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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#AV12X12). The report addresses basic system requirements, components breakdown, packing methods and temperature compliance data for the AV12X12 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) BP0P gel packs (white)

4. Preparing the Cooler for Initial Use

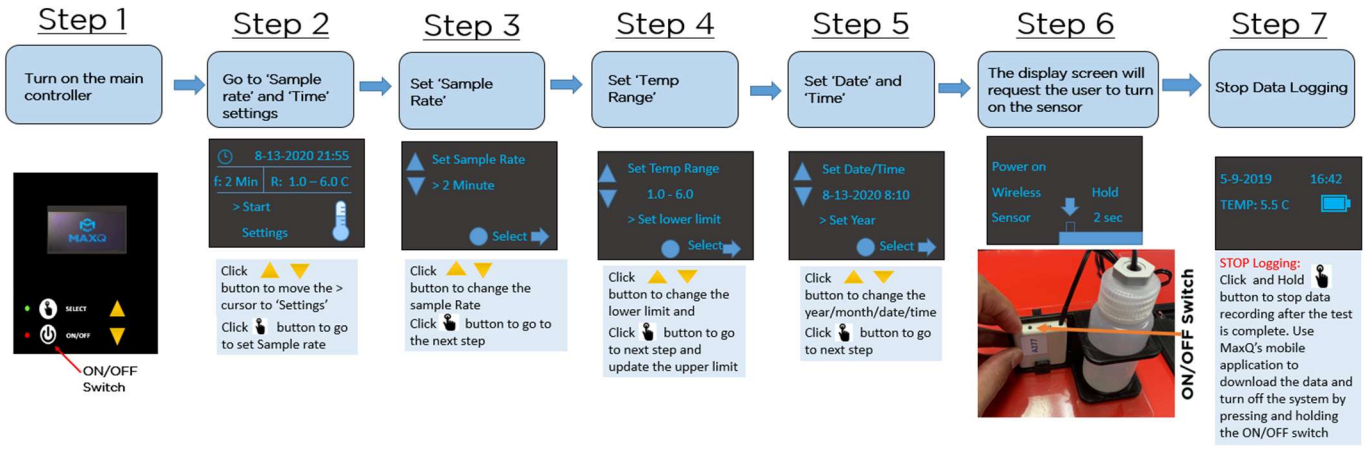
List of Assumptions:

- Minimum battery level: The main controller should at least be 50% charged before issuing the cooler.
- DO NOT PRESS THE ON/OFF BUTTON WHILE THE SYSTEM IS RECORDING TEMPERATURE DATA. Pressing the button will result in loss of data.

Follow the sections below to change default system settings.

4.1 Setting up the temperature monitoring rate (Sample time)

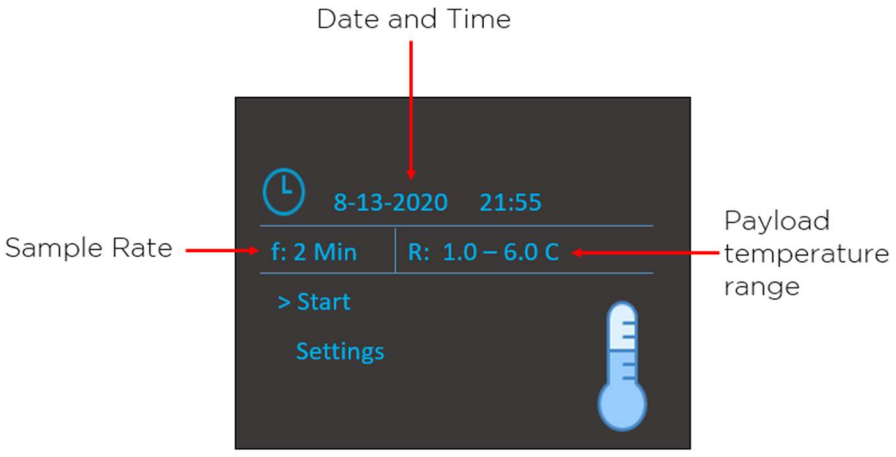
- Step 1: Turn the Main Controller ON by pressing the ON/OFF button once. The display will show battery level for the Main Controller module.
- Step 2: For those using the system for the first time, please check the 'Sample Rate' (how often the controller will record the temperature), 'Date and Time', and 'Temp Range' displayed on the screen. If these parameters need to be adjusted, the user can -



