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PAPER

Two Compact Refrigerators for Clinical Applications - Evaluation of Temperature Uniformity and Ranges

Helmer Scientific, August 2016

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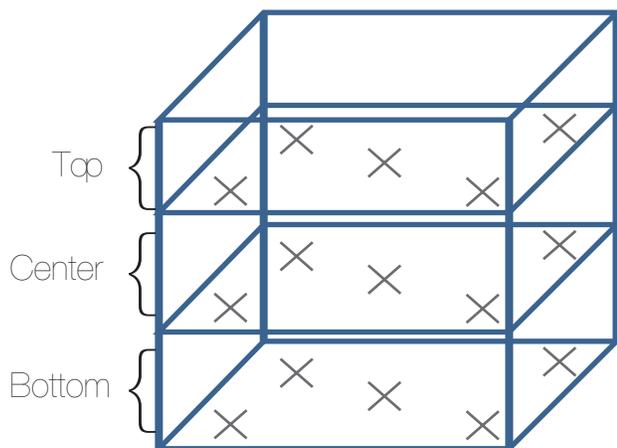
Introduction

As healthcare facilities drive continuous improvement initiatives to improve patient safety and increase the efficiency of the delivery of care, refrigeration used for clinical applications continues to be identified as an area of opportunity. The implications of inadequate refrigeration for the storage of vaccines, medications, reagents, or patient samples can be significant. Damaged or ineffective vaccines and medications can inhibit disease prevention and recovery. Irreplaceable patient samples critical for testing or research may be lost. In addition, inappropriate refrigeration can result in required disposal of expensive products and samples compromised by inappropriate storage conditions. Although multiple brands of cold storage products are marketed as medical-grade or pharmaceutical-grade, it is important to understand that there are significant differences among cold storage products based on their ability to provide uniform and tight temperature control across all storage locations. This article evaluates two compact refrigerators marketed for clinical applications in order to assess differences in performance.

Evaluation

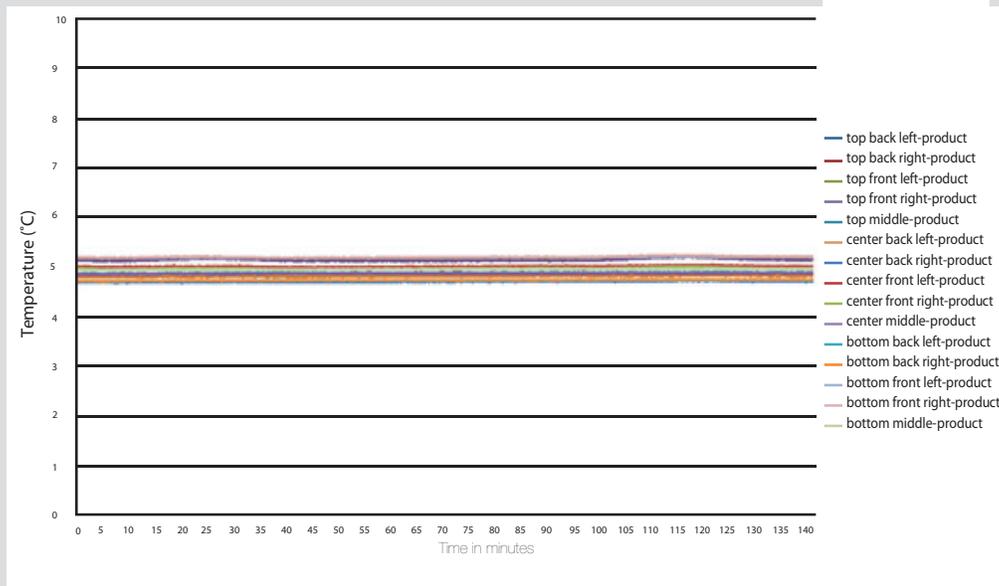
The evaluation protocol compared the Helmer Scientific MLR102 Countertop Refrigerator to a competitive free standing refrigerator. Units had standard three-shelf configurations. Fifteen T style thermocouples were used to measure both air and product temperature across each shelf in order to evaluate usable storage space in the front, middle, and back areas. See the diagram below for thermocouple locations. Product temperature was simulated using 10ml glycol bottles. Units were allowed to run for a 10 hour period without door openings to record and measure uniformity. Refrigerator temperature was set to 5°C.

