Vaccine Storage Equipment Safety: Temperature Performance Comparison of 2 “Purpose-Built” Vaccine Storage Units Using NSF/ANSI Standard for Vaccine Storage

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1.0 BACKGROUND

INTRODUCTION

In order to protect public health, the Centers for Disease Control and Prevention (CDC) developed guidelines and recommendations for vaccine handling and storage across the cold chain. The first CDC Vaccine Storage and Handling Toolkit was launched in 2012, and it continues to be updated on a periodical basis.

The toolkit was originally based on studies conducted by the Advisory Committee on Immunization Practices (ACIP) and the National Institute of Standards and Technology (NIST). Data collected in the studies clearly indicated the refrigerators and freezers used to store vaccines in clinics and hospitals were, and continue to be, a major risk point.

Failure to properly manage vaccine inventories can reduce potency, leading to ineffective vaccinations and poor protection against preventable, yet devastating diseases.

Using proper cold storage systems designed to maintain required temperature ranges, as well as calibrated temperature monitoring methods, is recommended (1). Following CDC vaccine storage recommendations will help ensure the effectiveness of vaccinations, reduce cost associated with discarded vaccines, and reduce the direct and indirect costs of revaccination.

VACCINE STORAGE CHALLENGES AND RISKS

Vaccines require tight temperature storage ranges to ensure potency. Refrigerators are required to maintain temperatures between 35°F and 46°F (2°C and 8°C), and freezers are required to maintain temperatures between -58°F and +5°F (-50°C and -15°C). Mid-range set points are recommended to provide the best safety margin [(1)].

Exposing vaccines to temperatures above or below these ranges, even for a few minutes, can result in risk to patients receiving the improperly stored vaccine. Exposing refrigerated vaccines to freezing temperatures tend to have the greatest risk. Some vaccines have aluminum adjuvants to increase immune responses. Allowing this type of vaccine to freeze can result in a permanent loss of potency [(2)].

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"76% of healthcare sites had vaccines that were exposed to inappropriate temperatures for at least a 5-hour period due to the use of inadequate refrigerators and freezers. The value of vaccines at risk in a specific facility may be between $15,000 and $75,000. Exposing vaccines to out-of-range temperatures can result in patient safety issues and a permanent loss of potency."

Unless the vaccine is visibly frozen at the time of inspection, clinicians cannot use visual checks to accurately determine which vaccines may have been damaged as a result of exposure to improper temperatures.

Indirect costs related to ineffective or repeat vaccinations are extensive but very difficult to measure. One estimate, based on reported cases of ineffective vaccines due to improper storage, is individual states lose more than $3M a year [(1)].

According to a Department of Health and Human Services report "Vaccines for Children Program – Vulnerabilities in Vaccine Management" released in 2012, 76% of 45 healthcare sites included in a study had vaccines that were exposed to inappropriate temperatures for at least a 5 hour period due to the use of inadequate refrigerators and freezers. These 34 providers had more than 9,000 Vaccines for Children (VFC) doses, worth approximately $370,000 [(1)].

The value of vaccines on hand and at risk in a specific facility will vary, but this value may be between $15,000 and $75,000 with the average refrigerator storing $24,000 worth of vaccines (1). Healthcare systems that receive government-funded vaccines through programs such as Vaccines for Children (VFC) are most likely to be aware of these financial risks.

VFC providers routinely have agreements with State Departments of Health that include financial restitution policies that require providers to replace vaccines deemed non-viable due to provider negligence, including improper storage, on a dose-for-dose basis. These same provider agreements also include terms that allow for compliance site visits and unannounced inspections, further increasing provider risk [(1)].

Based on these direct and indirect cost risks related to improper vaccine storage, the CDC will continue to strengthen vaccine storage guidelines to help control costs and improve public and privately vaccination programs.

CDC RECOMMENDATIONS FOR REFRIGERATOR AND FREEZER SELECTION

The CDC is continuously updating guidelines related to selecting appropriate refrigerators and freezers used for vaccine storage. These guidelines are in place to help ensure that vaccines are only stored in refrigerators and freezers that offer protection of temperature sensitive vaccines. These units should have appropriate temperature uniformity, recovery and stability attributes in order to maintain vaccines in required ranges.

