DRAFT: Unpublished White Paper

ENSURING CONSISTENT CABINET-WIDE TEMPERATURE UNIFORMITY WITHIN MEDICAL GRADE FREEZERS AND REFRIGERATORS

OVERVIEW

Cold-storage units with hanging evaporators experience blocked air flow, hot or cold spots, and exacerbated open-door fluctuations, leading to product loss and wasted time. Systems distributing air evenly deliver temperature uniformity and quicker recovery to maintain products at temperature.

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EXECUTIVE SUMMARY

- Medical grade refrigerators and freezers must maintain precise temperature control to provide the highest safeguards for blood products, vaccines, medications, and other materials. However, many of the most popular products currently in use have a top-down arbitrary forced-air system that causes problems in blood centers, hospital labs, and pharmacies.
- Hanging evaporators inside cold storage cabinets produce areas within the chamber that are out of temperature, exposing valuable temperature-critical items to temperature fluctuations and storage areas that are either too hot or too cold. Technicians and staff are often unable to utilize the top racks, shelves, or trays in their storage units because products at the top are colder than other products thecabinet.
- Refrigerator and freezer systems with a back-panel plenum-design forced-air type of distribution, however, deliver cold air uniformly across each individual shelving level of the storage chamber. Such heavy-duty forced-air cooling delivers optimum temperature stability and equalized temperature distribution and air flow across each shelf or drawer throughout the cabinet, as well as quick recovery to maintain valuable products at the right temperature after door openings.

INTRODUCTION

The global market for cold-chain logistics was projected to be $9.3 billion by 2017 in a study published in the fourth edition of *Pharmaceutical Commerce's* Biopharma Cold Chain Sourcebook.[1] In fact, the 2016 Sourcebook stated that "spending on refrigerated (2–8°C) drugs is growing about 7% annually, or 41% during the 2014–2020 period. Looking at the entirety of pharmaceutical logistics, the Sourcebook projects that cold chain currently represents 19% ($12.6 billion) of a $78.8-billion industry, rising to 22% ($16.7 billion) of a $93.8-billion industry by 2020." [2]

With so much at stake in the industry, medical grade refrigerators and freezers that maintain precise temperature control, to provide the highest protections for blood, products, vaccines, medications, and other pharmaceuticals, are critical elements of cold-chain safeguards.

In the United States, for example, according to AABB Reference Standard 5.1.8A, whole blood and red blood cell components must be stored from 1°C to 6°C, and plasma components should be stored ≤ -18°C. Refrigerator and freezer units need to maintain temperature uniformity of +/- 1°C and provide quick recovery after door openings. [3]

Each year, millions of dollars' worth of vaccines are lost in the United States due to improper storage conditions. [4] Accidental freezing of refrigerated vaccine also represents a significant public and private healthcare cost. Freeze-damaged vaccines lose their effectiveness, putting public health at risk. To preserve drug efficacy, stored vaccines must be kept within strict, prescribed temperature limits. [5]

Many of the most popular cold storage units currently in use, however, have top-down forced-air ventilation systems with hanging evaporators inside the cabinet that cause problems in blood centers, hospital labs, and pharmacies, such as product instability, poor quality, loss and wasted time and effort by technicians and staff. [6]

PROBLEM:
OUT-OF-TEMPERATURE AREAS COMMON WITH HANGING EVAPORATORS

Hanging evaporators in top-down forced-air systems in refrigerators and freezers that are used to store blood products, reagents, vaccines, and other pharmaceuticals produce areas within sections of the cabinet that are out of temperature, exposing valuable temperature-critical items to areas that are too cold at the top, as well as to hot spots and fluctuations throughout the cabinet. [6]

Research indicates that such top-down forced-air systems regularly experience out-of-temperature ranges in the cabinet, as shown in Table 1. Temperature measurements map the whole cabinet, and data are recorded at specified time intervals. [6]

Consequently, technicians and staff are often unable to utilize the top racks, shelves, or trays in their storage units because products at the top are colder than other products within lower sections of the cabinet. Staff at some facilities report blocking these upper regions and not using this storage area at all. Others report being forced to rotate blood products around the cabinet, using temperature maps to monitor all locations in the unit, necessitating additional time and effort, as well as exposing products to potential temperature excursions with repeated door openings. [6]

SOLUTION:
EQUALIZED TEMPERATURE DELIVERY AND STABILITY WITH BACK-PANEL PLENUM-DESIGN FORCED-AIR DISTRIBUTION SYSTEMS

Refrigerator and freezer systems with back-panel plenum-design forced-air distribution deliver cold air uniformly across each individual shelving level of the storage chamber. Such heavy-duty forced-air cooling delivers optimum temperature stability and equalized temperature distribution throughout the cabinet, as well as quick recovery after door openings to maintain valuable products at the right temperature. [6]

Refrigeration and freezer systems with a back-panel forced-air type of distribution, however, deliver cold air uniformly across each individual shelving level of the storage chamber. Such heavy-duty forced-air cooling delivers optimum temperature stability and equalized temperature distribution throughout the cabinet (Figure 1), as well as quick recovery to maintain valuable products at the right temperature. [6]

