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Design Qualification Report for the MaxPlus Multi-Product Shipper

Intended for the transport of whole blood units cooling towards 20-24°C, whole blood units cooling towards 1-10°C, and red blood cells kept at 1-10°C

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1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the specifications, components, test methods, packing procedures and thermal performance data of the MaxPlus Multi-Product Shipper (SKU#R13V48) to transport Whole Blood (WB) units at 20-24°C, WB units cooling towards 1-10°C and Red Cells (pRBCs) maintained at 1-10°C for a minimum of 48 hours under ISTA 7E and 7D ambient profiles.

The MaxPlus Multi-Product Shipper has been designed for transporting unprocessed whole blood (WB) and processed red blood cells from various collection centers to processing labs under the following transport requirements:

- (x20) unprocessed whole blood units (cooling towards 20 – 24°C) for a minimum of 8 hours under ISTA 7D based summer and winter ambient conditions.
- (x16) unprocessed whole blood units (cooling towards 1-10°C) for a total of 24 hours under ISTA 7E based summer and winter ambient conditions
- (x24) pRBCs units between 1-10°C for a total of 48 hours under ISTA 7E based summer and winter ambient conditions.

2. Requirements Summary:

2.1 Unprocessed Whole Blood units (cooling towards 20 – 24°C):

Product type	Unprocessed Whole Blood units
Average unit volume	500 mL
Product capacity	Minimum: 1 unit Maximum: 20 units
Payload starting temperature	37°C (±1°C)
Required temperature range	Cooling towards 20 – 24 °C
Shipping type	Domestic
Shipping duration	Minimum of 8 hours

2.2 Unprocessed Whole Blood units (cooling towards 1 - 10°C):

Product type	Unprocessed Whole Blood units
Average volume	500 mL
Product capacity	Minimum: 1 unit Maximum: 12 units
Payload starting temperature	37°C (±1°C)
Required temperature range	Cooling towards 1 – 10 °C

Shipping type	Domestic
Shipping duration	Minimum of 24 hours

2.3 Processed Red Blood Cell units/Liquid Plasma units/Cold Stored Platelet units:

Product type	Processed Red Blood Cells/Liquid Plasma/Cold Stored Platelets
Average unit volume	250 - 350 mL
Product capacity	Minimum: 1 unit (Average volume 250 mL) Maximum: 24 units (Average volume 350 mL)
Payload starting temperature	Refrigerated (2 – 6°C)
Required temperature range	1 – 10°C
Shipping type	Domestic
Shipping duration	48 hours

3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic (Blue)
- Outer Dimensions: 14 in x 13.625 in x 14.25 in (LWH)
- Payload capacity: 1-20 WB units (cooling towards 20-24°C), 1-12 WB units (cooling towards 1-10°C) and 1-24 pRBC units (1-10°C)
- System Weight (excluding payload): 17-20 lbs.
- Components: Blue B15-PCM5 bottles (x4), Yellow B18-PCM5 bottles (x4), Payload insert (x1)

4. Packing Methods

4.1 R13V48 Unprocessed Whole Blood units (cooling towards 20-24°C) Packout Schematic:

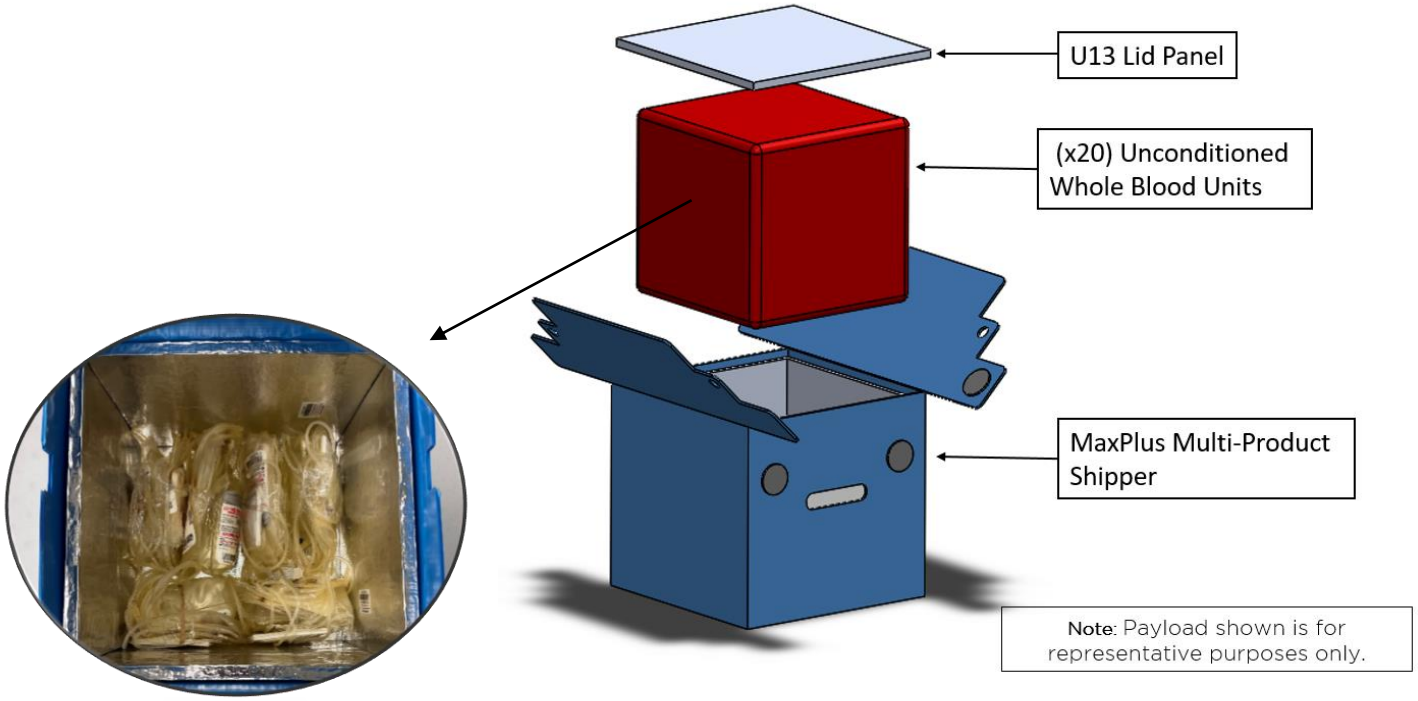


Figure 1. Packout Illustration for Unprocessed cold Whole Blood units (20-24°C)

4.2 Unprocessed Whole Blood (cooling towards 20-24°C) Coolant Conditioning Procedure:

- No coolant used

4.3 Unprocessed Whole Blood (cooling towards 20-24°C) Packing Instructions:

- Pack unprocessed whole blood units directly into the container following the packing orientation shown above.
  - (Note: Reference photo above for how to orient payload units to achieve full 20 -unit capacity)
- Place the lid on top, close the flaps and attach tamper evidence component if desired.
- The container is now ready for shipment.

Note: For packing anything less than maximum number of whole blood units, please use room temperature bubble wrap/dunnage to fill up any empty space on top to avoid movement of the products inside during transit.