Exhibit 1. Location of 15 thermocouples used to measure air and product temperatures

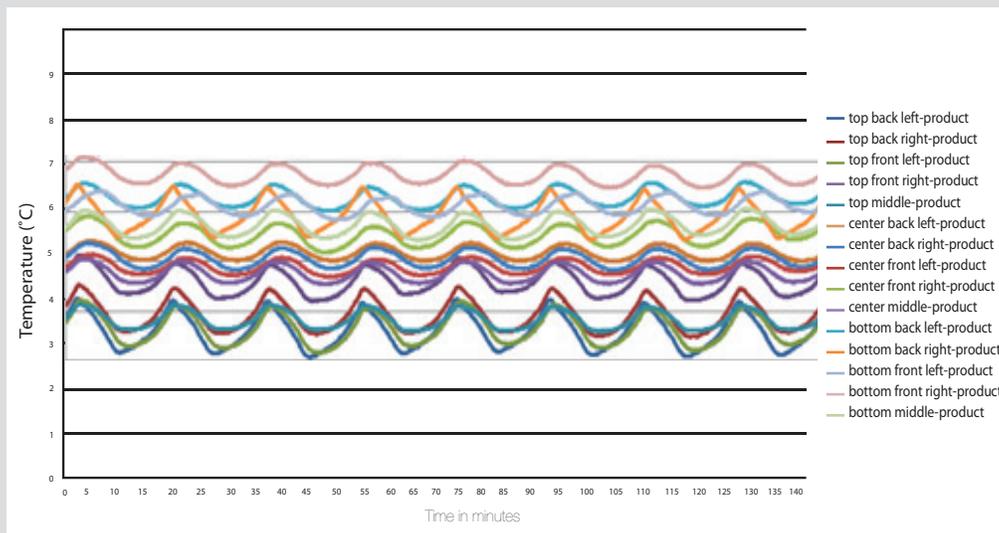


Product (Glycol Probe) Temperature Results

Graph 1: Helmer Scientific MLR102 Unit Uniformity - 10 ml Glycol Bottle



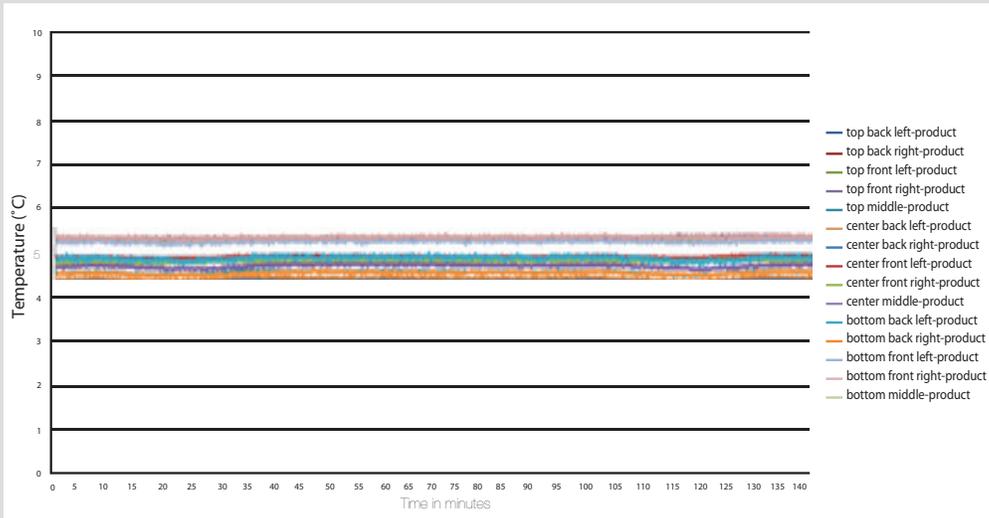
Graph 2: Competitive Unit Uniformity – 10ml Glycol Bottle



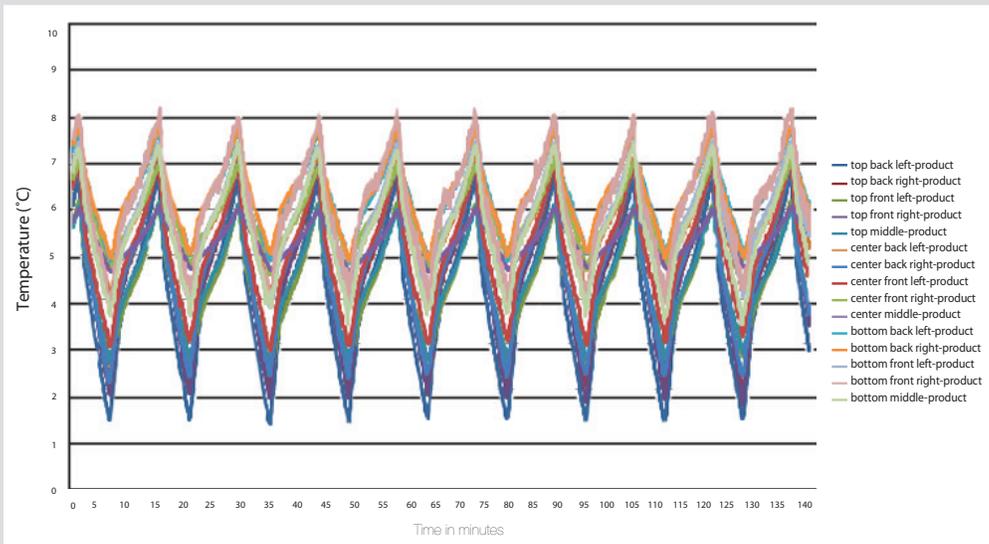
The Helmer Scientific MLR102 Countertop refrigerator displayed tight temperature control and uniformity throughout the evaluation period. Uniformity using 10ml glycol bottles to simulate temperature of product was calculated at 0.58°C. All recorded temperatures remained very close to the 5°C set-point. In contrast, the competitive free standing refrigerator displayed a wider temperature variance across storage locations, with temperatures fluctuating between 3°C and 7°C. Calculated uniformity for simulated product in the competitive free standing refrigerator was 3.24°C.