The CDC prohibits the use of dormitory-style/bar-style units and combination units with ice-maker compartments for vaccine storage. These units have been shown to pose a significant risk of freezing vaccines.

Certain stand-alone household refrigerators may be acceptable. However, it is the responsibility of the clinician to identify and restrict access to all areas of the refrigerator cabinet that do not provide stable temperatures. Areas in these types of units that are typically not acceptable include under vents, in drawers, on drawer shelves, and other easily misused locations. Identifying and restricting these storage locations is likely not practical in clinical environments, so it is recommended that "purpose-built" and "pharmaceutical-grade" equipment be used.

PURPOSE-BUILT / PHARMACEUTICAL-GRADE UNITS

These units are specifically designed and marketed to store vaccines and incorporate features including microprocessor-based temperature control, temperature alarms, and forced-air refrigerator systems to support specialized requirements for vaccine storage.

Storage units in this category may utilize special designs and features best suited to protect vaccines:

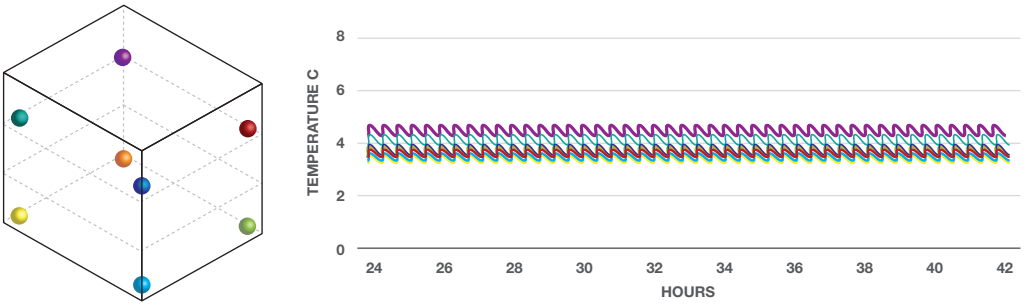
- Built-in digital data loggers with electronic interfaces that will allow continuous temperature monitoring and/or provide min/max temperatures.
- Available with a Certificate of Calibration generated using an ISO17025 reference thermometer.
- Uniformity and stability testing to confirm safety of all storage locations and to ensure primary control/monitoring probe is in the most appropriate location.
- Specially designed drawers and shelves to enable proper air circulation and support temperature uniformity and recovery requirements, as well as to support good inventory management practices.

When selecting "purpose-built" or "pharmaceutical-grade" equipment for vaccine storage, clinicians should take caution as the current CDC guidelines do not include specific temperature performance criteria for this equipment category. Temperature performance can vary significantly across vaccine refrigerators and clinicians should request data related to uniformity, stability, and recovery to confirm a product is adequate for this critical application. When evaluating vaccine refrigerators, it is important to choose equipment that will be safe and effective.

Temperature Uniformity

Uniformity refers to the ability of the refrigerator to maintain temperatures with limited deviations across storage locations. Tight temperature uniformity eliminates hard to detect hot and cold spots that could put contents at risk of significant temperature excursions.

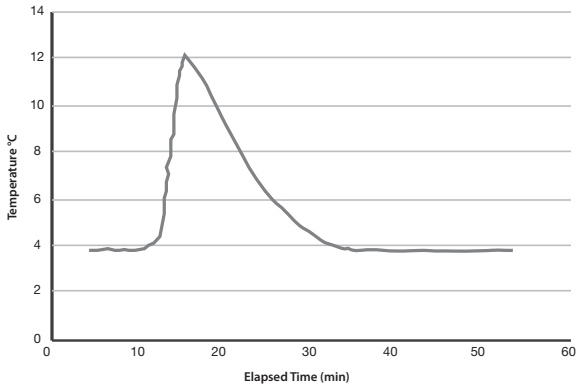
UNIFORMITY



Temperature Recovery

Temperature recovery refers to the time it takes for the unit to get back to set point after frequent or prolonged door openings. Faster recovery keeps contents at the right temperature under regular, daily use.

