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# Design Qualification Report for the MaxPlus Non-dry Ice Frozen Plasma Shipper

Intended for the transport of frozen plasma units kept below -18 °C



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## Ship frozen (brittle) plasma units with confidence.

Dry ice sublimates creating empty air pockets in your shipping container, placing plasma units at risk of breakages, during shipping. The Transfusion Blood Industry faces up to 10% loss in plasma unit shipment damages, in addition to the complexity of procuring and handling dry ice. By using reusable, form stabilized, phase change coolants that melt and freeze below -18°C, your plasma units are protected both thermally and physically in our purpose-designed MaxPlus “Non-Dry Ice” Frozen Plasma shippers.

## 1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the MaxPlus Non-dry Ice Frozen Plasma Shipper (SKU#PL13V48-N). The report addresses basic system requirements, components breakdown, packing methods and temperature compliance data captured for the PL13V48-N to transport frozen plasma units below -18°C for a minimum of 48 hours.

## 2. Requirements Summary:

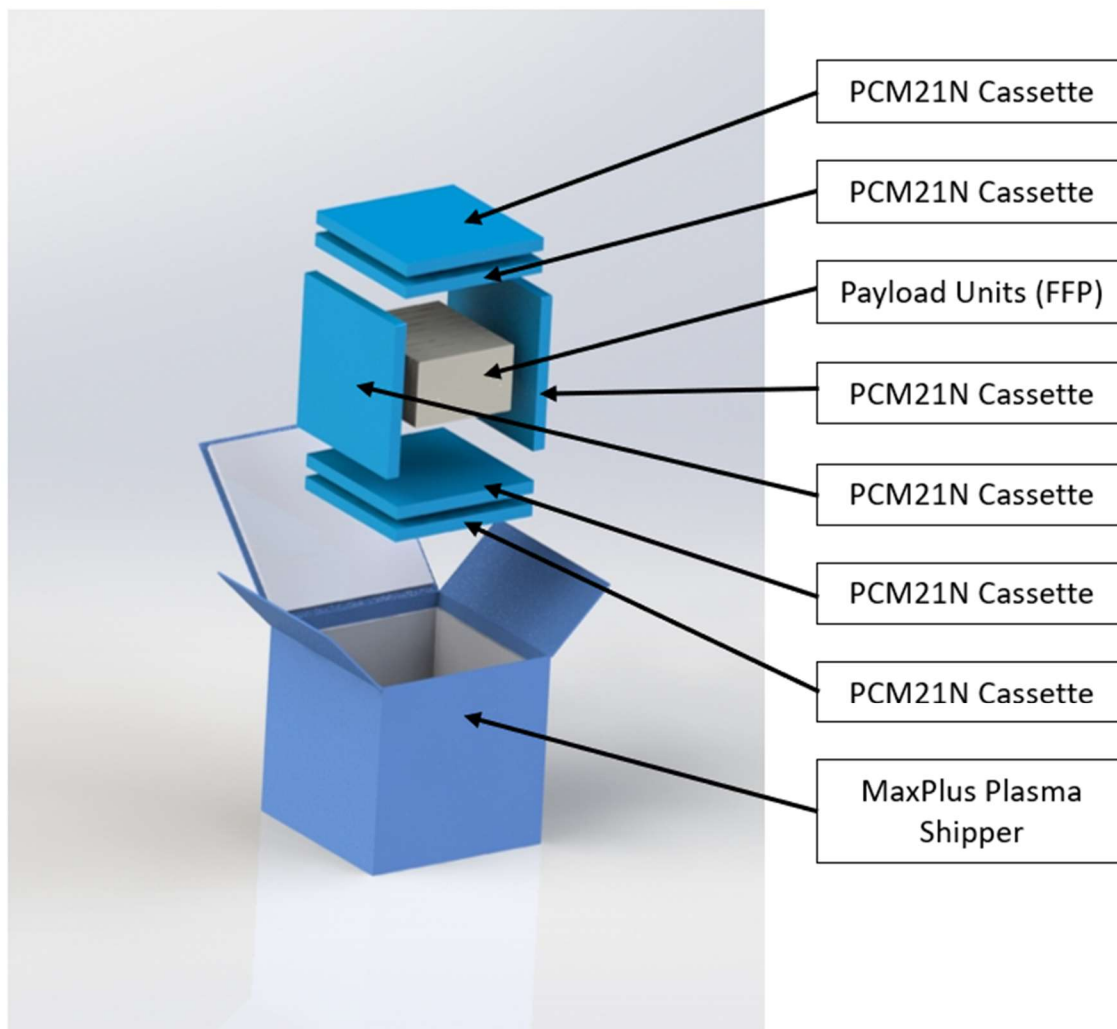
Payload type	Plasma units
Payload form factor and unit volume	300mL plasma bags (FFP) inside craft cardboard boxes - 8.5"x5.5"x1"
Payload volume	15.7L
Payload capacity	1 to 9 frozen units (FFP size)
Payload temperature	below -18°C ( $\pm$ 0.5°C)
Validation	48 hours against ISTA 7D standards

