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Design Qualification Report for the MaxPlus Vaccine Cooler

Exclusive system designed for the 2-8°C short term transport of vaccines OR to aid in the off-site/curbside storage of vaccines during mass immunization sessions



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1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the components and thermal performance of the MaxPlus Vaccine Cooler (SKU#V12X12). The report addresses basic system requirements, components breakdown, packing methods and temperature compliance data for the V12X12 to aid in the 2-8°C short-term transport of vaccines OR to aid in the off-site/curbside storage of vaccines during mass immunization sessions for a minimum of 12 hours under controlled temperature (20-24°C).

2. Requirements Summary:

Payload type	Refrigerated Vaccine Products
Payload form factor	Vaccine trays
Payload temperature	2-8°C
Validation	12 hours at controlled room temperatures (20-24°C)

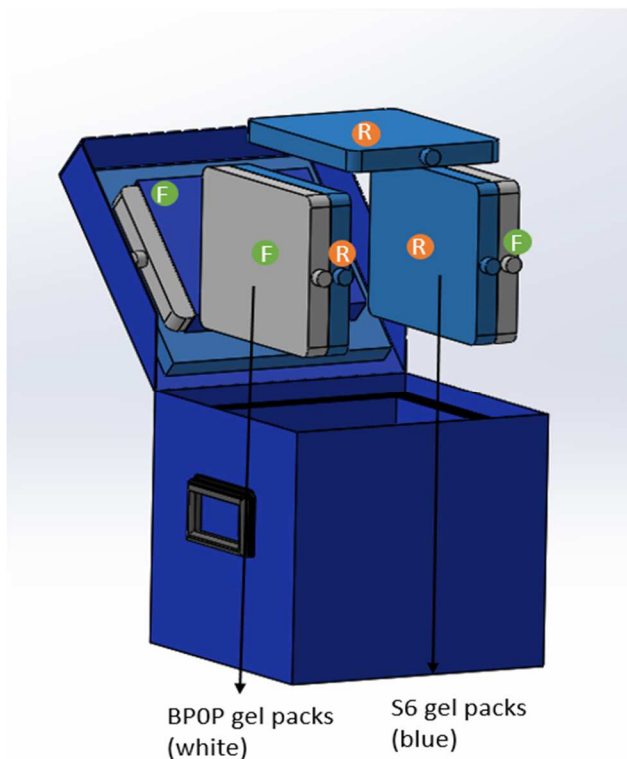
3. Product Summary and Components:

- Outer Shell Material: Corrugated plastic, highly reusable
- Outer Dimensions: 14"x13.5"x13" (LWH)
- Payload Dimensions: 5.75"x10"x8" (LWH)
- System Weight (excluding payload): 17 lbs.
- Phase Change Coolant: (x3) S6 gel packs (blue), (x3) BPOP gel packs (white)



4. Packing Methods

4.1 V12X12 Packout Schematic:



Gel pack arrangement:

3 x Frozen (White bottles) – 2 against left and right walls, 1 on lid

3 x Refrigerated (Blue bottles) – 2 against left and right walls and one on top of payload units

4.2 V12X12 Coolant Conditioning Procedure:

- Place three white gel packs in the freezer (-20°C for a minimum of 12 hours)
- Place three blue S6 gel packs in the refrigerator (1-6°C for a minimum of 12 hours)

4.3 V12X12 Packing Instructions:

- 1) Place two frozen white gel packs against the left and the right cooler walls.
- 2) Place two refrigerated blue S6 gel packs against the inside face of the white gel packs. As seen in the packout illustration above.
- 3) Insert the last frozen gel pack into the pouch attached to the lid. Close the lid and leave shut for 30 minutes to allow the cooler to climatize.
- 4) Place DDL (if applicable) and the payload (Vaccine vials) inside the cooler.
- 5) Insert last remaining refrigerated S6 bottle on top, close the lid and issue the cooler.

Disclaimer: The MaxPlus Vaccine Cooler (V12X12) packed with three S6 gel packs and three BPOP gel packs has been qualified for a minimum of **12 hours to hold 2 to 8°C for up to 8L of refrigerated vaccines** in the described laboratory tests. The ambient temperature profile for a specific location may vary. MaxQ cannot guarantee that the payload can maintain required temperature range without any excursions if the ambient 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 presented V12X12 Vaccine Cooler with S6 gel packs (x3) and BPOP gel packs (x3) is designed to accommodate the two use-cases outlined below in sections 5.1.1 and 5.1.2. The system was tested at controlled room temperatures (20-24°C) for each use-case. A glycol encased data logger (NIST traceable calibration) was used to measure internal temperature during testing and the cooler was prepared and packed following the methods listed in Section 4. At the end of each test run, payload temperature data was downloaded and analyzed to assess the systems' performance

- 5.1.1 **Short-term transport use-case:** Maintain vaccine units between 2-8°C for a minimum of 12 hours in a controlled cabin of a fleet vehicle (20-24°C). This use case simulates the coolers' ability to maintain vaccine temperature when being transported from local or regional vaccine hubs to immunization sites.
- 5.1.2 **Short-term storage/depletion use-case:** Maintain vaccine units between 2-8°C for a minimum of 12 hours in a rapid depletion mass immunization session at controlled temperatures (20-24°C). This use-case simulates the cooler being used during a mass immunization session to store vaccines. The cooler is opened and closed for a set number of times in a 12-hour period to simulate real world use.