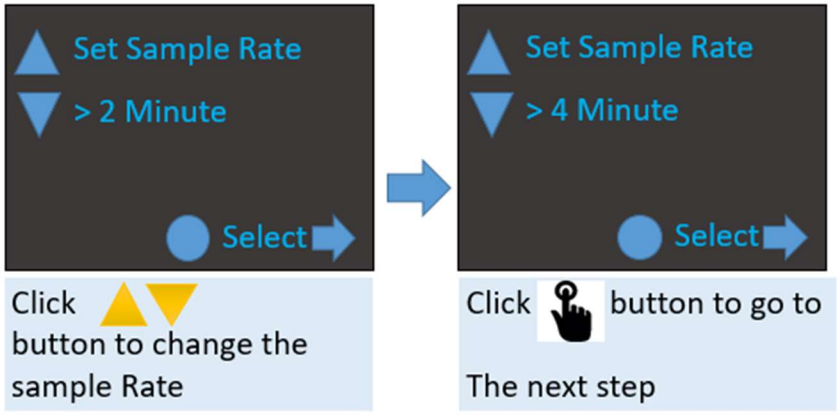
  - Use the 'DOWN' button to move the > (cursor) to 'Settings' and press the 'Select' button to go into 'Sample Rate', 'Temp Range' and 'Date/Time' setting.

Note: Select "Start" if there is no change to 'Sample Rate', 'Temp Range' and displayed Date and Time

- Step 3: Please set how often the controller shall record temperature (Sample rate)

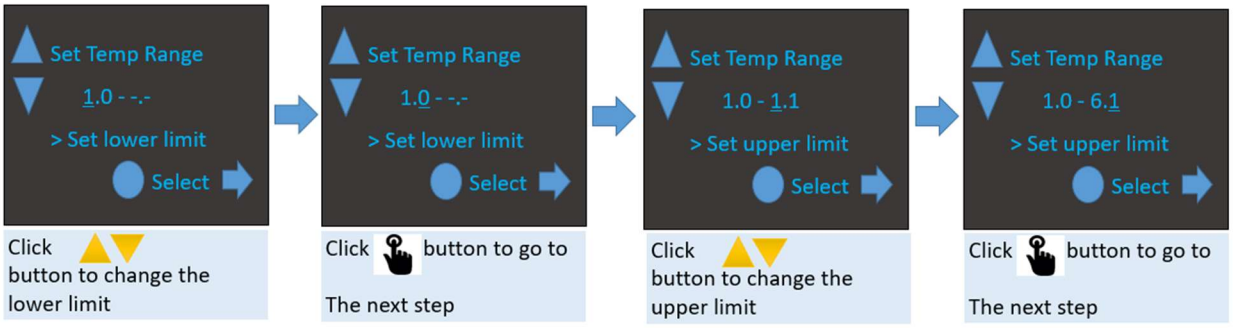


- Use the '**UP**' or '**DOWN**' button to change the sample rate. The default sample rate is 2 which means one temperature data recorded every 2 minutes (30 data points every hour). This is the minimum sample rate. The user can increase the number to decrease the sample rate. For example, a sample rate of 10 would mean payload temperature data recorded once every 10 minutes (6 data points every hour).
- Press the '**SELECT**' button to accept the changes and go to the next screen.



4.2 Setting up payload temperature range

- Step 4: Under this step, the user can select the acceptable lower and upper payload temperature range for the product that will be stored inside the cooler. The standard temperature range for the cooler is 2-8°C for refrigerated vaccines.