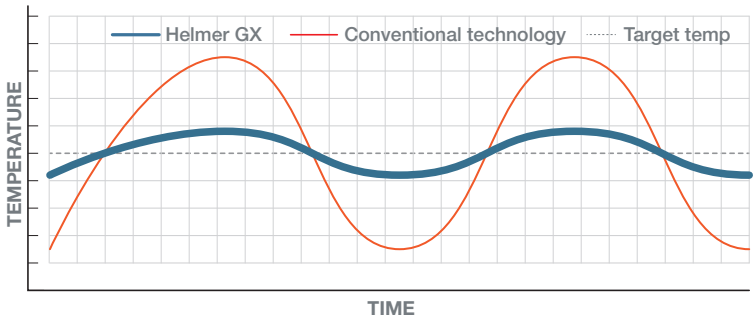
RECOVERY



Temperature Stability

Medical-grade refrigerators and freezers maintain superior temperature stability, creating fewer deviations from the set point and avoiding rapid, significant changes or swings in temperature.

STABILITY



NOTE: Immunization programs can help determine which purpose-built units meet VFC program requirements. It is recommended to check with your immunization program before purchasing any unit that will be used to store VFC vaccines.

2.0 REFRIGERATOR EVALUATION USING NSF JOINT COMMITTEE ON VACCINE STORAGE STANDARD

Until 2021, there were no testing protocols used across manufacturers to standardize performance testing of vaccine storage equipment. The NSF Joint Committee on Vaccine Storage has finalized the NSF/ANSI 456 Vaccine Storage Standard that can be used to certify performance of a vaccine storage unit. This Joint Committee includes members representing public health/regulatory, end-users, and industry sectors involved in vaccine storage. Helmer Scientific evaluation testing in this paper was conducted according to protocols in the standard.

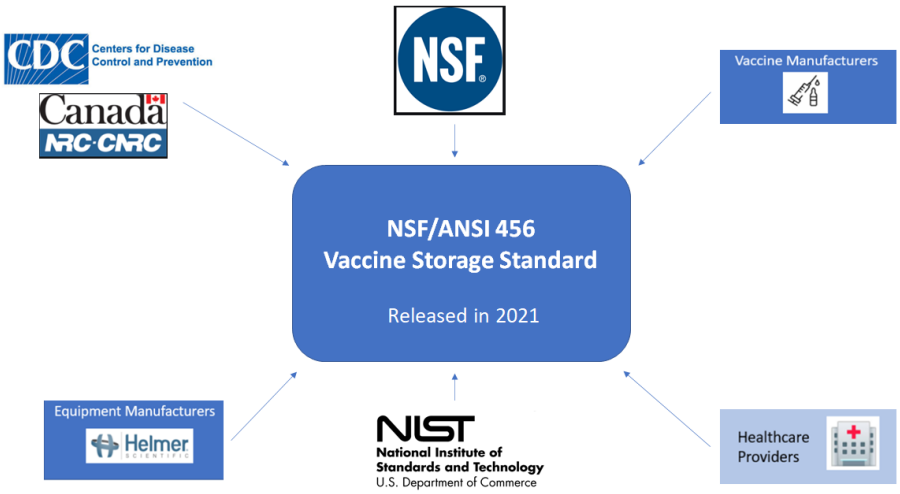


Figure 1: NSF/ANSI 456 Vaccine Storage Standard was developed by a diverse group of professionals committed to improving vaccine administration safety.

3.0 EVALUATION USING NSF/ANSI 456 STANDARD - METHODS

A side-by-side comparison was conducted of the Helmer Scientific GX Solutions medical-grade under-counter refrigerator and a competitive “purpose-built” under-counter refrigerator to investigate differences in temperature performance of equipment marketed for vaccine storage applications.

All protocols utilized a Helmer Scientific GX Solutions under-counter refrigerator and a competitive “purpose-built“ undercounter pharmacy unit. Units had standard shelf configurations and were tested loaded with product to simulate real-world usage, as well as with an empty cabinet to simulate out of the box operation. Fifteen T-style thermocouples with aluminum ballasts were used to measure vaccine temperature at different locations within the chambers. Thermocouples were placed on all shelves of each test unit and positioned across locations. Each line in graphs displayed in the results section indicates a temperature taken from these different locations.