4.4 Processed Red Blood Cell units (1-10°C) OR Unprocessed Whole Blood units (cooling towards 1-10°C) Packout Schematic:

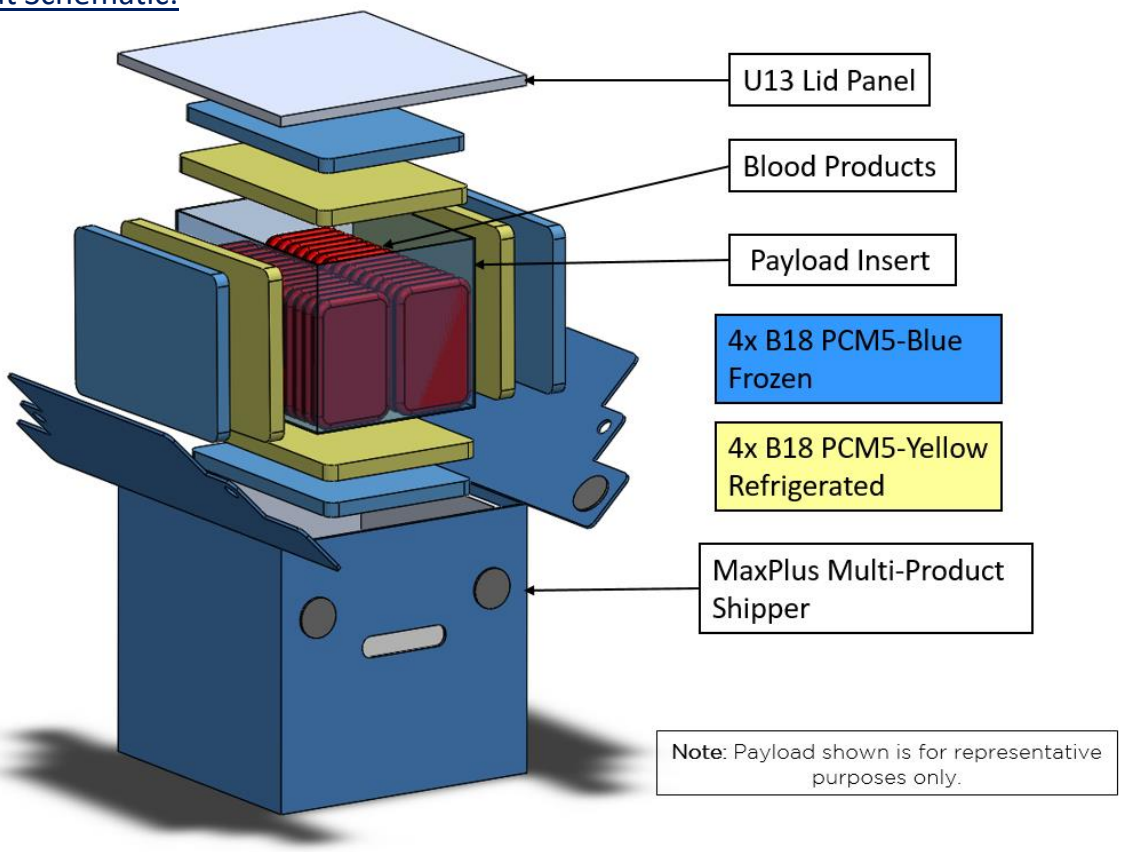


Figure 2. Packout Illustration for Processed Red Blood Cell units (1-10°C) and Unprocessed cold Whole Blood units (cooling towards 1-10°C)

4.5 Processed Red Blood Cell units (1-10°C) OR Unprocessed Whole Blood units (cooling towards 1-10°C) Conditioning Procedure:

- 4 x blue B15-PCM5 bottles stored in the freezer (below -20°C) to bring them to a frozen solid state for a minimum of 24 hours
- 4 x yellow B15-PCM5 bottles stored in the refrigerator (2-6°C) for a minimum of 24 hours

4.6 Processed Red Blood Cell units (1-10°C) OR Unprocessed Whole Blood units (cooling towards 1-10°C) Coolant Packing Instructions:

- **Step 1:** Place (x1) blue B18-PCM5 from the freezer in the bottom of the container followed by (x1) yellow B18-PCM5 from the refrigerator on top of the blue bottle.
- **Step 2:** Place the payload insert into the container centered on top of the bottom yellow bottle.
- **Step 3:** Place frozen blue B18-PCM5 bottles on the left and right walls of the container followed by refrigerated yellow B18-PCM5 bottles placed on the inside face of the frozen bottles as shown in the model above.
- **Step 4:** Load pRBCs OR unprocessed WB units into the payload insert.
- **Step 5:** Place (x1) refrigerated yellow B18-PCM5 bottle on the top of the payload insert followed by (x1) frozen blue B185-PCM5 bottle on top.
- **Step 6**: Place lid on top, Velcro down the flaps and attach tamper evidence component if desired. The container is now ready for shipment.

Note: For packing anything less than maximum number of pRBCs or WB units, please use room temperature bubble wrap to fill up any empty space in the payload insert to avoid movement of the products inside during transit.

Disclaimer: The ambient temperature profile for a specific location may vary. MaxQ cannot guarantee that the payload can maintain the aforementioned performance specifications without any excursions if the temperature exposure of the packed system is not within the tested temperature range.

5. Design Qualification Test Methods and Results:

5.1 Test Methods: The MaxPlus Multi-Product Shipper was packed according to the instructions specified above (Page # 3-6), and exposed to both ISTA-7D and ISTA-7E summer and winter ambient profiles in a NIST calibrated programmable thermal chamber. Mock WB units filled with 500mL of saline solution and mock processed red blood cell units filled with 250-350mL of saline were used as payload simulant during minimum and maximum payload testing. NIST calibrated precision temperature loggers were attached to the payload units (2 probes for maximum payload condition – top, and bottom) and the unit temperature was recorded every 2 minutes during the test duration. At the end of test cycle, payload temperature data was analyzed and the shipper performance was evaluated according to the following criteria, established based on the AABB Reference Standard 5.1.8A - Requirements for Storage, Transportation, and Expiration (Source: Standards for Blood Banks and Transfusion Services, 31st edition).