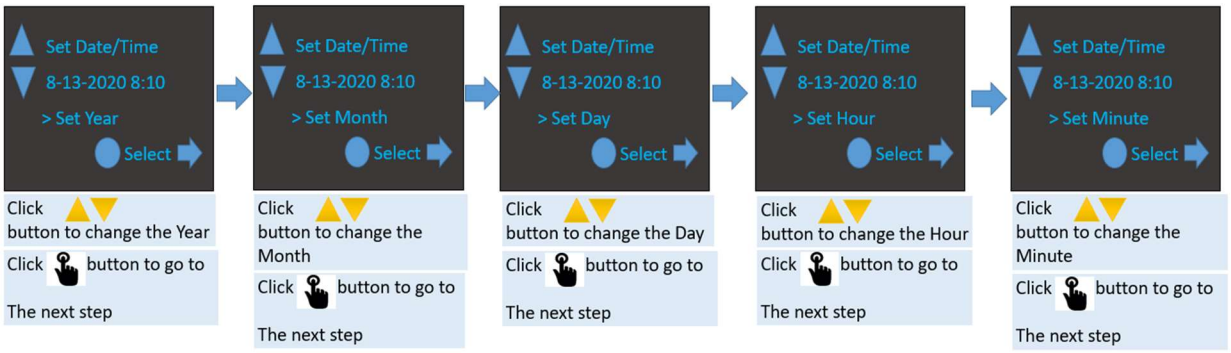


- Setting the lower limit: Use the '**UP**' or '**DOWN**' button to increase or decrease the value
- Press '**SELECT**' to accept the change and move to the next screen.

- Setting the upper limit: Use the '**UP**' button to increase the value to acceptable upper temperature value.
- Press '**SELECT**' to accept the change and move to the Date/Time Screen

4.3 Setting up Date and Time on the main controller

- Step 5: Inside the Date and Time setting the user can change year, month, day, hour and minute sequentially (pictures below).



- Use the '**UP**' or '**DOWN**' button to increase or decrease the value
- Press '**SELECT**' to accept the change and move to the next screen.

After the user has adjusted the 'minute' and accepted the change, the system will automatically go to the next screen.

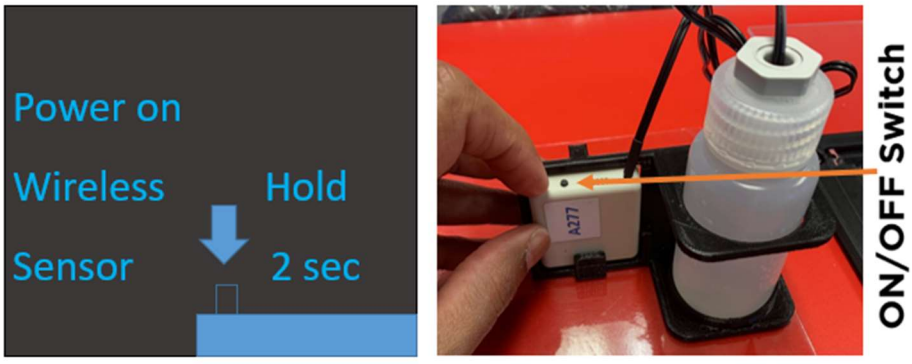
4.4 Starting the logger

Follow the steps below to start the system before issuing the cooler. **Note:** Please follow the instructions in the previous sections to change the default system settings.

- Step 6: Place the Main Controller into the dedicated slot on top of the cooler lid.

  Note: Do not turn ON the Main Controller device before placing it inside the dedicated slot. The glycol-encased temperature probe pairing will not work if the main controller device is not placed properly on the cooler lid.

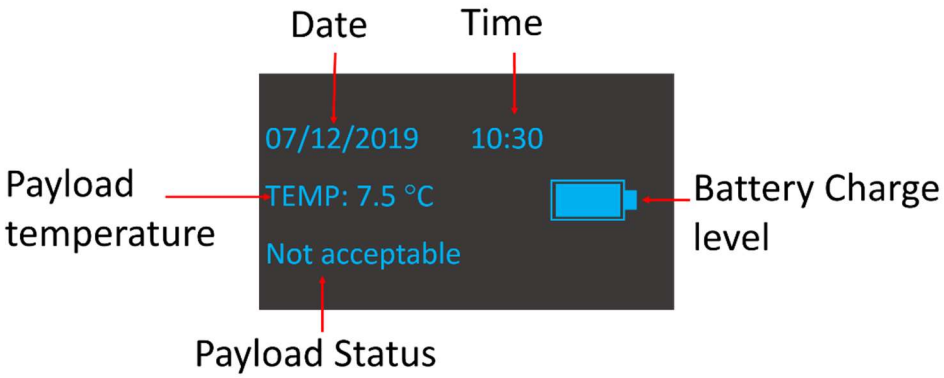
- Step 7: The next screen will ask the user to turn the glycol-encased temperature probe ON. Push and hold the black button for 2 seconds to turn the sensor ON.