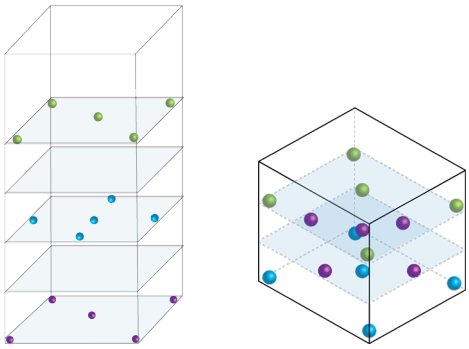


Figure 2: Example probe locations in temperature uniformity testing study..

These aluminum ballasts are smaller and more responsive than typical glycol bottles to better represent temperatures of vaccines that may be in small vials or syringes. The evaluation included temperature measurements across cabinet locations during steady-state (door closed) and during frequent and extended door openings to simulate real-world clinical use. Testing was also completed with the cabinet empty and the cabinet filled with boxes to simulate a fully packed refrigerator.

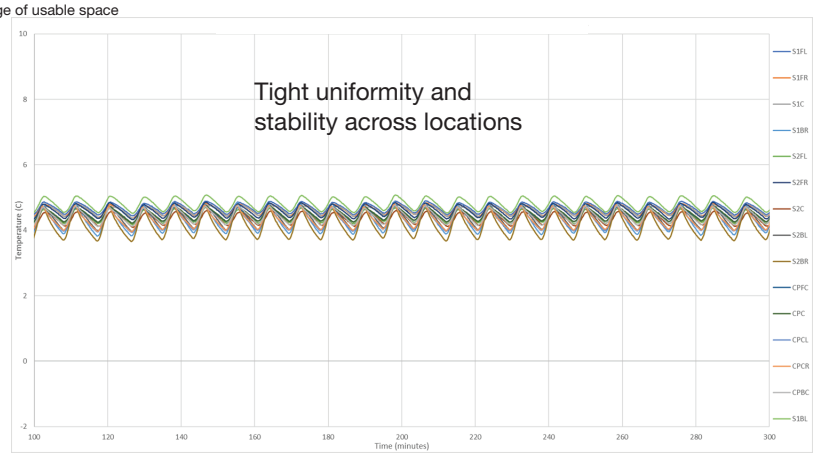
4.0 RESULTS

PROTOCOL 1 – EMPTY CABINET WITH DOOR CLOSED; TEMPERATURE ACROSS LOCATIONS

Helmer Scientific GX Solutions Undercounter

- Tight uniformity across all 15 locations (all locations remained in range)
- Tight stability with very limited temperature variations required to maintain setpoint

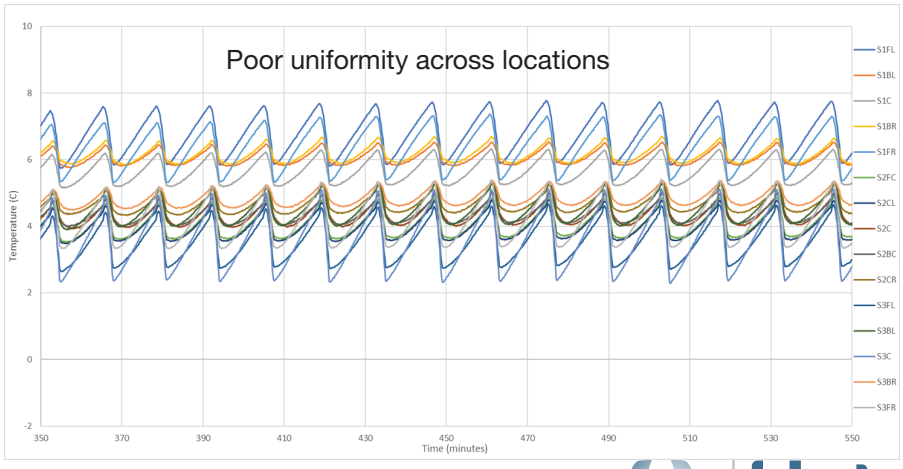
Helmer Scientific GX Solutions Unit
5 cf refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Empty cabinet



