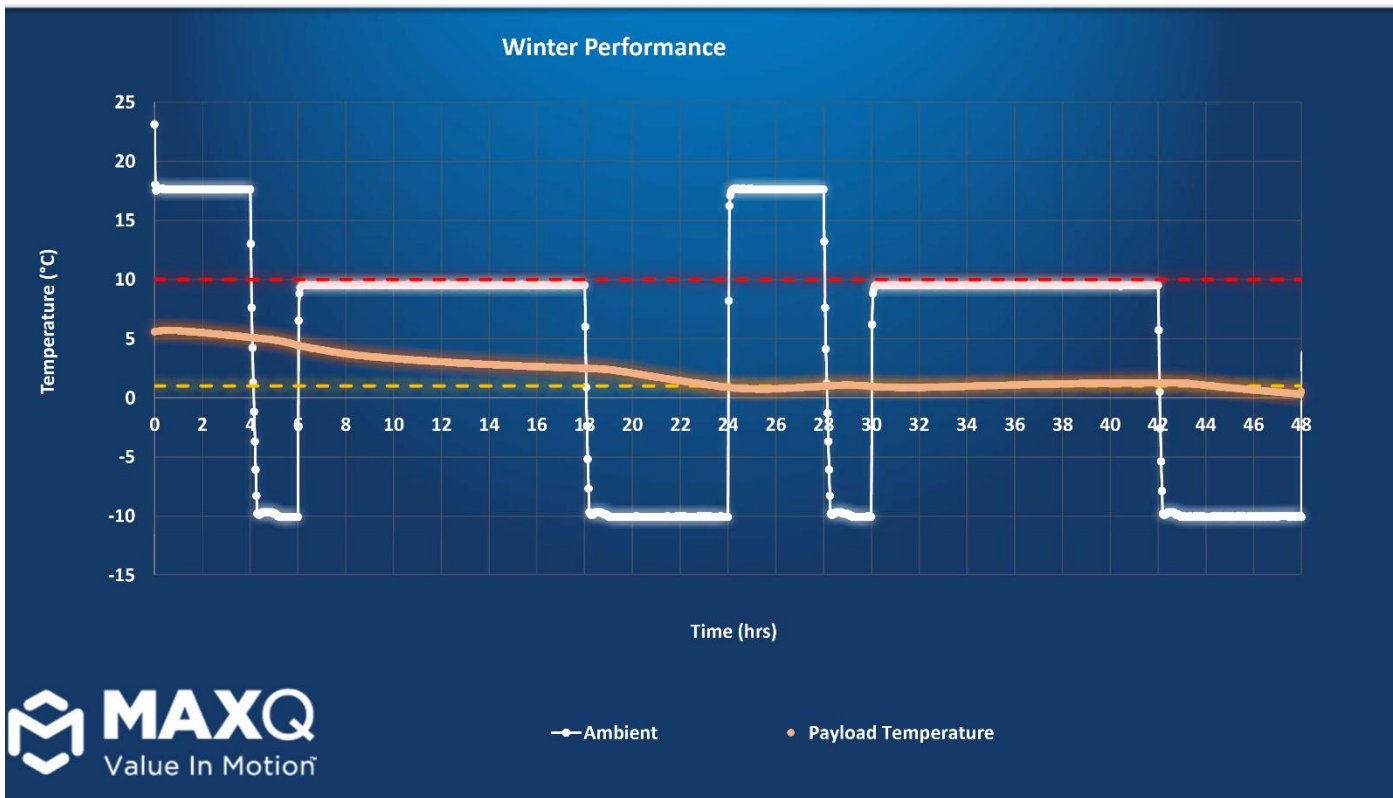
Total time (hours) payload-maintained 1-10°C		Minimum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
48	48	1.0	1.5

