

eBook
A Guide for Vaccine Storage Providers

UNDERSTANDING HOW TO SAFELY AND EFFECTIVELY STORE VACCINES.

HELMER SCIENTIFIC



VACCINE STORAGE AND YOU.

If you store vaccines, you know that there are two critical areas of concern: safe storage and preventing waste

Ensuring vaccine safety is a critical component within the cold chain. In order to mitigate the risk of spoiled vaccines, health care organizations should understand how to safely and effectively store vaccines.

Key Objectives

After reading this eBook you should understand the following:

- Why continuous monitoring should be used on ALL vaccine units
- Why alarms and notifications should be utilized
- Why medical-grade cold storage should be used for vaccine storage
- Why you should have a plan and be prepared for temperature excursions

Vaccines require a lot of care in order to remain potent and viable. It is our goal to provide you the information you need to make your job as worry free as possible.

THE TRUE COST OF VACCINE LOSS

Cold storage plays an important role in maintaining efficacy and viability of vaccines. This eBook provides information on what you can do to ensure your cold storage meets medical-grade requirements and will protect your valuable vaccines.



PREVENTING VACCINE LOSS



In 2012, the U.S. Department of Health & Human Services conducted a *study* that measured vaccine refrigerator and freezer temperatures at more than 45 locations across the country in order to assess storage conditions.

During the two week study, **76% of the 45 selected providers had vaccines exposed to inappropriate temperatures for at least 5 cumulative hours.** The Department of Health & Human Services saw this as a huge opportunity to provide better guidelines on how to safely and effectively store vaccines. This led to the creation of the first CDC Vaccine Storage and Handling Toolkit. The toolkit is updated periodically, but the foundation on how to properly store vaccines remains.

Proper vaccine storage plays a major role in preventing and eradicating vaccine-preventable diseases. If vaccines are stored incorrectly, this can result in an inadequate immune response in patients leading to poor protection against disease and the need for re-vaccination (if the improper storage is determined).

If the improper storage conditions are not identified and the patient is not re-vaccinated, the patient could remain at risk unknowingly.

These issues can cause patients to lose confidence in vaccines and providers. Moreover, many providers have suffered significant financial loss due to wasted vaccines.

The following steps will help your practice avoid a devastating vaccine loss:

- Read the [CDC Vaccine Storage & Handling Toolkit](#)
- Use continuous temperature monitoring on ALL of your vaccine units
- Utilize alarms & notifications
- Select [medical-grade refrigerators and freezers](#) that meet NSF/ANSI 456 vaccine storage standard
- Have a plan and be prepared for temperature excursions

ARE YOUR VACCINES AT RISK?

CDC Guidelines for Vaccine Administration Sites

The Centers for Disease Control and Prevention (CDC) has gone to great lengths to provide recommendations for vaccine handling and storage across the cold chain. Exposing vaccines to out-of-range temperatures can result in permanent loss of potency, putting patients at risk for receiving ineffective vaccinations. Following CDC recommendations will help ensure the effectiveness of vaccinations, reduce cost associated with discarded vaccines, as we as reduce the direct and indirect costs of re-vaccination.

Because vaccines require storage at specified temperature ranges, refrigerators and freezers play an extremely important role when it comes to vaccine storage and handling. According to the Department of Health and Human Services report, "Vaccines for Children Program - Vulnerabilities in Vaccine Management", 76% of healthcare sites exposed to inappropriate temperatures for at least 5 hours due to the use of inadequate refrigerators and freezers, also included more than 9,000 Vaccines for Children doses, worth approximately \$370,000(1).

Choosing Appropriate Storage

The CDC provides guidelines on selecting appropriate cold storage solutions to store refrigerated and frozen vaccines. These guidelines were created to ensure vaccines are stored in the correct type of unit, the correct location within the unit, and at the correct temperature. The CDC makes it very clear that the use of dormitory or bar style refrigerators is unacceptable for vaccine storage. These units typically have a freezer compartment inside of the refrigerator, putting vaccines at risk of freezing. Moreover, the use of household combination units is not preferred. These units do not consistently keep vaccines at the correct temperature because the unit is cooled by circulating air from the freezer compartment into the refrigerator compartment. This poses a significant risk of vaccines being exposed to freezing temperatures and losing potency.



Understanding Medical-Grade Cold Storage

The CDC recommends the use of stand-alone refrigerator and freezer units or pharmaceutical/medical-grade units that meet vaccine storage guidelines(2). Pharmaceutical/medical-grade units are specially designed for the safe storage of vaccines. Forced air systems allow for more usable space and decrease the risk of placing vaccines in areas of the refrigerator that do not maintain required temperatures. Pharmaceutical/medical-grade cold storage is also designed to quickly recover to set temperature after door openings. Forced air systems typically utilize specially designed drawers and shelves to enable proper air circulation, which also assists in temperature uniformity and recovery. In addition, pharmaceutical/medical-grade refrigeration enables precise temperature control and set points, alarms, and may include built-in temperature monitoring that meets CDC recommendations related to calibration.