5.2 Ambient profiles used for testing:

For design qualification testing, the MaxPlus Vaccine Cooler (SKU#V12X12) was exposed to controlled temperatures (20-24°C) for 12 hours during performance validation testing.

5.3 Pass and Fail Criteria

Pass Criteria: Payload temperature stayed between 2-8°C during the 12 hours of test duration

Fail Criteria: Payload temperature did not stay within 2-8°C during the 12 hours of test duration

5.4 Thermal Performance Results:

5.4.1 Short-term Transport | Vaccines Maintained at 2-8°C | Empty Payload Configuration

Note: The MaxPlus Vaccine Cooler was validated using an empty container with a single glycol-encased temperature probe (as recommended in the CDC Vaccine Storage and Handling Toolkit) and was tested to simulate short-term transport scenario inside of a temperature-controlled fleet vehicle (20-24°C) for 12 hours.

Container	MaxPlus Vaccine Cooler (V12X12)
Gel packs	S6 (3 units), BP0P (3 units)
Preconditioning	Three BP0P gel packs stored at -20°C for 12 hours and three S6 gel packs stored in the refrigerator (1-6°C)
Test payload	Glycol buffer solution in a glass bottle with a temperature probe. (CDC recommendation compatible DDL)
Temperature data loggers	VWR Glycol Buffer Probe Logger – Probe 1 Ambient temperature – MaxQ Logger 33* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 24°C
Test duration	12 hours

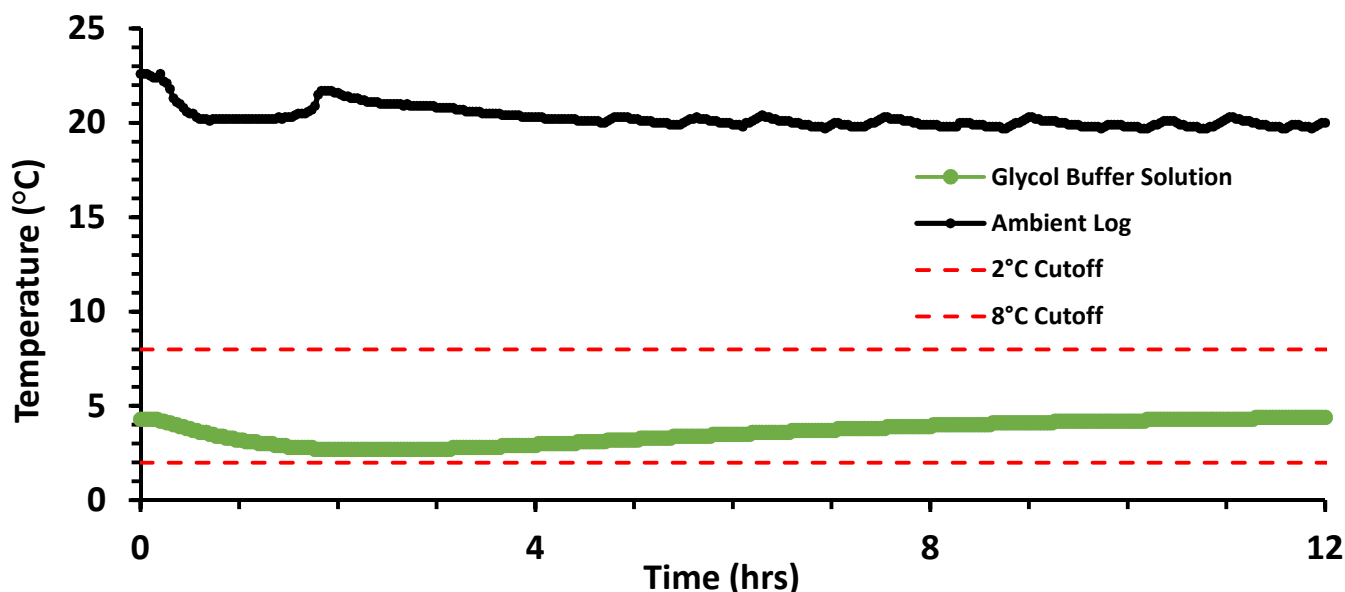
5.4.2 Payload Preparation

- Payload used for validation test should be pre-conditioned at appropriate temperature for at least 12 hours prior to start of the test.
 - **Recommendation:** Glycol buffer bottle with temperature probe (CDC requirement compatible DDL) shall be stored inside refrigerator (2-8°C) for at least 12 hours and used as a simulant for cooler validation. This would represent the worst-case scenario for the cooler.