### 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)
44	0.3

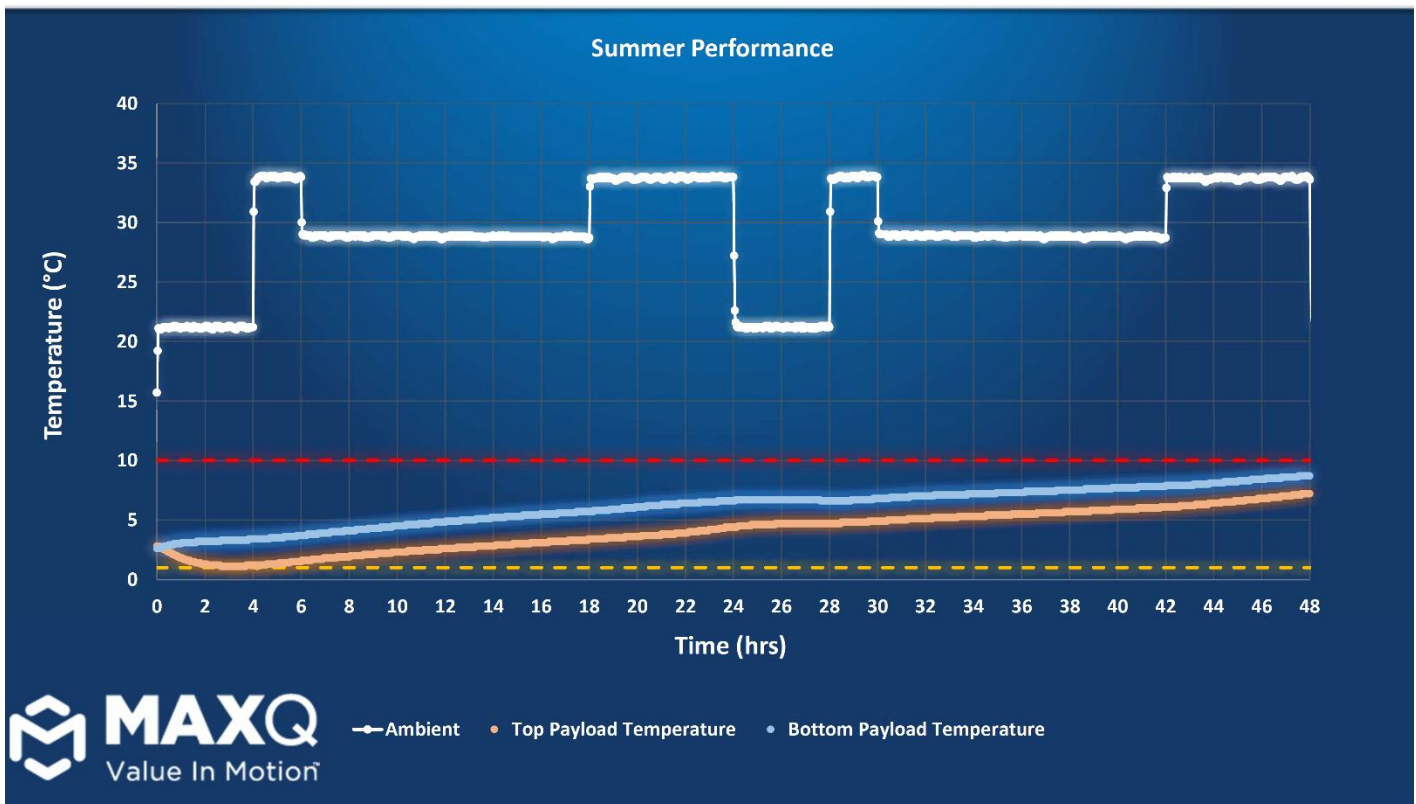


### 3.5.3.3 Chilled Red blood Cells (1-10°C) | Summer Ambient | Maximum Payload

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	7.2	8.7

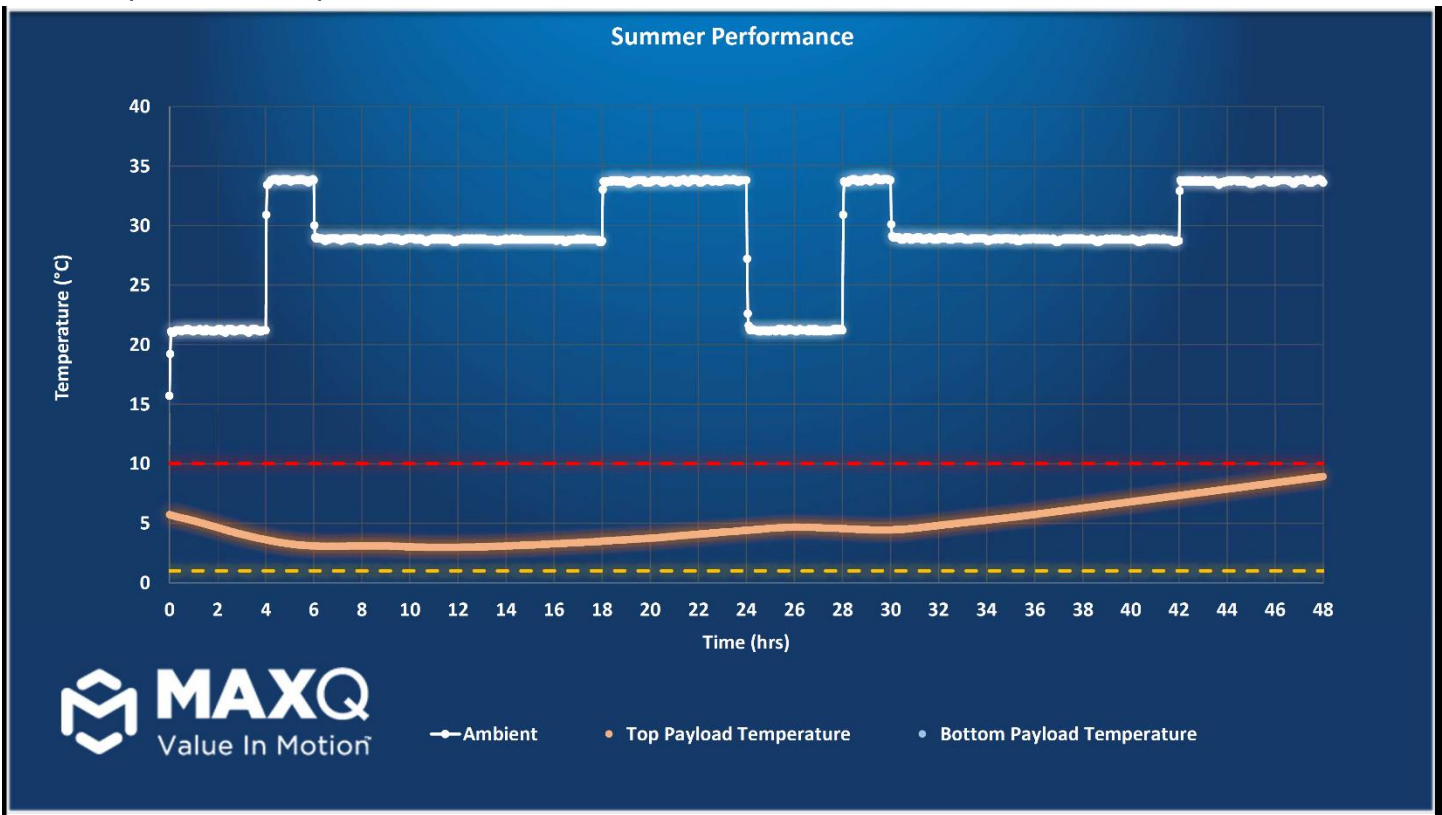


### 3.5.3.4 Chilled Red blood Cells (1-10°C) | Summer Ambient | Minimum Payload

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	8.9

## 4. Design Qualification for Transport of Frozen Plasma units using Dry Ice

### 4.1 Scope:

The scope of this section of the Design Qualification (DQ) report is to summarize the MaxOne Universal shipper dry Ice Frozen Plasma Shipper (SKU#E17V48). The report addresses basic shipper specifications, components breakdown, packing methods and temperature compliance data captured for the E17V48 to transport frozen plasma units below  $-18^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{C}$ ) for a minimum of 48 hours.