## 3. Product Summary and Components:

- Outer Shell: Corrugated plastic (Blue), highly reusable
- Insulation: 0.5" VIPs (vacuum insulated panels)
- Outer Dimensions: 13.75" x 13.75" x 14" (l x w x h)
- Payload Dimensions: 10" x 12" x 8" (l x w x h)
- Payload Volume: 15.7L
- Phase Change Coolant: 6 x PCM21N plastic cassettes
- System Weight (excluding payload): 23.5 lbs.

## 4. Packing Methods

### 4.1 PL13V48-N Packout Schematic:



### 4.2 PL13V48-N Coolant Conditioning Procedure:

- Charge six PCM21N phase change cassettes (blue plastic) in the freezer at  $-30^{\circ}\text{C}$  or below for a minimum of 24 hours. Plasma freezers are acceptable.

*Note: PCM21N is a dry ice replacement phase change coolant that melts/freezes around  $-21^{\circ}\text{C}$ . The coolant needs to be conditioned at or below  $-30^{\circ}\text{C}$  for it to charge completely.*

### 4.3 PL13V48-N Packing Instructions:

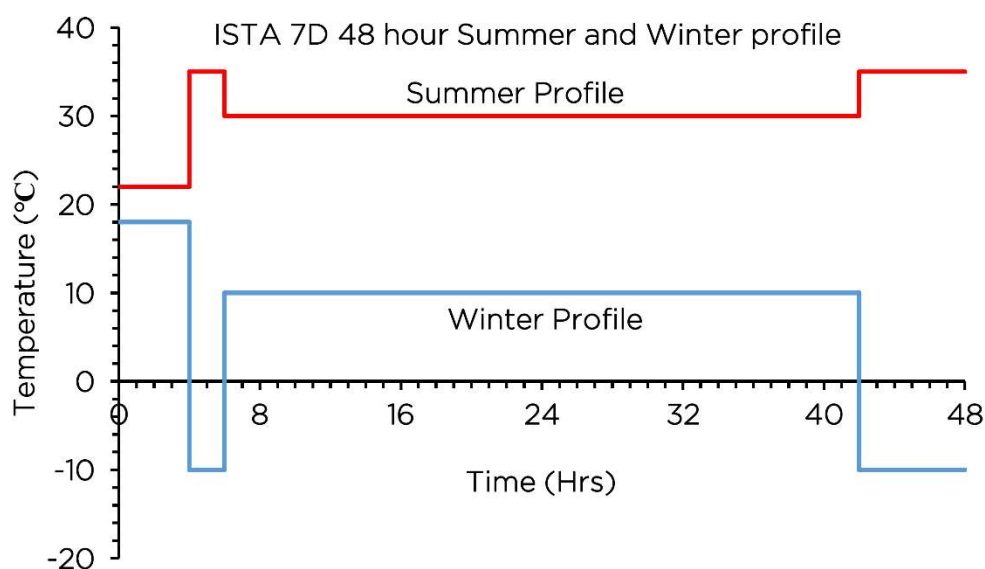
- **Step 1:** Place two frozen PCM21N phase change cassette (blue plastic) in bottom of the shipper.
- **Step 2:** Place two frozen PCM21N phase change cassette (blue plastic) against the left and right walls of the shipper.
- **Step 3:** Place the payload units directly on top of the bottom phase change cassettes.
- **Step 4:** Place the last two frozen PCM21N phase change cassettes directly on top of the payload units. Fill any empty space inside the payload volume with packaging material (bubble wrap, etc.) to avoid payload shifting during shipment.
- **Step 5:** Close and seal the lid properly using packaging tape.

**Disclaimer:** The MaxPlus Plasma Shipper (PL13V48-N) packed as described above has been qualified for up to 48 hours of frozen plasma transport below  $-18^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{C}$ ). The ambient temperature profile for a specific location may vary. MaxQ cannot guarantee that the payload can maintain required temperature without any excursions if the ambient temperature exposure of the packed system is not within the tested temperature range.

## 5. Thermal Performance Testing

### 5.1 Ambient profiles used for testing

The MaxPlus Non-Dry Ice Frozen Plasma Shipper was exposed to the following 48-hour ISTA 7D based summer profile inside a precision environmental chamber for performance testing.