References:

(1) US Department of Health and Human Services. Office of the Inspector General. [VFC Program Vulnerabilities in Vaccine Management](#). June 2012

(2) US Department of Health and Human Services. Centers for Disease Control and Prevention. [Vaccine Storage and Handling Toolkit](#). 2021

NSF/ANSI 456 VACCINE STORAGE STANDARD

In addition to CDC guidelines, the NSF Joint Committee for vaccine storage has published a new standard to safeguard vaccines. The NSF/ANSI 456 Vaccine Storage Standard is designed to ensure vaccine storage equipment can maintain 5°C +/- 3°C across all potential storage locations under varying load conditions to simulate real-world clinical environments.

Understanding that vaccine providers face a diverse range of conditions and levels of expertise at clinics, private practices, and hospitals, the committee was focused on performance criteria aligned with how equipment is used in clinical environments.

The standard recognizes that door opening may result in temperatures temporarily exceeding this range, but equipment must have the capacity to quickly recover into recommended ranges. The testing protocol will help ensure equipment designed to comply with the standard will provide safe and effective storage for refrigerated medications and vaccines.

Based on initial testing, not all cold storage units will have the temperature performance required to meet this new standard and appropriately safeguard vaccines.

THE IMPORTANCE OF CONTINUOUS TEMPERATURE MONITORING

Due to the increased pressure from organizations such as the Joint Commission, the Board of Pharmacy (one in each state), and the Centers for Disease Control and Prevention (CDC), healthcare providers are starting to move away from recording temperatures twice per day and toward continuous monitoring of cold storage temperatures. To do so, many facilities are investing in continuous temperature monitoring solutions, which are bringing many refrigeration issues to the surface that providers never knew existed.

Some medical-grade refrigerators include options for continuous monitoring systems that are integrated into the unit. With these types of systems, data can be reviewed and downloaded directly from the refrigerator's controller. Facilities may also use separate monitoring devices that include independent probes. Most medical-grade refrigerators have a designated probe port that allows 3rd party probes to enter the unit.

With the use of continuous monitoring, facilities are finding many of the dormitory-style and household refrigerators and freezers they have been using for years are unable to maintain appropriate temperatures for the safe storage of medications and vaccines. These units tend to have hot and cold spots within the cabinet, and frequent door openings will cause temperatures to quickly rise, potentially setting off alarms and putting contents at risk.

We recently spoke to one of our customers who is working to replace the dormitory and food-grade refrigerators throughout the hospital and corresponding clinics. They shared with us that trying to convince administration of the need for medical-grade refrigeration has been a 10-year battle. So what finally convinced them?

THE IMPORTANCE OF CONTINUOUS TEMPERATURE MONITORING



"The tipping point was when our outpatient clinics started losing money. By losing money, I mean having to destroy vaccines that ended up being stored out of the appropriate temperature range. We never would have known this was happening when we were only recording the temperature twice a day. Once we switched to continuous monitoring, the data was shocking."

Medications and vaccines stored out of appropriate temperature ranges must be evaluated for safety. Medication and vaccine manufacturers typically help determine if product can be used or if it must be discarded after products are exposed to inappropriate temperatures. Not only can this have a major cost implication, it is also extremely time-consuming. Staff and administration are already pressed for time, and there is often a lengthy process and procedure that must be followed when disposing of medications or vaccines which were stored inappropriately. Using medical-grade equipment can help avoid these types of problems.

SELECTING A CONTINUOUS TEMPERATURE MONITORING DEVICE

CDC RECOMMENDS USING A CONTINUOUS TEMPERATURE MONITORING DEVICE FOR EACH STORAGE UNIT

The CDC recommends using a continuous temperature monitoring device for each storage unit. These devices continuously monitor the temperature to ensure users are aware if there has been a temperature excursion. Min / max thermometers only measure the warmest and coldest temperatures during a period of time. This does not provide enough detailed information to investigate how long the vaccines were out of range or what time of day the excursion occurred.

CDC recommended devices include the following:

- Digital display on the outside of the unit that allows users to read the temperature without opening the door
- Detachable probe housed in a bottle with a thermal buffer, such as glycol, to accurately reflect vaccine temperatures
- Alert when temperature is out of range
- Accuracy within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)
- Low battery indicator
- Continuous monitoring and recording capabilities
- Display of current and min/max temperature



SELECTING A CONTINUOUS TEMPERATURE MONITORING DEVICE



Many medical-grade refrigerators have these temperature monitoring features built into the unit, as well as provide functionality that would be available with a digital data logger. Digital data loggers provide many of the same features as continuous temperature monitoring devices, but they also allow for the data to be downloaded and presented on a computer or retrieved from a website for further analysis.