Competitive "Purpose-Built" Undercounter Refrigerator

- Looser uniformity across all 15 locations compared to Helmer Scientific unit, but all locations remain within 2°C - 8°C range
- Greater temperatures shifts according to compressor cycles

Non-Helmer Scientific "Purpose-Built" Unit
UC refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Empty cabinet

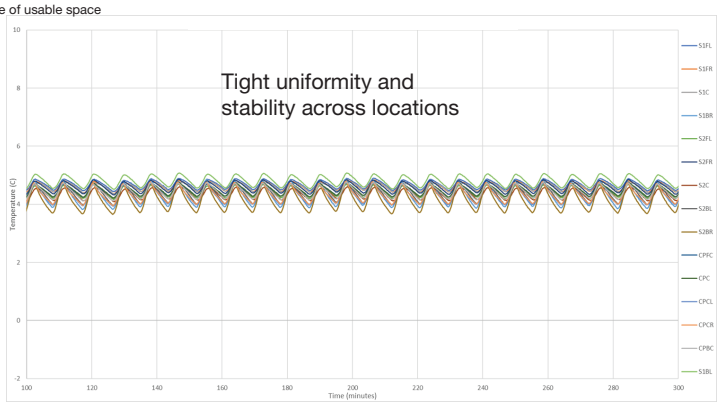


PROTOCOL 2 – LOADED CABINET WITH DOOR CLOSED; TEMPERATURE ACROSS LOCATIONS

Helmer Scientific GX Solutions Undercounter

- Tight uniformity across all 15 locations (all locations remained in range)
- Tight stability with very limited temperature variations required to maintain setpoint

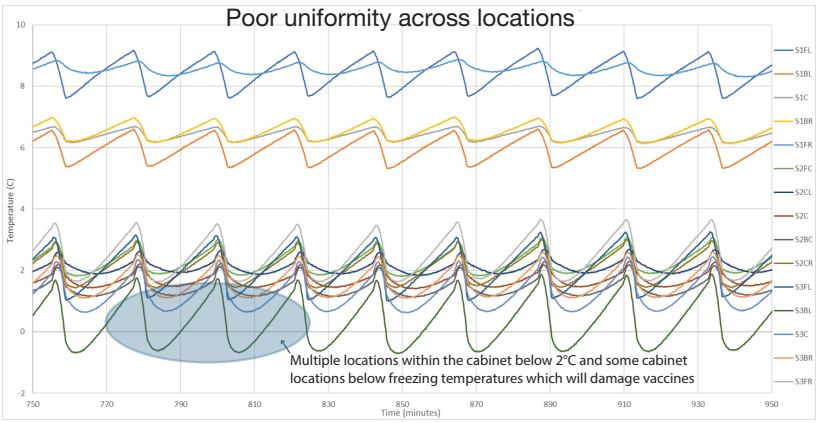
Helmer Scientific GX Solutions Unit
5 cf refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Empty cabinet



Competitive "Purpose-Built" Undercounter Refrigerator

- Poor uniformity across all 15 locations (some locations below 0°C freezing temperatures, >7°C variation across locations)
- Poor temperature stability; shifts according to compressor cycles

Non-Helmer Scientific "Purpose-Built" Unit
UC refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Loaded cabinet