For verification, check the blue LED status light on the glycol-encased temperature probe. If the blue LED on the sensor blinks once then the sensor is ready. The display on the main controller will show battery level (similar to figure below) for the glycol-encased temperature probe and automatically start logging payload temperature. The LCD display during temperature logging is shown below:

DO NOT PRESS THE ON/OFF BUTTON WHILE THE SYSTEM IS RECORDING TEMPERATURE DATA. Pressing the button will lead to loss of data.

- The screen will show

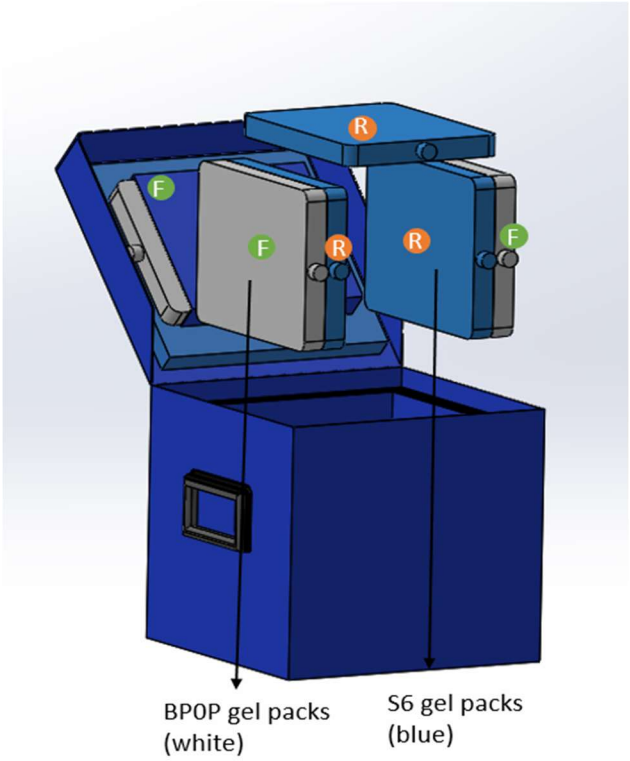


- Date and Time
- Temperature of the payload
- Payload status – Not Acceptable if payload temperature went below or above the user defined thresholds
- Battery level - % of charge remaining in the main controller

- Step 8: To STOP recording, press and hold the SELECT button for a few seconds and release. The screen will display 'Logging stopped' and ask the user to download the data before turning the Main Controller off. For turning the glycol-encased temperature probe off push and hold the black button for 2 seconds.