5.2 Pass and Fail Criteria

Unprocessed Whole Blood Units (20 to 24°C)

Pass criteria: Payload temperature continuously cools toward 20 to 24°C for at least the first 8 hours of the total test duration

Fail criteria 1: Payload temperature fails to continuously cool towards 20 to 24°C for at least the first 8 hours of the total test duration

Fail criteria 2: Payload temperature drops below 20 °C within the first 8 hours of the total test duration

Unprocessed Whole Blood Units (cooling towards 1 to 10°C)

Pass criteria: Payload temperature continuously cools toward 1 to 10°C for at least the first 24 hours of the total test duration

Fail criteria 1: Payload temperature fails to continuously cool towards 1 to 10°C for at least the first 24 hours of the total test duration

Fail criteria 2: Payload temperature drops below 1 °C within the first 24 hours of the total test duration

Processed Red Blood Cell Units (1 to 10°C)

Pass criteria: Payload temperature stayed within 1 to 10°C for the entire test duration

Fail criteria: Payload temperature went below 1°C or above 10°C during the entire test duration

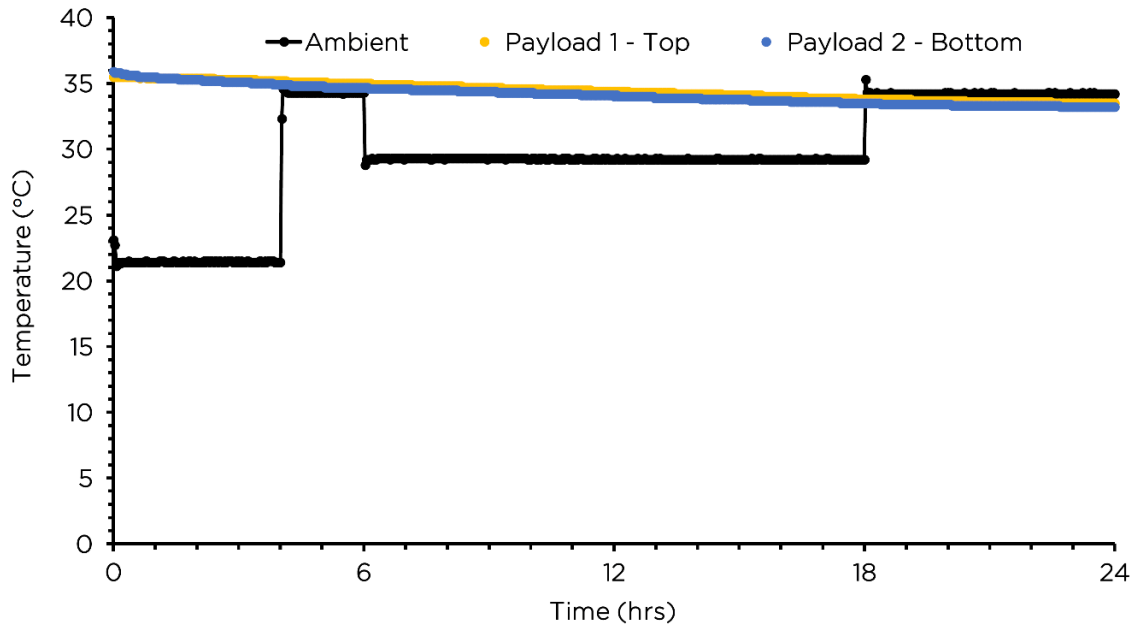
5.3 Test Results:

5.3.1 Unprocessed whole blood cooling towards 20-24°C | Summer | Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	No coolant
Preconditioning	None
Test payload	20 units of 500mL saline filled mock WB bags stored at 37°C for 12 hours
Temperature data loggers	Bottom Payload temperature – MaxQ Logger 35* Top Payload temperature – MaxQ Logger 27* Chamber temperature – MaxQ Logger 11* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	24 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

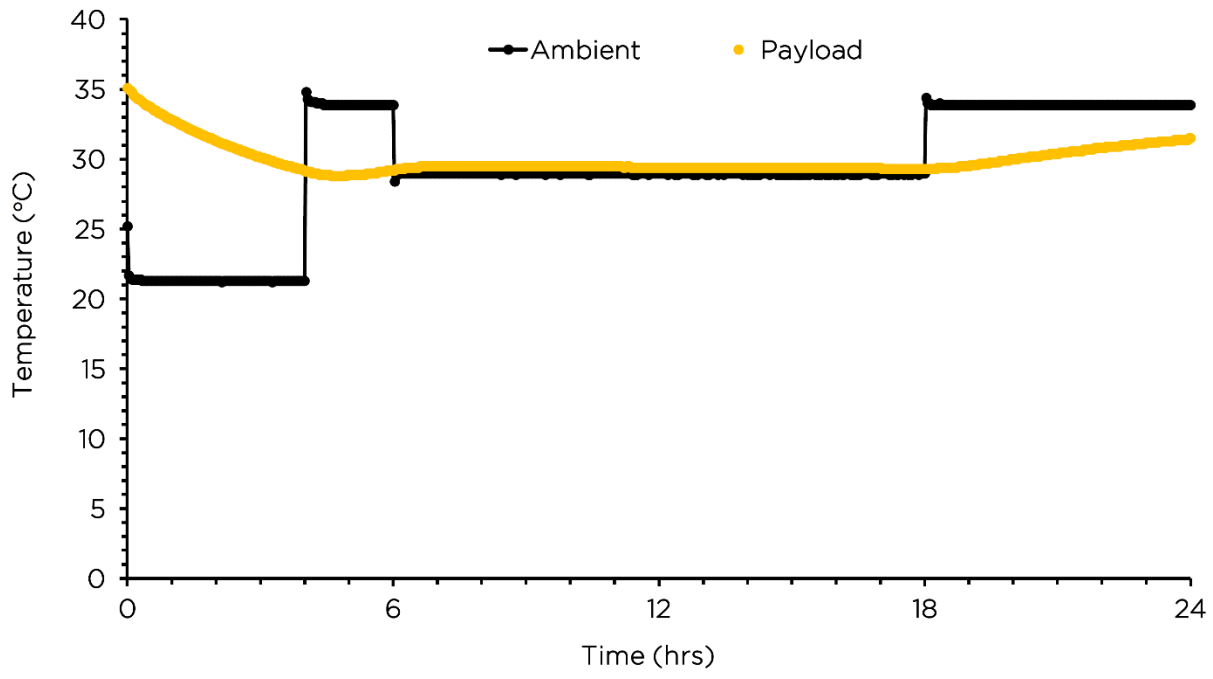
Total time (hours) payload cooling towards 20-24°C	Payload temperature after 8 hours		Result
24	Payload 1 - Top	Payload 2 - Bottom	Pass
	34.8°C	34.5°C	

5.3.2 Unprocessed whole blood cooling towards 20-24°C | Summer | Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	No coolant
Preconditioning	None
Test payload	1 unit of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 24* Chamber temperature – MaxQ Logger 11* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	24 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