## 5.2 Shipper performance evaluation

The MaxPlus Non-Dry Ice Frozen Plasma Shipper was packed according to the instructions specified above (Pages # 3, 4), and exposed to the summer ambient profile shown above in a NIST calibrated programmable thermal chamber. The shipper was not tested against winter conditions, since summer ambient represents the worst-case scenario for frozen plasma units. To further simulate the worst-case scenario only one plasma simulant unit (300ml) was used in the testing. An NIST calibrated precision temperature logger was taped to the plasma simulant unit to record surface temperature of the unit every 2 minutes. At the end of test cycle, payload simulant temperature data was analyzed and the shipper performance was evaluated according to the following criteria:

**Pass Criteria :** Payload temperature stayed below -18°C (±0.5°C) during the 48 hours of test duration

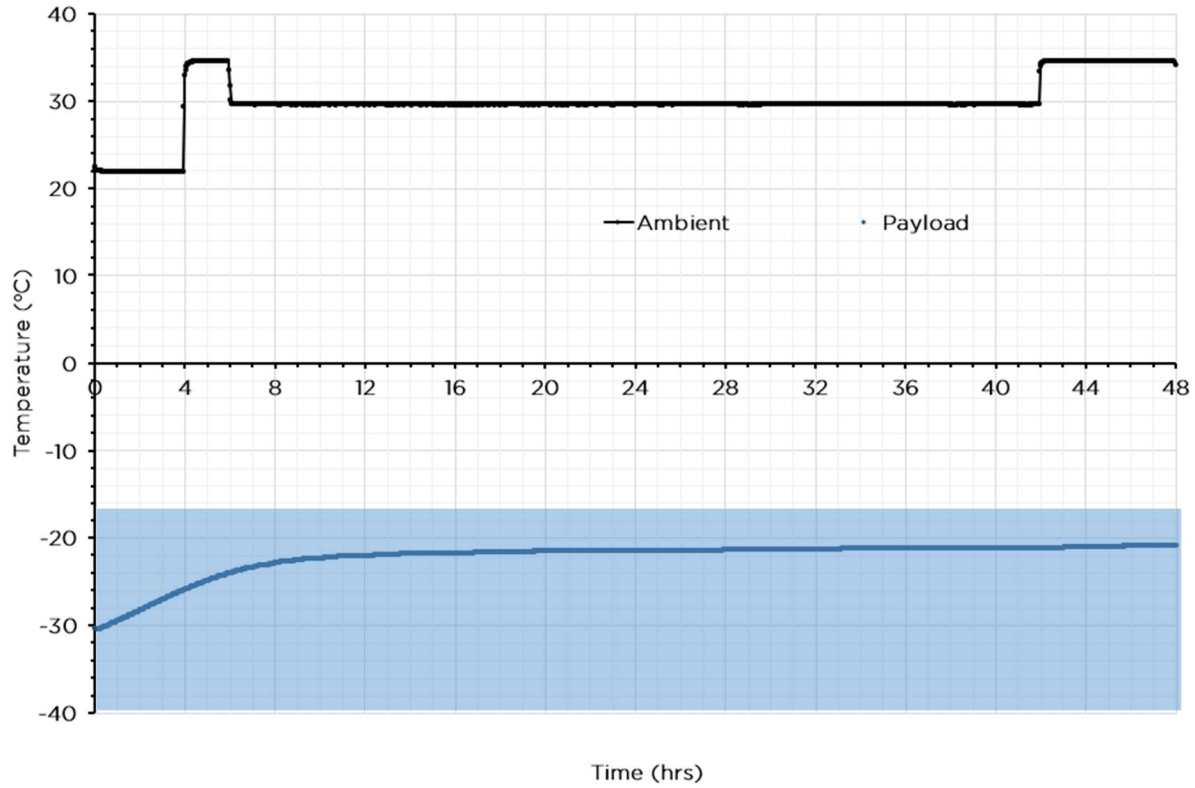
**Fail Criteria :** Payload temperature went above -18°C (±0.5°C) during the 48 hours of test duration

## 5.3 Design qualification results:

### Test setup:

Container	PL13V48-N
Gel packs	6 x PCM21N cassettes (Blue)
Preconditioning	Charge 6 x PCM23N cassettes (Blue) in the freezer (below -30°C for a minimum of 24 hours).
Test payload	1 x 300ml plasma unit conditioned at -30°C
Temperature data loggers	Payload temperature - MaxQ Logger 11* Ambient temperature - MaxQ Logger 34*  *NIST traceable temperature data loggers. Certificates available upon request. *Loggers were set to record temperature every 2 mins
Ambient	Summer (Section 5.1)
Test duration	48 hours

**Thermal performance plot:**



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

Total time (hours) payload remained below -18°C	Payload temperature after 48 hours	Result
48	-20.9°C	Pass