5. Packing Methods

5.1 AV12X12 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

5.2 AV12X12 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)

5.3 AV12X12 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.

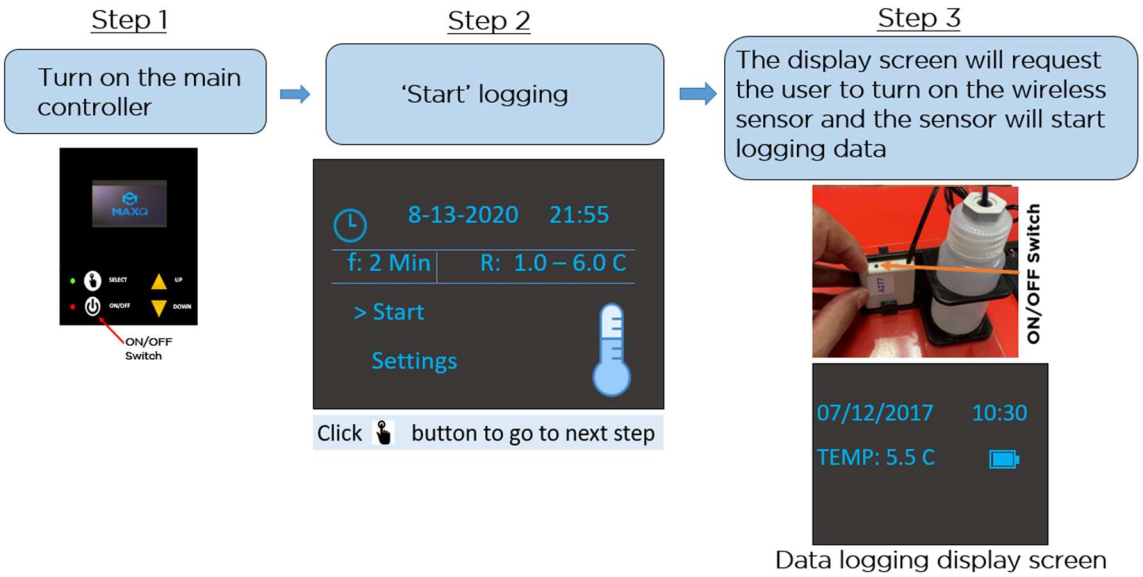
5.4 Start Temperature Monitor:

4) Place the Main Controller into the dedicated slot on top of the cooler lid.

Note: Do not turn ON the Main Controller device before placing it inside the dedicated slot. The glycol-encased temperature probe pairing will not work if the main controller device is not placed properly on the cooler lid.

5) Turn ON the Main Controller and follow on-screen instructions.

6) When prompted, turn ON the glycol-encased temperature probe (hold black button for 2 seconds and release). Wait till you see the first temperature data on the display, Open the cooler lid and then place sensor inside the container.



Data logging display screen

MaxTrace starting and cooler issue procedure.

Note: After the sensor has been turned on, the user is requested to allow the sensor to establish secure communication with the main controller (15-20 seconds) before opening the lid of the cooler to place the sensor inside the cooler. The user can confirm established connection between the glycol-encased temperature probe and the display by verifying temperature data that will be displayed on the screen. After verifying the temperature data is displayed on the screen, then the user may open the cooler to place the sensor. *Please note that opening the lid of the cooler before the glycol-encased temperature probe has been able to communicate with the main controller can result in data loss and prevent the cooler from logging the temperature.*

5.5 Finish Pack-out of the Cooler

7) Place DDL (if applicable) and the Vaccine vials/trays inside the cooler.

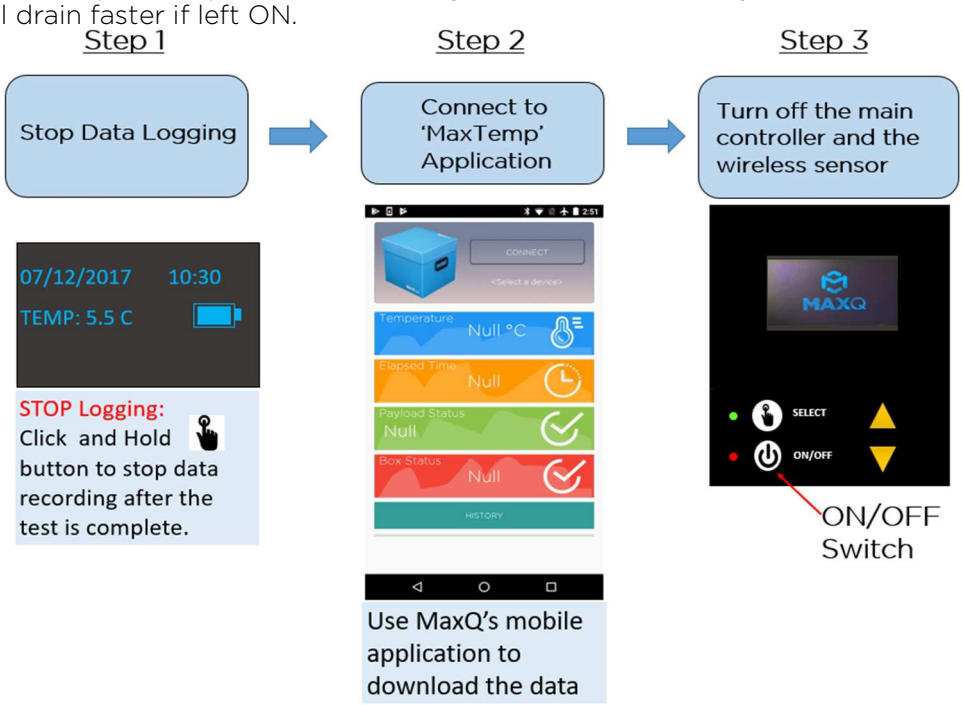
8) Insert last remaining refrigerated S6 bottle on top, close the lid and issue the cooler.