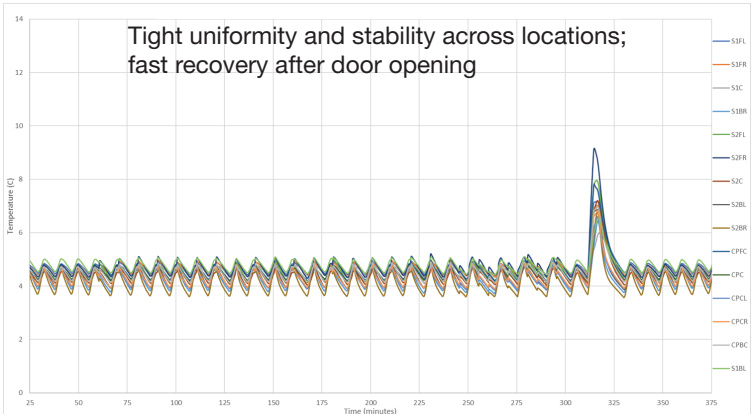


PROTOCOL 3 – UNLOADED CABINET WITH DOOR OPENING; TEMPERATURE ACROSS LOCATIONS

Helmer Scientific GX Solutions Undercounter

- Tight uniformity across all 15 locations (all locations remained in range)
- Rapid recovery after 3-minute extended door opening

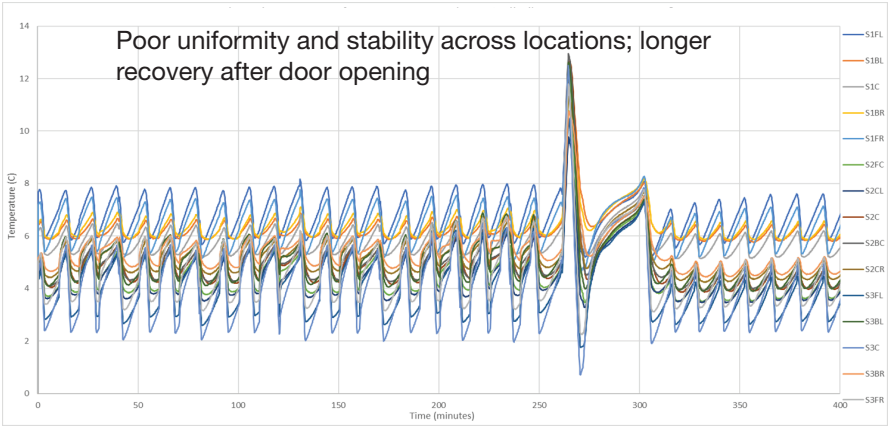
Helmer Scientific GX Solutions Unit
5 cf refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Empty cabinet



Competitive "Purpose-Built" Undercounter Refrigerator

- Looser uniformity across all 15 locations compared to Helmer Scientific unit, but all locations remain within 2°C-8°C range
- Greater temperatures shifts according to compressor cycles

Non-Helmer Scientific "Purpose-Built" Unit
UC refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Empty cabinet

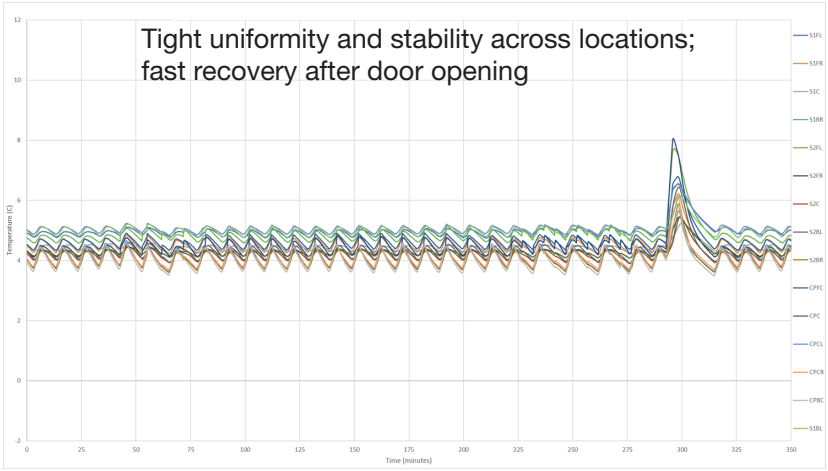


PROTOCOL 4 – LOADED CABINET WITH DOOR OPENING; TEMPERATURE ACROSS LOCATIONS

Helmer Scientific GX Solutions Undercounter

- Tight uniformity across all 15 locations (all locations remained in range)
- Rapid recovery after 3-minute extended door opening