### 4.2 Product/Payload Specifications:

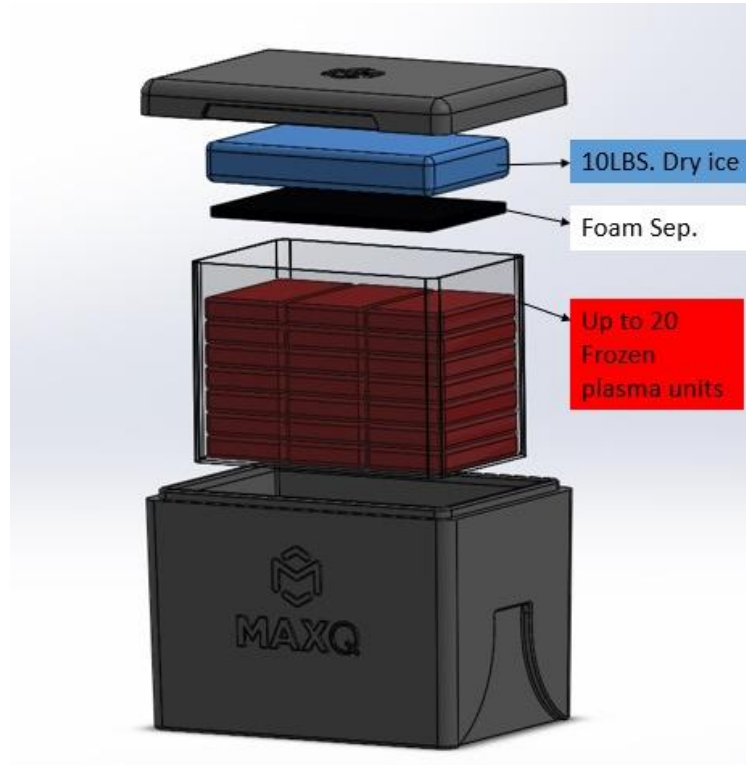
Type	Frozen Plasma
Form factor	Plasma bags
Volume	300mL per unit
Capacity	Up to 20x Frozen Plasma units
Required Temperature	Below $-18^{\circ}\text{C}$ ( $\pm 0.5^{\circ}\text{C}$ )
Validation Standards	48 hours against ISTA 7D standards

### 4.3 Shipper Specifications:

- Outer Shell Material: Expanded polypropylene foam, durable and highly reusable
- Outer Dimensions: 17.25 x 13 x 13.25in (LWH)
- Payload Dimensions: 15.75 x 11.5 x 10.375 (LWH)
- System Weight (excluding payload): 14.5 lbs.
- Coolant: 10 lbs. dry ice

## 4.4 Packing Methods

### 3.4.1 Packout Schematic:



### 4.4.2 Coolant Conditioning Procedure:

- Dry ice in a plastic bag (no conditioning required)

### 4.4.3 Packing Instructions:

- 1) Place Up to 20 units of Frozen plasma Units in the bottom of the container.
- 2) Put 0.5 separator on top of the units.
- 3) Place one bag of dry ice (approx. 10lbs.) on top of the separator.
- 4) Close the lid.

## 4.5 Test Methods and Results:

### 4.5.1 Test Methods:

The MaxOne Universal Shipper (SKU# E17V48) is designed to transport frozen plasma below -18°C ( $\pm 0.5^\circ\text{C}$ ) for a minimum of 48 hours. 1 test case was conducted to demonstrate the shipper's ability to maintain temperature under the extreme summer ambient based on ISTA 7D standard (GMP/GDP compliant). Thermal chambers with NIST traceable calibration were programmed with 48-hour summer ISTA-7D ambient profile 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. Winter test case was not conducted since the product transported need to be in the frozen state below -18C. Summer test case adequately covers shipper design qualification.