Data loggers may also allow for the user to set the desired frequency of temperature readings and review minimums and maximums over a period of time. Reviewing and recording temperatures a minimum of two times each workday, as well as minimum and maximum temperatures since the last reading, is still recommended with the use of continuous temperature monitoring devices and data loggers.

Data should be downloaded and reviewed at least once per week. All facilities must keep an ongoing file of temperature data, hard copy and downloaded data, for three years.

CDC does not recommend the following temperature monitoring devices:

- Chart recorders
- Fluid-filled biosafe liquid temperature monitoring devices
- Bi-metal stem temperature monitoring devices
- Household mercury temperature monitoring devices
- Infrared temperature monitoring devices
- Any device that is not calibrated.

CHOOSING YOUR VACCINE REFRIGERATOR



The CDC offers detailed recommendations in regards to the proper storage and handling of vaccines. These recommendations aim to help healthcare providers store, handle, and administer vaccines efficiently and effectively in order to protect patients and the population from devastating diseases. These recommendations are driving providers away from storing vaccines in a household or commercial refrigerator or freezer, and toward the use of medical-grade cold storage solutions. However, there is a major difference in performance between many "medical-grade" refrigerators and freezers on the market.

TEMPERATURE UNIFORMITY

The CDC specifically recommends performing various temperature readings inside of your refrigerator to locate the most stable area for storing vaccines. At Helmer, we refer to this testing as temperature mapping. Temperature mapping is an important part of determining how safe your refrigerator is for vaccine storage.

When creating a temperature map, all areas within a medical-grade refrigerator should reflect uniform temperatures. When performing temperature mapping on a household or commercial unit, you will most likely find temperatures throughout the unit vary immensely. In this type of unit the only safe area for vaccine storage is often in the middle of the refrigerator away from walls, ceilings, cooling vents, doors, the floor, and the back of the unit. It is likely that all other locations inside the refrigerator may expose vaccines to warm or freezing temperatures putting their efficacy at risk. This poor uniformity leaves little usable storage space. Refrigerators that do not provide a uniform storage environment throughout are not true medical-grade.

CHOOSING YOUR VACCINE REFRIGERATOR



TEMPERATURE RECOVERY

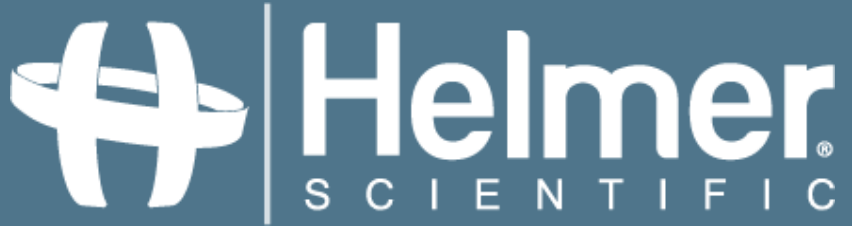
The CDC stresses the importance of not letting the refrigerator door stand open unnecessarily. This negatively affects temperature in the unit and may cause the unit temperature control to respond to the warmer air temperature in the room. Higher temperature may cause the unit to work harder and overcompensate cooling making some areas of the unit prone to freezing. This tends to be a major problem with household and commercial units. They are not designed to quickly recover to set temperature after the door is shut leaving vaccines at risk.

Medical-grade refrigerators are designed to quickly recover to set temperature after door openings, ensuring vaccine temperatures are not affected by users opening and closing the refrigerator door many times throughout the day. These units may also have a self-closing door and an open door alarm to help prevent temperature excursions from occurring.

AN EVALUATION OF TWO REFRIGERATORS

Many manufacturers of refrigerators and freezers are aware of the increasing demand for high performing, medical-grade refrigeration. To capitalize on this demand, they have enhanced household and commercial units to appear as if they provide superior storage for vaccines, medications, and samples. Many of these units provide a similar storage environment to a household or commercial refrigerator. Ask your refrigerator manufacturer if they are able to provide temperature mapping data (uniformity data) and recovery data that reflects medical-grade performance.

To highlight the importance of storing vaccines in a true medical-grade refrigerator a side-by-side comparison of the Helmer Scientific medical-grade undercounter refrigerator and a competitive undercounter refrigerator was conducted. This evaluation included measurement of temperature uniformity across multiple locations in the refrigerator cabinet, temperature recovery after short and extended door openings, and temperature recovery time (pull-down test) from ambient to simulate power loss. Read the [full report](#).



EVERY VACCINE DOSE MUST COUNT

Vaccine demand is rising. The CDC Guidelines and the new NSF/ANSI 456 Vaccine Storage Standard provide guidance for storing and administering vaccines that remain potent and viable. Together we can rise to the challenge of safe and effective vaccine storage.

Helmer Scientific is a manufacturer and worldwide distributor of medical-grade cold storage products. We have more than 40 years of experience in providing high-quality temperature controlled environments to more than 100 countries worldwide.

NEED VACCINE COLD STORAGE?

Contact Helmer Scientific today for your medical-grade cold storage solutions.



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