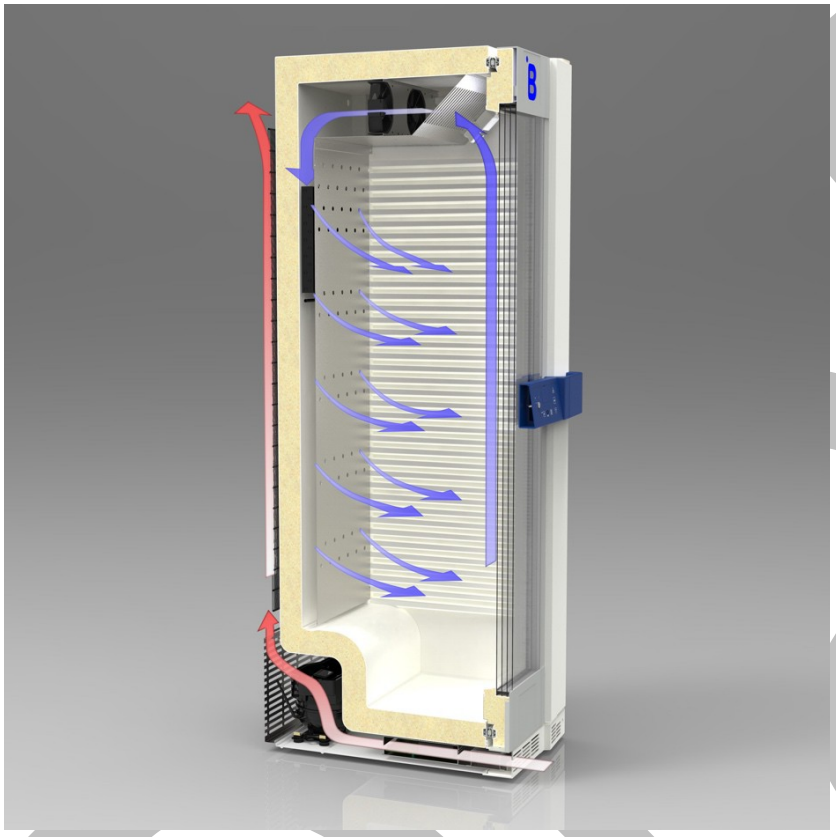

Figure 1. Back-panel forced-air cooling system distribution flow [6]

Additional benefits of back-panel forced-air distribution include:[6]

- Elimination of hanging evaporators, providing additional cubic feet of storage space within the cabinet
- Consistent temperature for all products, even on densely populated or heavily loaded shelves
- Maximum airflow without overloading compressors for greater energy efficiency
- Temperature recorder for data monitoring and recording.

What to look for in back-panel plenum-design forced-air medical grade refrigerators and freezers

In addition to temperature stability and equalized temperature distribution, medical grade refrigerators and freezers that employ back-panel forced-air distribution utilize other components as well to assure the highest safeguards for storing blood products and other pharmaceuticals, such as integrated multi-function electronics with high-temperature and door-open alarms to provide protection against temperature excursions due to door openings, with easy access for data monitoring and recording. [4, 6, 7, 8]

Versatile modularity for customized arrangement of specially designed shelves and drawers takes maximum advantage of storage capacity and allows air to flow around and through them, while insulated doors with heavy-duty lock mechanisms help reduce loss of cooling when the doors are opened. Medical grade freezers also offer easy deicing and defrosting, often with automatic defrost for optimum temperature stability. [4, 6, 7, 8]

RESEARCH RESULTS

Research conducted with back-panel plenum-design forced-air distribution units collected measurements that mapped the whole cabinet with 25 sensors. Temperature sensors on the cooling systems components provided additional data. Temperature and current consumption were continuously measured during the tests. [6]

Test requirements were measurable data and the test specification written so the data necessary to assess the requirements was measured. To collect the data, thermocouples were placed according test specifications for replicable testing These thermocouples and the measurement chains (from the sensor to the acquisition systems) are calibrated annually and certified for the testing. The climatic chamber was calibrated and configurable in terms of temperature and humidity. [6]

Temperature stability and distribution

Table 2 shows the temperature stability measured in specific time intervals. Temperature distribution remained consistent throughout the cabinet during the tests. [6]

Temperature recovery after door opening

Temperature recovery is affected by multiple variables such as how much product is stored in the unit, the ambient temperature of the room, and how quickly air is circulated inside the cabinet when the door is closed. Test results show that consistent, stable, and uniform cooling distributed throughout the cabinet, with a fan that stops running when the door is open, helps reduce cold-air loss when the door is opened. [4, 6, 7, 8]

CONCLUSIONS

When cold storage systems for blood products, vaccines, medications, and other pharmaceuticals go out of range, safety and product loss risks are multiplied, along with a drain on resources when technicians and staff are pulled away from more important tasks to address an out-of-range system.

Research indicates that medical grade refrigerators and freezers with back-panel forced-air cooling distribution systems ensure temperature consistency and are able to bring temperatures down much more quickly than traditional hanging evaporator systems.

This advanced airflow design delivers cold air uniformly across each individual shelving level of the storage chamber to provide:

- the highest safeguards against temperature-critical product degradation and loss;
- greater efficiency in both time savings and storage space by eliminating unusable hot spots; and,
- quick recovery by reducing open-door temperature fluctuations.

Such heavy-duty forced-air cooling delivers optimum temperature stability and top-to-bottom equalized temperature distribution throughout the cabinet, as well as quick recovery to maintain valuable products at the right temperature, eliminating wasted time and effort and reducing safety and product loss risks.

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