Disclaimer: *The MaxPlus Vaccine Cooler (V12X12) packed with three S6 gel packs and three BP0P 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.*

5.6 Retrieve Temperature Data

- Step 1: To STOP recording, press and hold the SELECT button for a few seconds and release. The screen will display 'Logging stopped' and ask the user to download the data before turning the Main Controller off.
- Step 2: Connect with "MaxTemp" iOS, Android, or Windows 10 Desktop application to download temperature data.
- Step 3: After successfully retrieving the data, turn both the main controller and sensor OFF. If the cooler needs to be issued right away, please press the "ON/OFF" button and the system will reboot and ready for next trip in seconds! The glycol-encased temperature probe will also have to be turned off (press and hold the black button for 2 seconds) and turned on back again for the next trip.

Note: After the trip is complete, DO NOT forget to turn OFF the Glycol-encased temperature probe. The battery will drain faster if left ON.



MaxTrace sensor stopping and data retrieval.

Disclaimer: The MaxPlus Vaccine Cooler (AV12X12) packed with three S6 gel packs and three BP0P 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.

6. Design Qualification Test Methods and Results:

6.1 Test Methods: The presented AV12X12 Vaccine Cooler with S6 gel packs (x3) and BP0P 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

6.1.1 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.

6.1.2 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.

6.2 Ambient profiles used for testing:

For design qualification testing, the MaxPlus Vaccine Cooler (SKU#AV12X12) was exposed to controlled temperatures (20-24°C) for 12 hours during performance validation testing.

6.3 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

6.4 Thermal Performance Results:

6.4.1 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 (AV12X12)
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