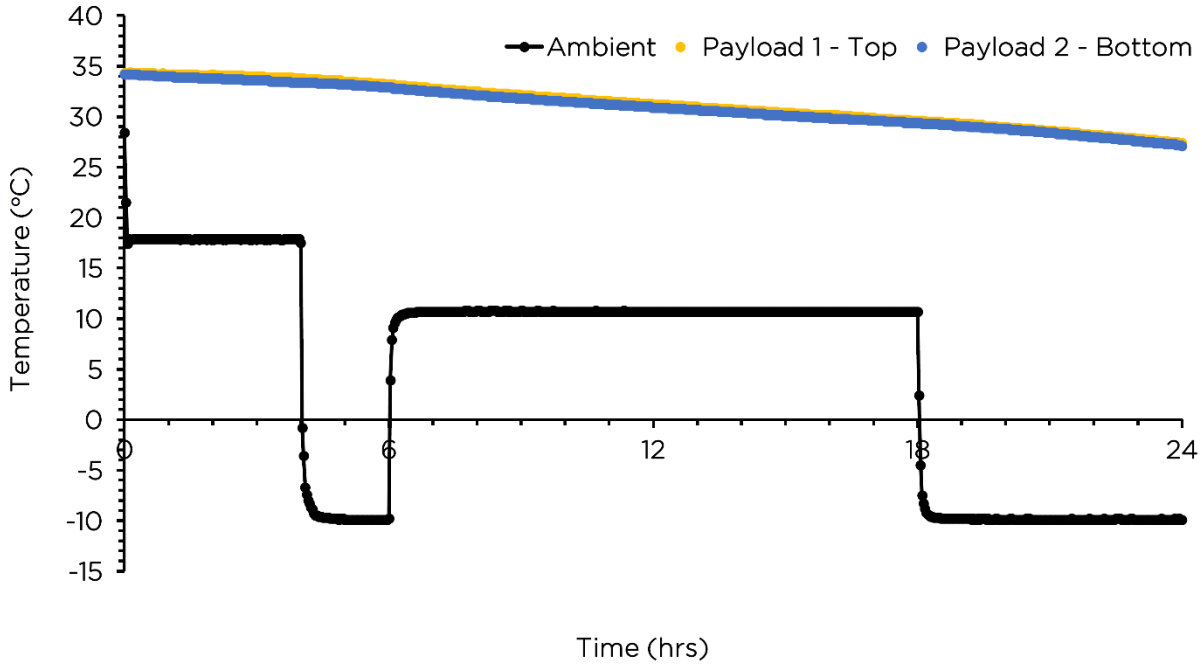
Total time (hours) payload cooling towards 20-24°C	Payload temperature after 8 hours	Result
8*	29.5°C	Pass

5.3.3 Unprocessed whole blood cooling towards 20-24°C | Winter | Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	No coolant
Preconditioning	None
Test payload	20 units of 500mL saline filled mock WB bags stored at 37°C for 12 hours
Temperature data loggers	Bottom Payload temperature – MaxQ Logger 35* Top Payload temperature – MaxQ Logger 27* Chamber temperature – MaxQ Logger 11* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	24 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

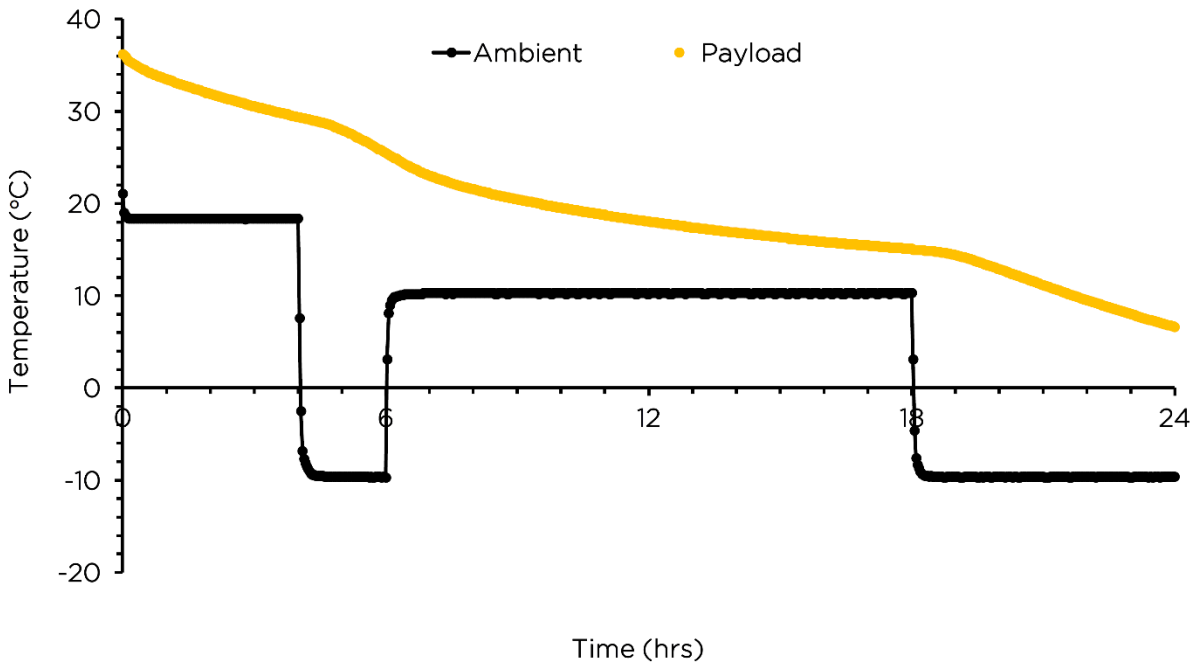
Total time (hours) payload cooling towards 20-24°C	Payload temperature after 8 hours		Result
24	Payload 1 - Top	Payload 2 - Bottom	Pass
	32.5°C	32.1°C	

5.3.4 Unprocessed whole blood cooling towards 20-24°C | Winter | Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	No coolant
Preconditioning	None
Test payload	1 unit of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 10* Chamber temperature – MaxQ Logger 24* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	24 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

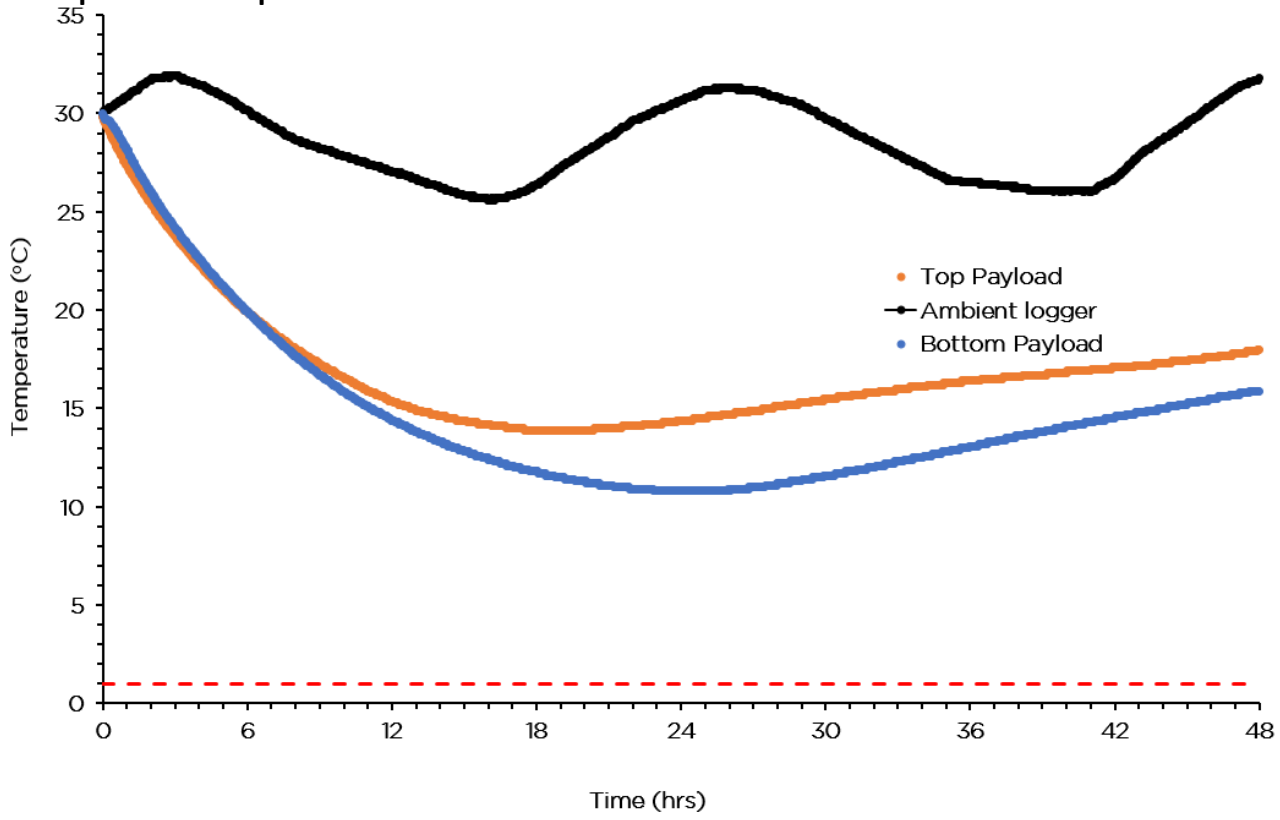
Total time (hours) payload cooling towards 20-24°C	Payload temperature after 8 hours	Result
9.5	21.6°C	Pass