Air Probe Temperature Results

Graph 3: Helmer Scientific MLR102 Unit Uniformity - Air Probe



Graph 4: Competitive Unit Uniformity - Air Probe



The Helmer Scientific MLR102 Countertop refrigerator displayed tight temperature control and uniformity throughout the evaluation period even when using air temperature probes. Uniformity using air temperature probes was calculated at $.59^{\circ}\text{C}$. All recorded air temperatures remained very close to the 5°C set-point. As with the product temperature probes, the competitive free standing refrigerator displayed a wider temperature variance across storage locations. Certain locations within the refrigerator had recorded temperatures below 2°C (top shelf, back left location) while other locations had recorded air temperatures that exceeded 8°C (bottom shelf, front right location). The competitive unit produced multiple air temperatures below 2°C and above 8°C , the typical recommended storage range for many common vaccines, medications, and reagents.

Discussion

Temperature uniformity indicates the ability of a refrigerator to maintain temperature control across all locations within the storage cabinet. Refrigerators without adequate uniformity or temperature control can put sensitive samples, vaccines, medications or reagents at risk because they may not consistently maintain safe temperature ranges at all storage locations. As an example, certain vaccines will rapidly lose potency if exposed to freezing temperatures. The CDC implemented guidelines in their CDC Vaccine Storage and Handling Toolkit that do not allow the use of “dormitory” and household-style refrigerators or the use of combination refrigerators/freezers as these types of units have been proven to have inadequate uniformity and temperature control. In these types of refrigerators, certain storage locations are prone to freezing temperatures that may damage sensitive, expensive, and life-saving vaccines. Inadequate temperature uniformity is a risk that applies to any patient sample, medication, or reagent that has specific guidelines for cold storage temperature ranges.

With non-medical-grade equipment, users may need to avoid the use of certain locations within the refrigerator. Otherwise, sensitive therapies and samples may not be stored according to regulatory requirements, manufacturer’s recommendations, or clinical best practices. Unfortunately, this practice is inefficient, impractical, and reliant on staff compliance. Employing data loggers or remote monitoring systems only monitor temperatures in a single location. Using medical-grade refrigeration is a fail-safe in that it ensures good temperature control for all storage locations within the unit. Medical-grade refrigerators used for pharmacy or laboratory applications typically require uniformity of +/- 1.5 °C. It is important to note that not all refrigerators marketed for clinical applications offer the performance that should be expected from a medical-grade refrigerator. Although many refrigerators are marketed as medical-grade, this evaluation demonstrates that some units may not have acceptable performance for certain clinical applications.

Exhibit 2: Summary of Uniformity and Temperature Control

| | Uniformity with Glycol Probe (°C) | Uniformity with Air Probe (°C) | Air Temperatures outside of 2°C to 8°C when Set-point at 5°C |
|---------------------------|-----------------------------------|--------------------------------|--------------------------------------------------------------|
| Helmer Scientific MLR102 | 0.58 | 0.59 | NO |
| Competitive Free Standing | 3.24 | 2.63 | YES |

As listed in the summary in Exhibit 2, there are significant differences in performance between the two compact refrigerators tested. This evaluation confirmed that the performance of the MLR102 medical-grade refrigerator meets the demands of common clinical cold storage applications. When compared to the competitive unit, the MLR102 had significantly better temperature uniformity, and more importantly, no location within the cabinet had air temperatures outside of the typical 2°C to 8°C allowable range when the unit was set to 5°C.

The Helmer Scientific MLR102 has been designed specifically for clinical applications. By incorporating AdvanceCore™ thermoelectric cooling technology and an internal forced-air fan, the MLR102 unit is able to maintain set temperature within a very tight range and meet medical-grade uniformity performance criteria. Data in this evaluation supports the performance claims of the Helmer Scientific MLR102 Countertop Refrigerator.

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