Thermal Performance Results:

	Payload temperature (°C)		Result
	Start Time - 0 hrs.	End Time - 12 hrs.	
Glycol Buffer Solution	4.8	5.9	Pass

Performance graph



Minimum Payload Simulant Temperature: 2.1 °C
 Maximum Payload Simulant Temperature: 5.9 °C

5.4.3 Short-term Storage/Depletion | Vaccines Maintained at 2-8°C | Empty Payload Configuration

Note: The MaxPlus Vaccine Cooler was validated using an empty container with a single glycol-encased temperature probe (as recommended in the CDC Vaccine Storage and Handling Toolkit) and was tested to simulate in a mock mass immunization scenario to hold 2 to 8°C under controlled room temperature conditions for at least 12 hours. The cooler was packed with all coolant and left closed for 30 minutes to stabilize air temperature inside the cooler. A DDL (digital data logger) was then placed in the cooler and the lid was opened for 15 seconds every 5 minutes for 2 hours to simulate a mass immunization session where multiple lid opening events occur. Following the two hours of lid opening events the cooler was then left shut for the remaining 10 hours of the 12-hour tested duration.

Container	MaxPlus Vaccine Cooler (V12X12)
Gel packs	S6 (3 units), BPOP (3 units)
Preconditioning	Three white BPOP gel packs stored at -20°C for 12 hours and three blue S6 gel packs stored in the refrigerator (1-6°C)
Test payload	Glycol buffer solution in a glass bottle with a temperature probe. (CDC recommendation compatible DDL)
Temperature data loggers	Glycol Buffer Probe Logger – Probe 1 Ambient temperature – MaxQ Logger 33* *Loggers were set to record temperature every 2 minutes *Thermocouple was taped to the water bag to measure payload temperature
Ambient temperature	20 to 24°C
Test duration	12 hours

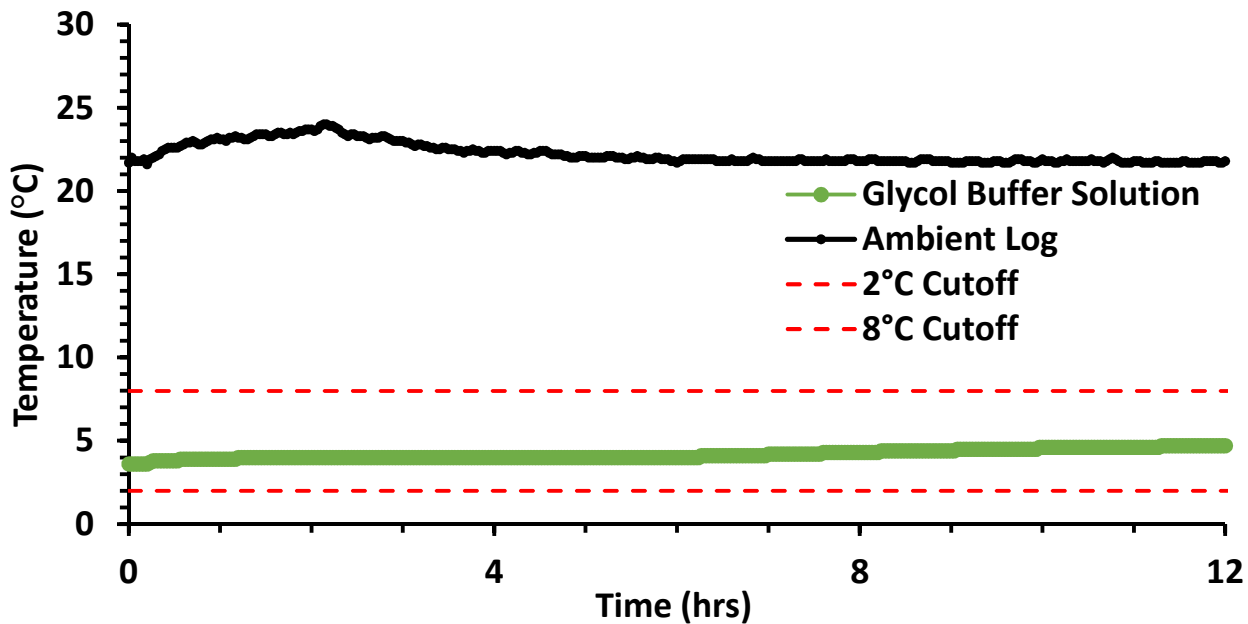
5.4.4 Payload Preparation

- Payload used for validation test should be pre-conditioned at appropriate temperature for at least 12 hours prior to start of the test.
 - **Recommendation:** Glycol buffer bottle with temperature probe (CDC requirement compatible DDL) shall be stored inside refrigerator (2-8°C) for at least 12 hours and used as a simulant for cooler validation. This would represent the worst-case scenario for the cooler.

Thermal Performance Results:

	Payload temperature (°C)		Result
	Start Time - 0 hrs.	End Time - 12 hrs.	
Glycol Buffer Solution	4.1	6.8	Pass

Performance graph



Minimum Payload Simulant Temperature: 4.1°C
 Maximum Payload Simulant Temperature: 6.8°C

Validation of MaxPlus Vaccine cooler for any payload configuration other than the recommended one could result in shorter validation duration. Please contact MaxQ Research at sales@packmaxq.com if your validation test criteria are different than what is listed in this validation guide.