5.3.5 Unprocessed whole blood cooling towards (1-10°C) | Summer | Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B18-PCM5-Blue (4 units), B18-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	12 units of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Bottom Payload temperature – MaxQ Logger 22* Top Payload temperature – MaxQ Logger 21* Chamber temperature – MaxQ Logger 38* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

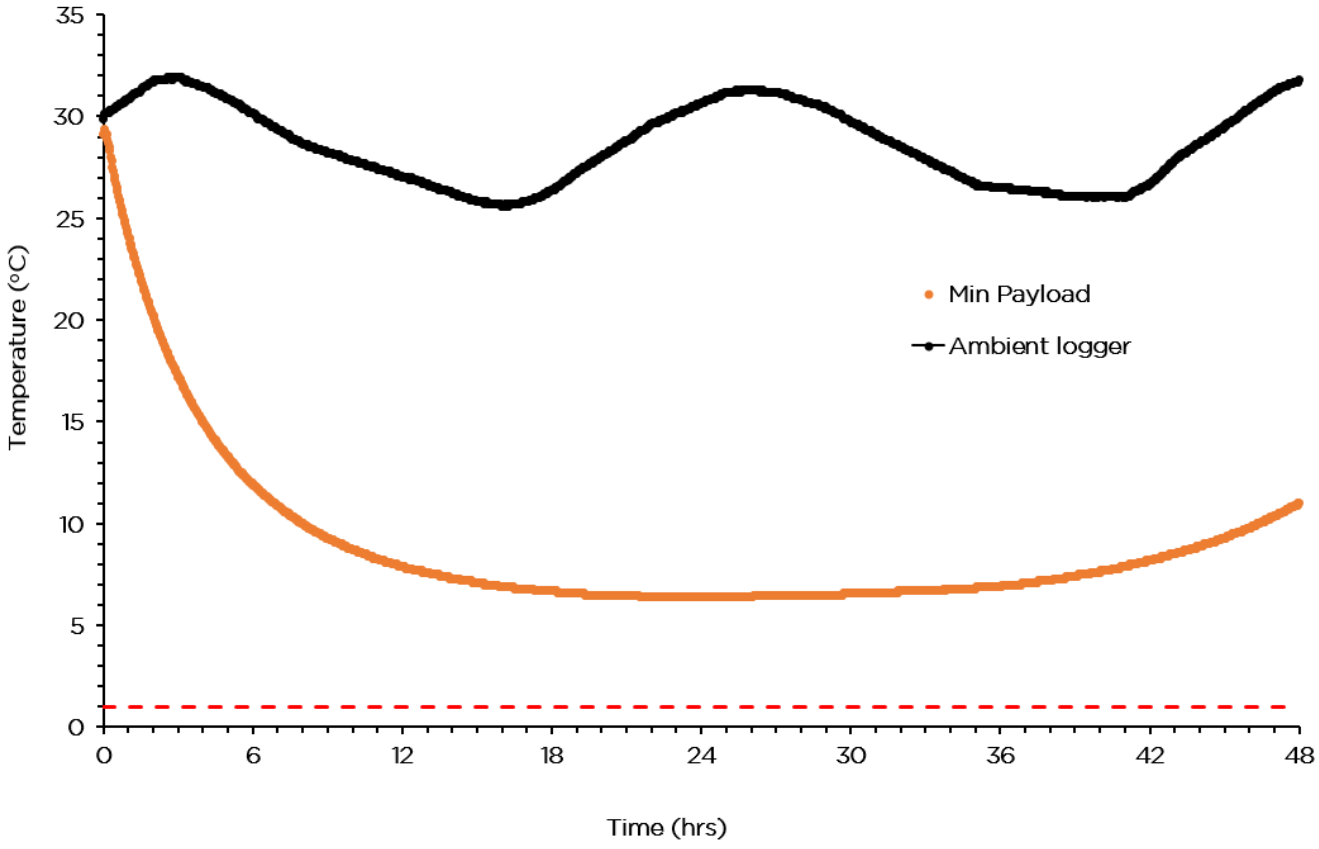
Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours		Result
48	Payload 1 - Top	Payload 2 - Bottom	Pass
	18°C	15.9°C	

5.3.6 Unprocessed whole blood cooling towards (1-10°C) | Summer | Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B18-PCM5-Blue (4 units), B18-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	2 units of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 32* Chamber temperature – MaxQ Logger 38* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