### 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 below -18°C ( $\pm 0.5^\circ\text{C}$ ) during the 48 hours of test duration.

**Fail Criteria:** Payload temperature went above -18°C ( $\pm 0.5^\circ\text{C}$ ) during the 48 hours of test duration.

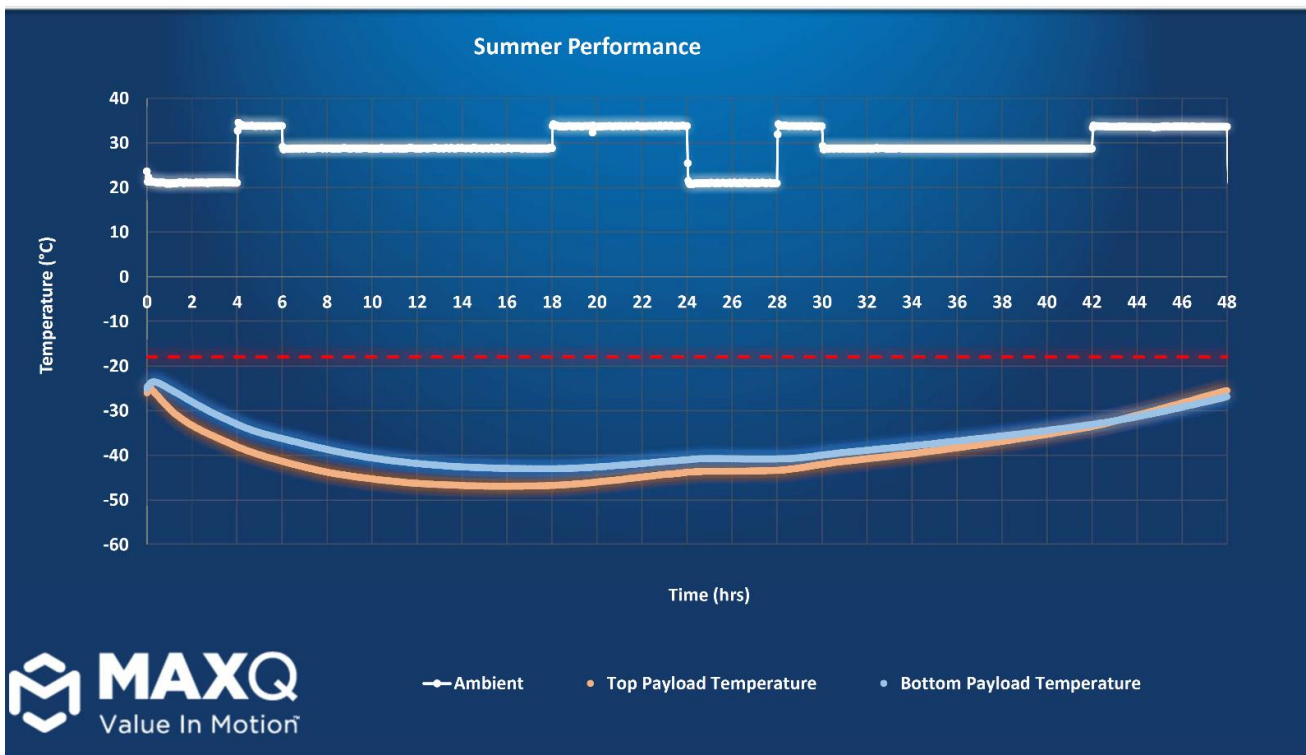
### 4.5.3 Test Results:

#### 4.5.3.1 Frozen plasma (Below -18°C) | Summer Ambient | Maximum Payload

Test setup:

Test payload	20 x 300mL mock plasma units kept at -20 °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 below -18°C		Maximum payload temperature during tested duration (°C)	
Top Payload	Bottom Payload	Top Payload	Bottom Payload
48	48	-24.9	-26.9

## Revision History:

Revision Number	Revision Date	Revision Description	Revised by	Approved by
V1.0	4-18-23	Original document	George Jett	Arif Rahman