

Demystifying the Medical-Grade Refrigerator

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INTRODUCTION

Healthcare facilities are under increased pressure to ensure consistent and reliable refrigeration for the storage of temperature sensitive medications, vaccines, reagents, and patient samples. There are significant implications when a refrigerator used for clinical applications fails to provide a safe storage environment.

Improper refrigerators used for clinical, cold storage may:

- Negatively affect patient safety and delivery of care due to the administration of damaged or ineffective therapies
- Cause financial loss due to expensive, compromised products requiring disposal
- Result in the loss of irreplaceable and precious patient samples that are critical for lab testing or research
- Lead to unnecessary staff time and resources to resolve issues noted above
- Cause disruptions to workflow
- Lead to time and cost of replacing essential cold storage equipment

Given the serious consequences of improper or unreliable refrigeration in clinical applications, healthcare facilities are looking to manufacturers for medical-grade refrigerators and freezers.

However, because there is no universal definition for a medical-grade refrigerator, it can be hard to understand what “medical grade” means. The goal of this paper is to give guidance on what types of features and benefits a refrigerator designed specifically for clinical applications should have.

REFRIGERATOR AND FREEZER DEFINITIONS

In the 2020 CDC Vaccine Storage and Handling Toolkit, the CDC include specific definitions for every style refrigerator that is available on the market including dormitory units as well as pharmaceutical-grade units.

When purchasing your medical-grade refrigerator, regardless of the application, it is important to keep these definitions in mind.

- **Dormitory-style (Bar-style) Storage Unit**
 - A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.
- **Household-grade Storage Unit**
 - A storage unit that is primarily sold for home use
- **Purpose-built/Pharmaceutical-grade/Medical-grade Storage Unit**
 - Units that are specifically designed to store clinical products, vaccines, and/or other biologics.
- **Stand-alone Storage Unit**
 - A storage unit that operates independently of any other device or system for its desired function (i.e., a refrigerator that only functions as a refrigerator or a freezer that only functions as a freezer).

While these CDC definitions help clarify the types of refrigerators and freezers a healthcare facility may encounter, they do not thoroughly describe what constitutes a “medical-grade” refrigerator.

DEMISTIFYING MEDICAL-GRADE REFRIGERATION

Although there is no universal definition for a medical-grade refrigerator, the following attributes will help demystify what makes a refrigerator designed specifically for medical applications.

Temperature Stability

Medical-grade refrigerators and freezers maintain superior temperature stability, creating fewer deviations from the set point and avoiding rapid, significant changes in temperature. Over time, a medical-grade refrigerator will not deviate significantly from the set point.

Temperature Uniformity

Uniformity refers to all areas of the cabinet maintaining temperature with few temperature deviations from place to place. Tight temperature uniformity eliminates hot and cold spots that could put contents at risk of temperature excursions.

Uniformity requirements vary based on storage application, but true medical-grade refrigerators will meet even the strictest uniformity requirements of ± 1 degree C. When purchasing a new refrigerator for clinical applications, ensure the manufacturer can provide a uniformity specification.

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.

Temperature Monitoring

Maintaining set temperatures for sensitive medications, vaccines, patient samples, or reagents is critical to protect patient safety. Medical-grade refrigerators will use microprocessor temperature controllers and digital displays to ensure precise temperature regulation.

Essential Alarms

Medical-grade refrigeration will also include standard alarms designed to notify healthcare professionals of problems or events that can put stored contents at risk. High and low, power failure, and door ajar alarms are typically standard on a medical-grade unit.

Some manufacturers also include software and displays that allow users to view historical temperature data, an event log, and interactive temperature graphs. These systems may also record minimum and maximum temperatures during a defined period to satisfy regulatory requirements.

Because it is important to understand temperature history during power loss, medical-grade refrigerators may include options for back-up battery systems that continue capturing temperature data even if main power is lost.

Understanding that many healthcare facilities use 3rd party monitoring solutions for their equipment, medical-grade refrigerators and freezers offer specialized features to accommodate this type of use. Depending on the intended installation location, options can include dry alarm contacts or special ports to allow independent temperature probes to conveniently be placed inside the cabinet.

Security & Access Control

Due to the sensitive and valuable nature of clinical samples and medications, medical-grade refrigerators and freezers will offer options to restrict access to authorized users. Most common options are keyed locks. Some refrigerators also offer electronic access control that uses passwords or pins to control and track access.

Customization and Configurations

Most manufacturers of medical-grade cold storage equipment offer multiple sized units, but some will also allow for custom configuration of storage options such as the type, number, and location of drawers, shelves, and baskets.

Using the right storage options for the application can help reduce errors and promote patient safety by making it quick and easy for healthcare professionals to load and remove contents of the refrigerator. In addition, shelves and drawers in medical-grade refrigerators are specially designed to allow adequate airflow.

FDA Registered Suppliers & Medical Device Regulation

True Medical Grade cold storage units are very different from commercially available refrigerators in the way they are designed, manufactured, and supported post-sales. Medical-grade refrigerators are more than just a cold storage device and should be considered medical devices by the supplier.

FDA Registered suppliers of medical-grade refrigeration are required to use a different set of standards than other suppliers. ISO 13485 (Quality Management System for Medical Devices) require strict compliance of regulation related to design controls, product testing and validation, and post-market surveillance and vigilance.

ISO 13485 helps ensure suppliers design, manufacture, and support their medical devices at a quality level consistent with the needs of clinical applications. These organizations will also follow 21 CFR Part 820 (FDA quality system regulation) that requires periodic FDA audits and governance and accountability measures that ensure the ongoing quality of equipment and post-sales process.

Understanding if the supplier is FDA Registered (and therefore, also consider their refrigerators medical devices), will provide further confidence in the quality and reliability of the cold storage equipment.

Quality and Validation Certificates and Services

Due to the sensitivity of clinical samples, healthcare providers may require Certificates of Calibration from a supplier that provides evidence that the cold storage unit has been calibrated with a NIST ISO 17025 compliant measuring device.

In addition, suppliers of medical-grade refrigeration typically offer services designed specifically to meet the needs of clinical applications. These can include temperature mapping and validation services to prove temperature performance at all storage

locations, as well as guides for installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) for the site of installation.

High Quality Construction

High quality construction is required for all medical equipment. Medical-grade refrigerators should have options related to materials that make equipment specifically suited for installations in medical laboratories. Examples include the use of stainless steel or other materials designed for routine disinfecting such as anti-microbial powder coat finishes that are registered with the FDA and EPA.

Warranties & Technical Service

When considering medical-grade cold storage, post-sales service levels and warranties are critical. Understanding warranty periods and how service is delivered will help your facility manage the long-term costs of ownership of equipment. The supplier should offer confidence that equipment will be easily maintained and reliable for years to come.

CONCLUSION

There are many factors that continue to drive the adoption of medical-grade refrigeration across the healthcare system.

Patient safety, loss of product, expensive waste, quality control, and regulations continue to make the use of medical-grade refrigeration more necessary for healthcare facilities.

Although initial acquisition cost can be higher for a medical-grade refrigerator, the investment pays off quickly. True medical-grade refrigeration offers reliability and quality to help ensure long-term savings by limiting the need for frequent equipment service and/or replacement.

Savings resulting from appropriate storage of critical therapies, reagents and patient samples can also be gained by preventing waste and helping improve patient safety.