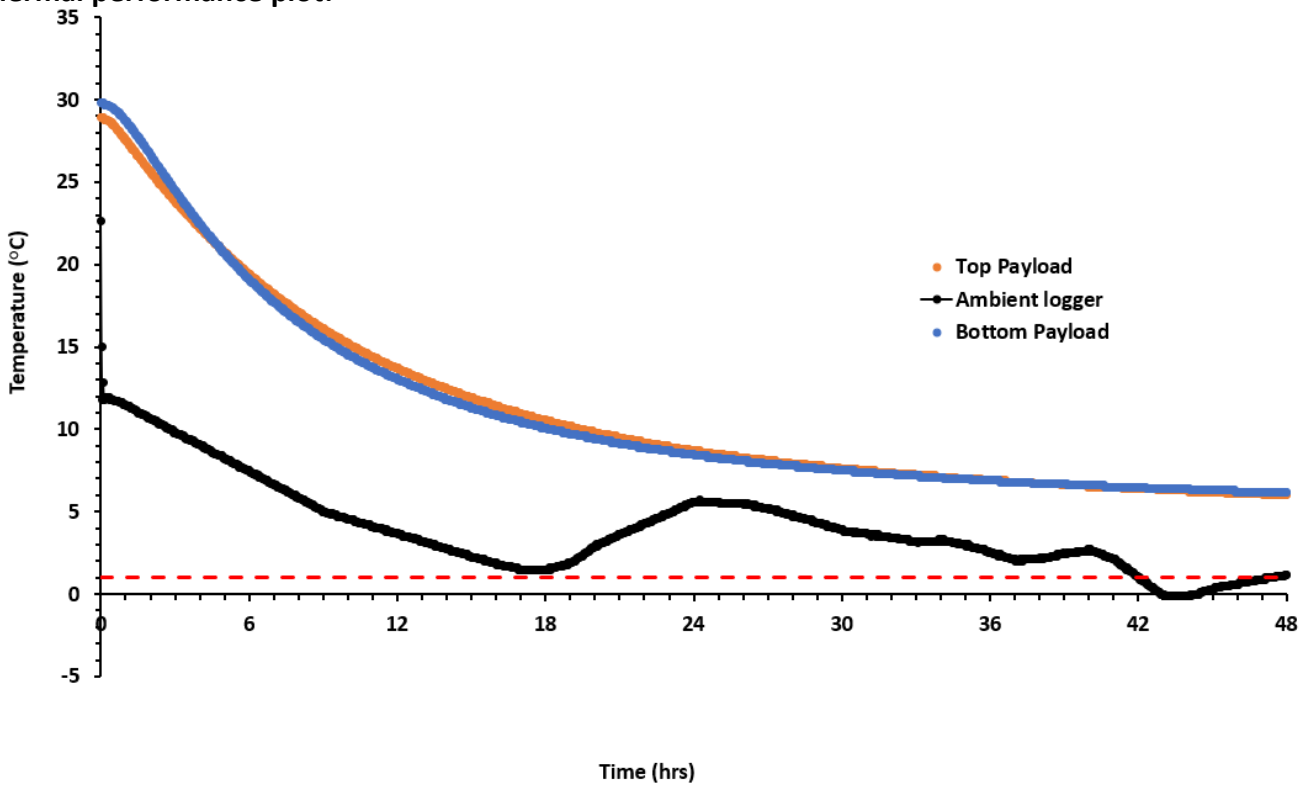
Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours	Result
46.433	11°C	Pass

5.3.7 Unprocessed whole blood cooling towards (1-10°C) | Winter | Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B18-PCM5-Blue (4 units), B18-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	12 units of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Bottom Payload temperature – MaxQ Logger 34* Top Payload temperature – MaxQ Logger 24* Chamber temperature – MaxQ Logger 10* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

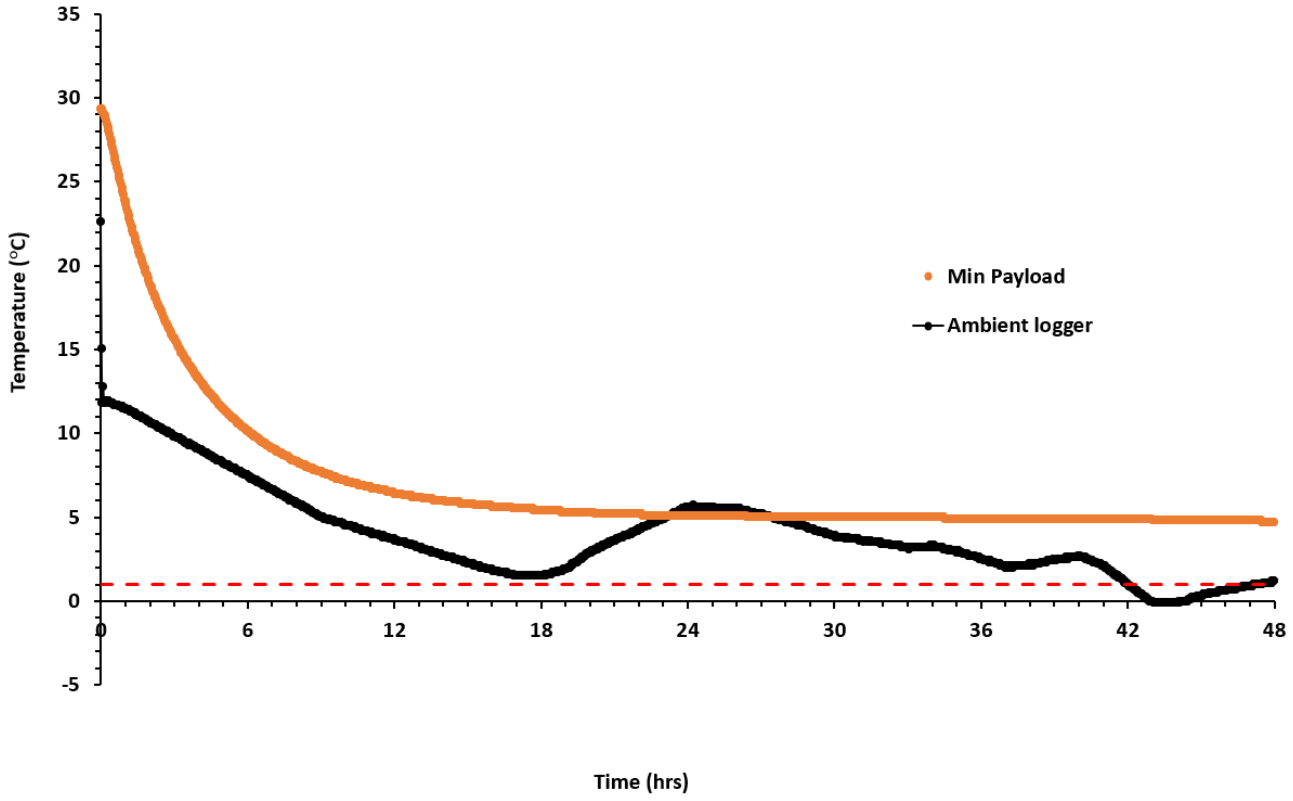
Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours		Result
48	Payload 1 - Top	Payload 2 - Bottom	Pass
	6°C	6.2°C	

5.3.8 Unprocessed whole blood cooling towards (1-10°C) | Winter | Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B18-PCM5-Blue (4 units), B18-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	2 units of 500mL saline filled mock WB bag stored at 37°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 22* Chamber temperature – MaxQ Logger 10* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