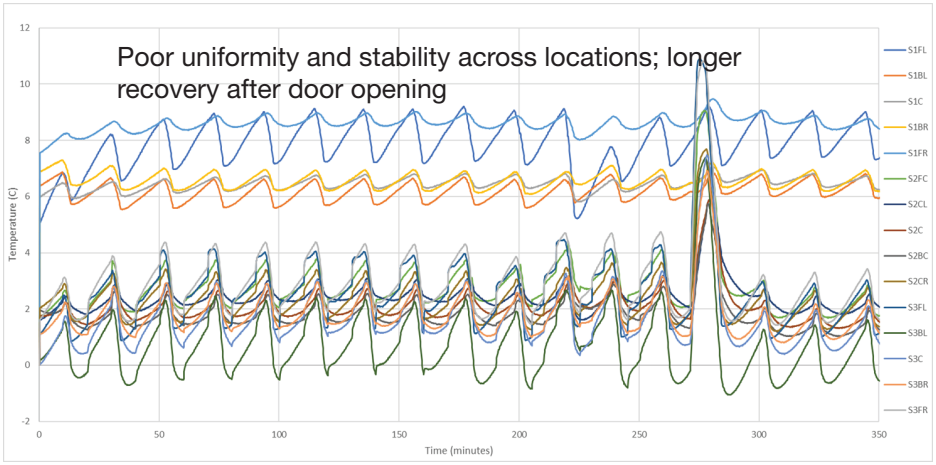
Helmer Scientific GX Solutions Unit
5 cf refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Loaded cabinet



Competitive "Purpose-Built" Undercounter Refrigerator

- Poor uniformity across all 15 locations, (some locations <2°C and one location <0°C)
- Poor temperature stability; shifts according to compressor cycles

Non-Helmer Scientific "Purpose-Built" Unit
UC refrigerator / NSF/ANSI 456 Standard
Aluminum weighted proves
Weighted probes at edge of usable space
Steady state data
Loaded cabinet



5.0 DISCUSSION

To support public health and safety, the CDC provides guidelines and recommendations related to vaccine storage. These recommendations recognize that there are differences between various cold storage options by restricting the use of certain type of equipment.

This evaluation demonstrates that when using a standardized test protocol to evaluate equipment marketed for vaccine storage major differences and safety issues can be exposed, even on “purpose-built” units. This data indicates that not all “purpose-built” refrigerators may have the temperature performance characteristics necessary to support safe vaccine storage.

The NSF/ANSI 456 Vaccine Storage Standard used for this evaluation recognizes that real-life use of vaccine storage includes challenging cold storage with various load conditions and door openings. Vaccine refrigerators are not always used in well-controlled environments, and levels of experience and expertise of staff managing equipment can vary greatly by site. Regardless, to protect public health vaccine storage units must maintain the safety of vaccines understanding that product load conditions/organization and frequency and duration of door openings are highly variable in the real-world.

6.0 CONCLUSION

The CDC Vaccine Storage and Handling Toolkit makes important recommendations to help protect the safety and efficacy of vaccines, and the new NSF/ANSI 456 Vaccine Storage Standard further defines appropriate temperature performance for vaccine storage equipment.

The use of the Helmer Scientific GX Solutions under-counter, pharmaceutical-grade refrigerator will assist healthcare facilities in meeting these requirements with superior temperature uniformity, recovery and stability. Data generated during this evaluation supports the performance claims of the Helmer Scientific undercounter refrigerator and demonstrates that performance characteristics of “purpose-built” vaccine storage units can vary and may have direct impact on the safety of vaccine administration programs.

Healthcare providers and administrators need to understand the performance data of their selected cold-storage systems and its ability to safely store vaccines. The NSF/ANSI Vaccine Storage Standard can assist clinicians in making these types of decisions by exposing true performance characteristics of cold storage units used for vaccine storage.

7.0 REFERENCES

1. US Department of Health and Human Services, Office of the Inspector General. VFC Program Vulnerabilities in Vaccine Management. June, 2012. https://oig.hhs.gov/oei/reports/oei-04-10-00430.asp
2. US Department of Health and Human Services. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. 2021. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html