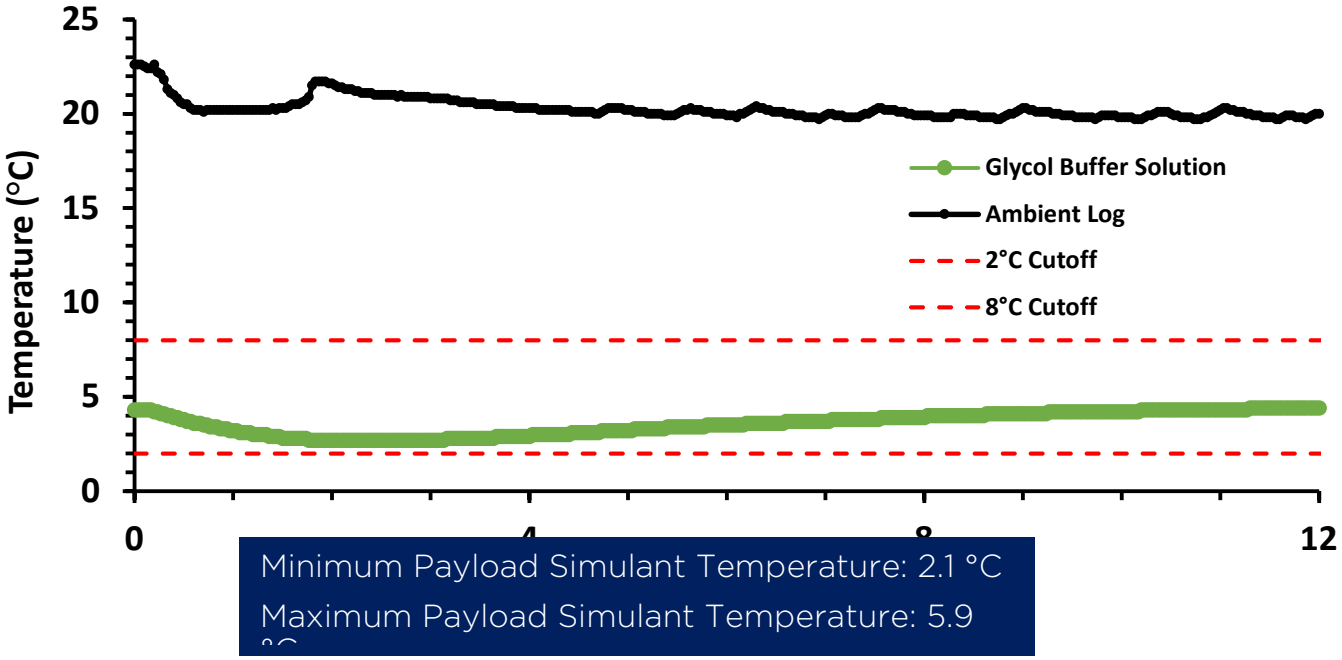
6.4.2 Payload Preparation

- 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



6.4.3 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), BP0P (3 units)
Preconditioning	Three white BP0P 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

6.4.4 Payload Preparation

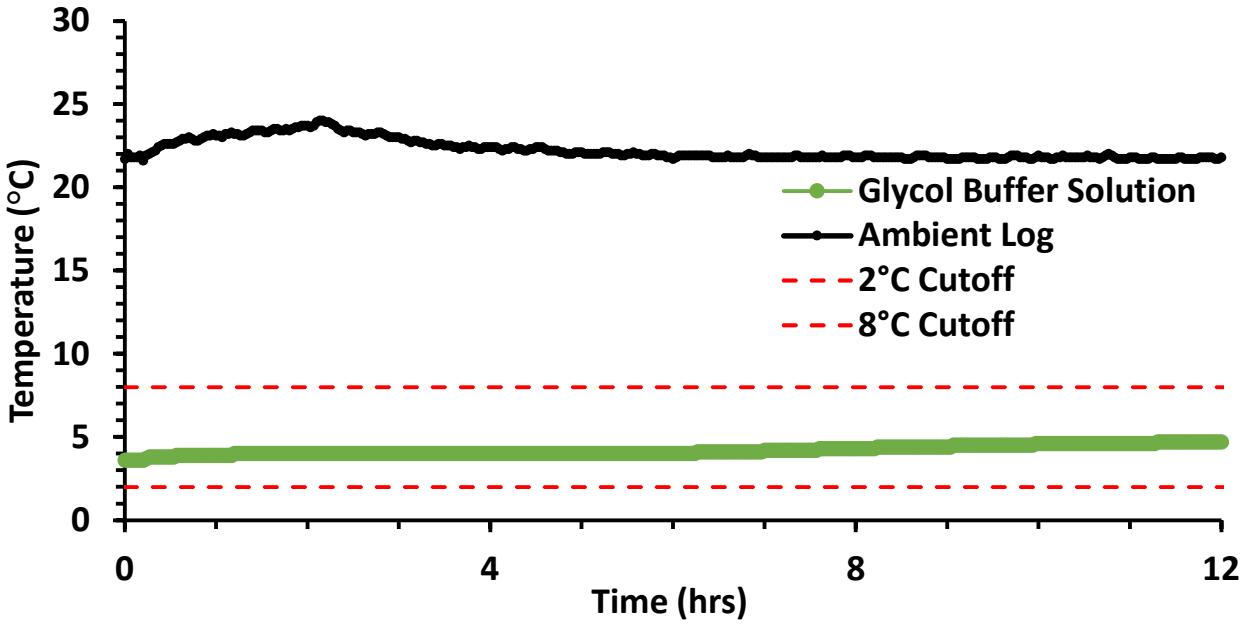
- Payload used for validation test should be pre-conditioned at appropriate temperature for at least 12 hours prior to start of the test.

- **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.