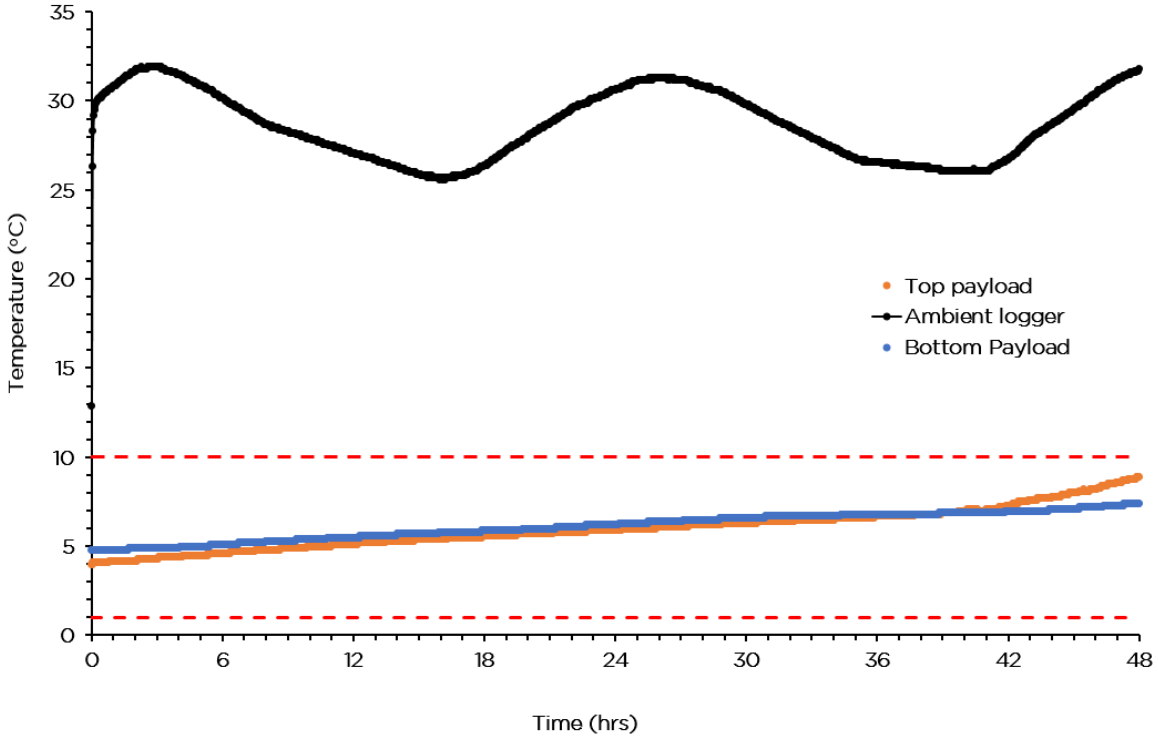
Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours	Result
48	4.7°C	Pass

5.3.9 Processed pRBCs (1-10°C) | Summer | Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B18-PCM5-Blue (4 units), B18-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	24 units of 250-350mL saline filled mock RBC bags stored at 2-6°C for 12 hours
Temperature data loggers	Bottom Payload temperature – MaxQ Logger 34* Top Payload temperature – MaxQ Logger 38* Chamber temperature – MaxQ Logger 40* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

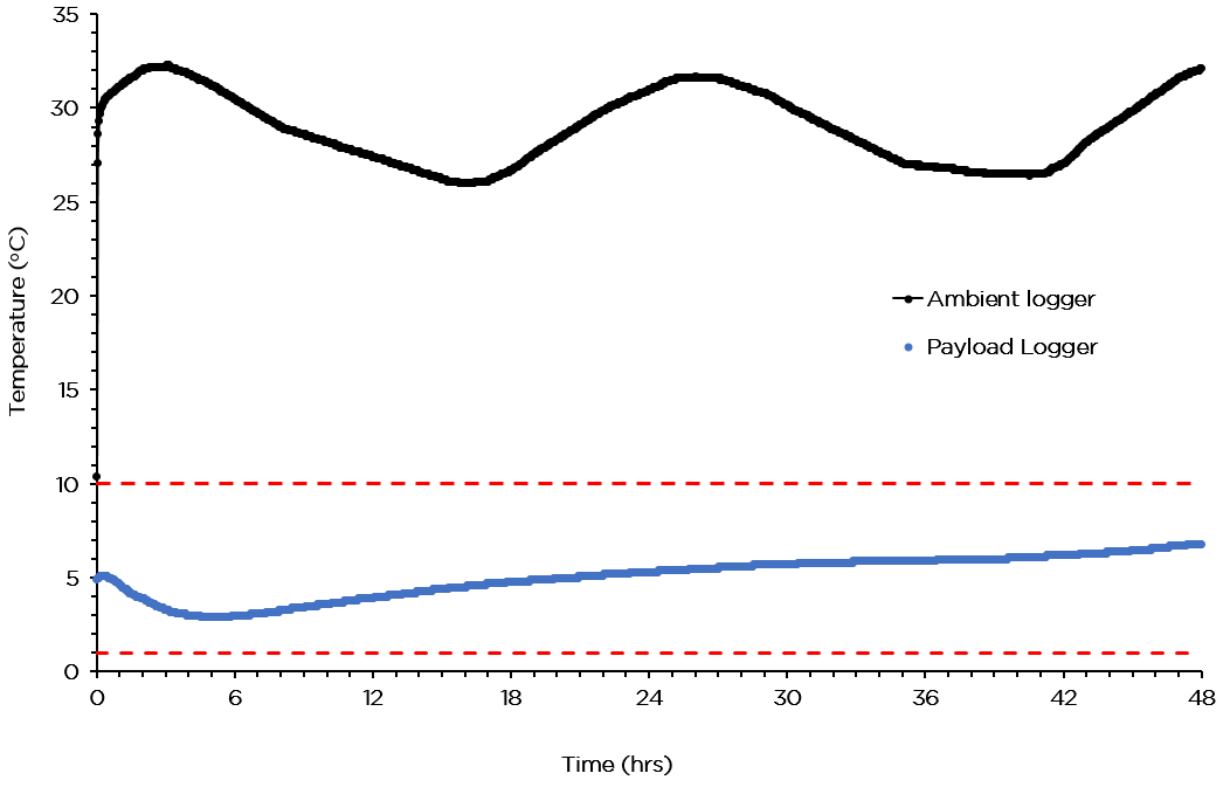
Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours		Result
48	Payload 1 - Top	Payload 2 - Bottom	Pass
	8.9°C	7.4°C	

5.3.10 Processed pRBCs (1-10°C) | Summer |Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B15-PCM5-Blue (4 units), B15-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	2 units of 250-350mL saline filled mock RBC bag stored at 2-6°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 38* Chamber temperature – MaxQ Logger 20* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Summer profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours	Result

