

Demystifying the Medical Grade Refrigerator

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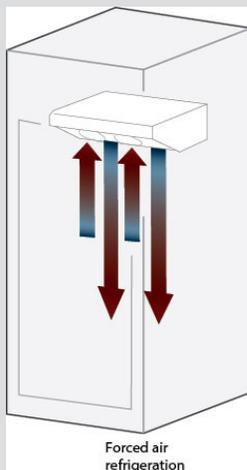
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Healthcare facilities are under increased pressure to ensure consistent and reliable temperature control for the storage of refrigerated medications, vaccines, reagents, and/or patient samples. The implications of refrigeration used in clinical applications either going out of range or failing are significant. Improper cold storage may:

- Negatively affect patient safety and delivery of care due to the administration of damaged or ineffective therapies, including vaccines, medications, or blood products
- 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
- Require unnecessary staff time, energy, as well as frustration, to resolve issues noted above, as well as having to invest time and additional financial resources to replace equipment

Given these serious consequences of improper or unreliable refrigeration in clinical applications, healthcare facilities are increasingly looking to manufacturers for Medical Grade equipment. However, because there is no universal definition for Medical Grade refrigeration, it is easy to become confused about what Medical Grade actually means when considering new equipment. The following information will help demystify Medical Grade refrigeration.

Forced-air Refrigeration: The heart of Medical Grade cold storage is the use of an effective forced-air system that can rapidly circulate cool air throughout all locations within the refrigerator cabinet. True Medical Grade refrigeration



uses forced air systems to maintain tight temperature uniformity across storage locations, and allows the refrigerator to quickly recover to set temperature after the door is opened and closed. Beware of units that advertise forced-air systems but do not have claims that support temperature uniformity. These types of units, which may be marketed in similar ways as a Medical Grade refrigerator, may require gel packs to maintain uniformity or have storage locations that cannot be used for samples due to lack of performance. Uniformity requirements for Medical Grade refrigerators can vary based on the application. For example, units used for blood storage require uniformity of $\pm 1^{\circ}\text{C}$ across the cabinet; units that will be used for pharmacy or laboratory applications typically require uniformity of $\pm 1.5^{\circ}\text{C}$ across the cabinet. These types of performance claims are

possible with effectively designed forced-air refrigeration systems.

Software and Controls: Maintaining set temperatures for sensitive medications, vaccines, patient samples, or reagents is critical to protect patient safety. Medical grade refrigerators will use microprocessor controls and digital displays to ensure precise temperature regulation as well as provide peace of mind that set-points are maintained. Medical Grade refrigeration will also include standard alarms designed to notify healthcare professionals of problems or events that can put stored contents at risk. These alarm options typically include high or low critical range, power failure, and door open notifications. Some manufacturers

also include software and displays that allow users to view temperature history graphs. These systems may record minimum and maximum temperatures during a defined period to satisfy regulatory or quality needs. 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 equipment offers 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 enter the cabinet.

FDA Registered Suppliers: Some Medical Grade cold storage units are different from commercially available refrigerators in the way they are designed, manufactured, and supported post-sales. FDA Registered suppliers use a different set of standards than other suppliers. ISO 13485 (Quality Management System for Medical Devices) requires 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 products at a quality level consistent with the needs of clinical applications. 21 CFR Part 820 (FDA quality system regulation) requires periodic FDA audits and governance and accountability measures that ensure the ongoing quality of equipment and post-sales process.

Quality and Validation Certificates and Services: Another area of differentiation for Medical Grade cold storage is the availability of validation certificates and services for the equipment. 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 true Medical Grade refrigeration typically offer additional 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.

Additional Considerations: When purchasing cold storage for clinical applications there are other factors that need to be considered. 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 your 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.

Medical Grade refrigerators also 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, or specialized anti-microbial powder coat finishes that are registered with the FDA and EPA. When considering Medical Grade cold storage, post-sales service levels and warranties are also critical. Understanding warranty periods and how service is delivered will help your facility manage the longer-term costs of ownership of equipment and provide confidence that equipment will be maintained and reliable for years to come. Finally, due to the sensitive and valuable nature of clinical samples and medications, Medical Grade units will routinely offer options to restrict access only to authorized users. Most common options are keyed locks or the option of electronic access control that uses passwords or pins to control an embedded door lock.

Managing risks to the delivery of patient care, limiting the potential expenses resulting from lost product or samples, as well as responding to regulation and quality improvement initiatives, continue to make the use of Medical Grade refrigeration more common and 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 reliability and quality helps ensure longer term savings by limiting the need for frequent equipment service 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.