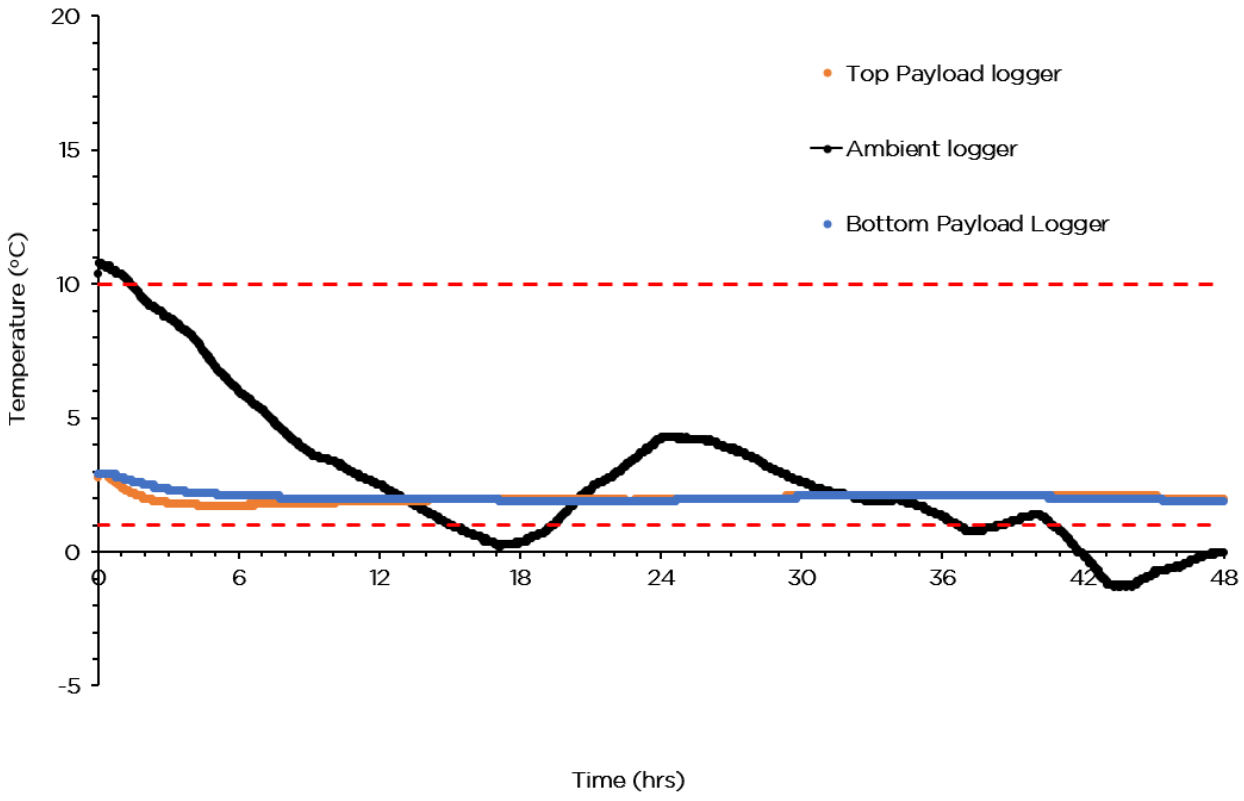
48	6.8°C	Pass

5.3.11 Processed pRBCs (1-10°C) | Winter |Maximum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B15-PCM5-Blue (4 units), B15-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	24 units of 250-350mL saline filled mock RBC bag stored at 2-6°C for 12 hours
Temperature data loggers	Bottom Payload Temperature – MaxQ Logger 34* Top Payload temperature – MaxQ Logger 38* Chamber temperature – MaxQ Logger 40* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours		Result
48	Payload 1 - Top	Payload 2 - Bottom	Pass

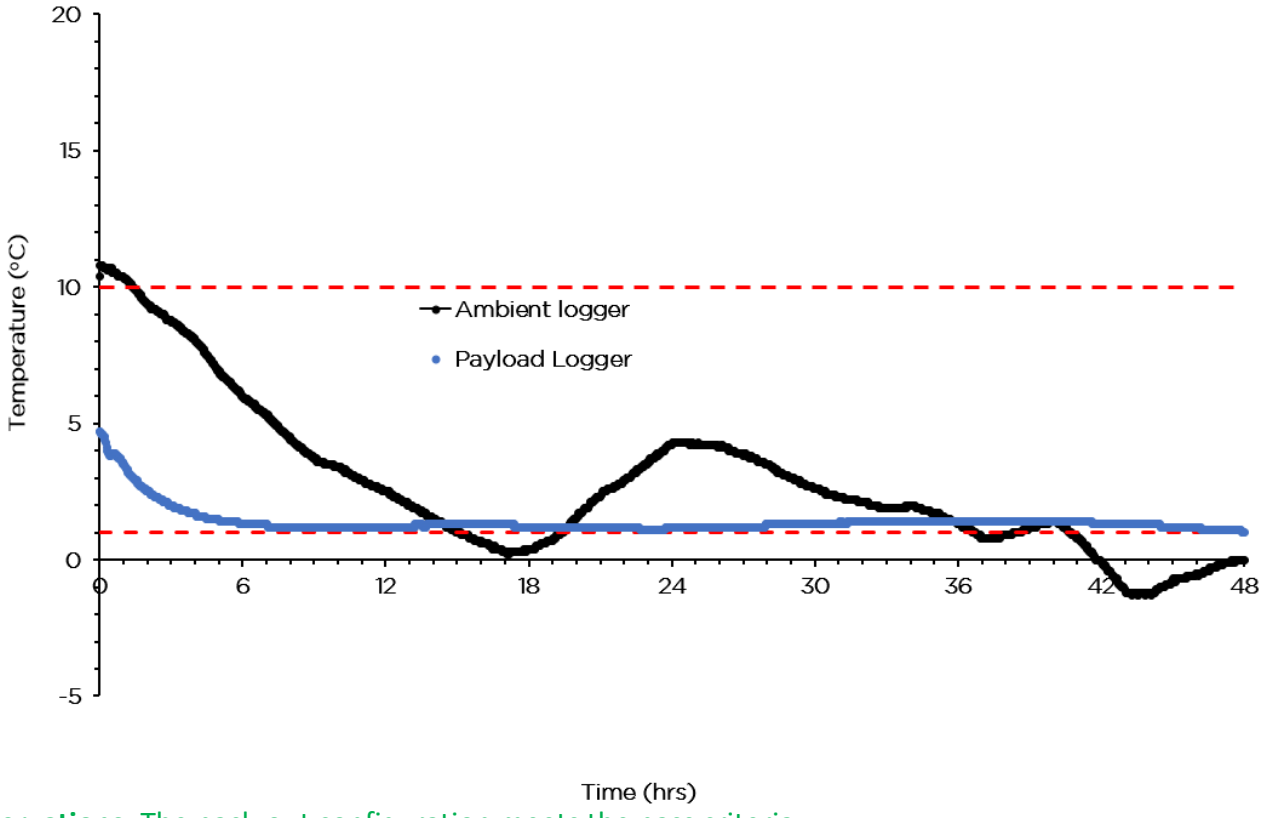
	2°C	1.9°C	

5.3.12 Processed pRBCs (1-10°C) | Winter |Minimum Payload Configuration

Test setup:

Container	MaxPlus Multi-Product Shipper (SKU#R13V48)
Gel packs	B15-PCM5-Blue (4 units), B15-PCM5-Yellow (4 units)
Preconditioning	(x4) blue B18-PCM5's stored at -20 °C for 24 hours and (x4) yellow B18-PCM5's stored at 2-6 °C for 24 hours
Test payload	2 units of 250-350mL saline filled mock RBC bag stored at 2-6°C for 12 hours
Temperature data loggers	Payload temperature – MaxQ Logger 38* Chamber temperature – MaxQ Logger 32* *Loggers were set to record temperature every 2 minutes *Temperature probe was taped to payload bags
Ambient temperature	**Winter profile**
Test duration	48 hours

Thermal performance plot:



Observations: The pack-out configuration meets the pass criteria.

Total time (hours) payload maintained between 1-10°C	Payload temperature after 48 hours	Result
48	1°C	Pass