PHONONIC

Application note

Temperature control and stability.

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Phononic Performance

Solid-state refrigeration providing superior temperature control for meeting stringent vaccine storage requirements.

The Centers for Disease Control's [CDC] guidelines for vaccine storage provide a detailed list of procedures ensuring vaccines are safely stored. The Phononic 5.5 cu. ft. medical-grade undercounter refrigerator eliminates many of these inefficient procedures because it was designed from the ground up to deliver exceptional temperature control ensuring safe vaccine and drug storage. This evaluation shows Phononic provides unprecedented temperature stability and uniformity while never exceeding the 2 °C – 8 °C range.

Cost and danger of spoiled vaccines

CDC's vaccine storage guidelines are very stringent – and for good reasons. A vaccine exposed to freezing temperatures for even a short amount of time loses potency and poses a health risk to the patient and community. According to a meta-analysis in Vaccine*, between 14% and 35% of the vaccines the CDC distributes through the Vaccines for Children each year [total value of $3 billion] are subjected to inappropriate temperatures. With no visible signs of vaccine spoiling, recipients are at risk for receiving an ineffective dose.

Vaccine storage guidelines

Updated CDC guidelines adjusted the temperature range to 36 °F - 46 °F and 2 °C - 8 °C. This range is defined by vaccine manufacturers as the proper storage condition to preserve potency.

Additional guidelines a result of inferior refrigeration technology

When the CDC issued its vaccine guidelines, a medical-grade refrigerator with a chamber temperature uniformity of +/- 1.0 °C did not exist, explaining some of the additional "make-shift" guidelines. For traditional standalone refrigerators that depend on compressor cycling, chamber temperatures are often uneven creating microclimates inside the chamber. These microclimates can render some areas unsafe for vaccine storage. Without a vaccine storage option available to handle these obstacles, the CDC issued additional guidelines to compensate for the inaccurate and unstable temperature range in today's traditional refrigerators. With solid-state refrigeration, these additional guidelines become obsolete, allowing you to safely use all the available storage with confidence.

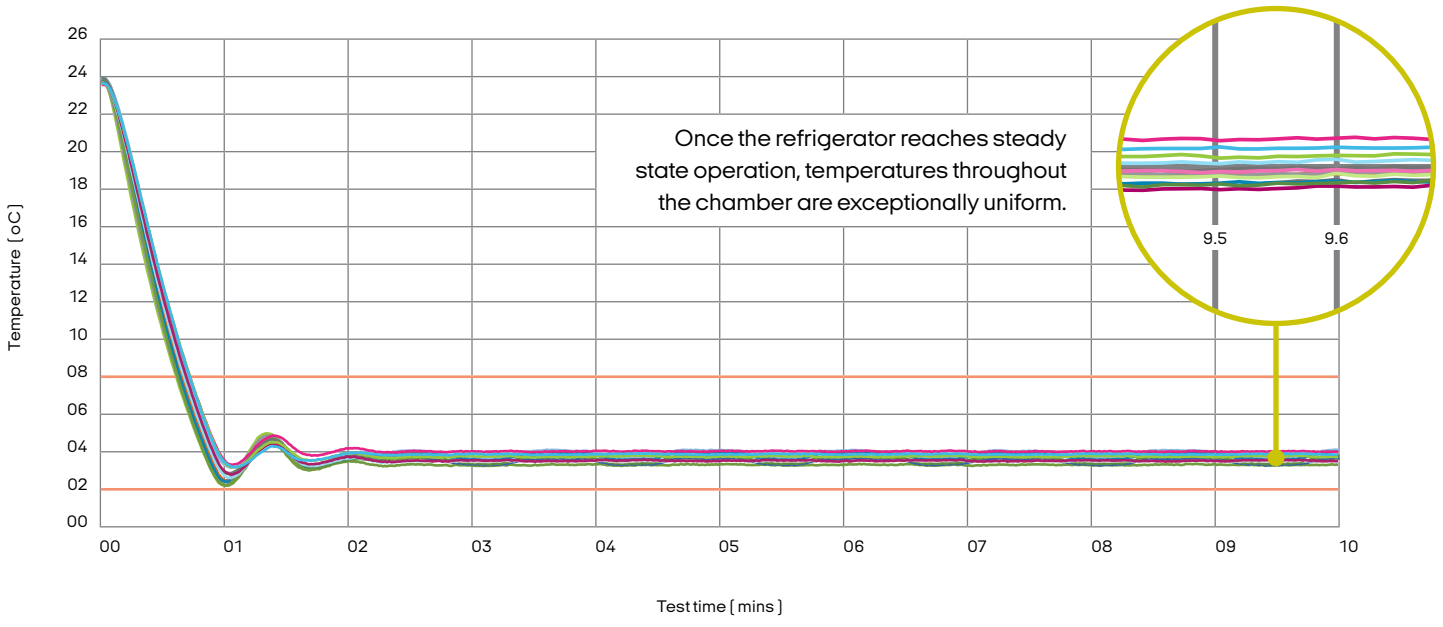
Summary of Phononic performance results in a high-use test simulation

- Excellent temperature uniformity of +/- 1 °C across the entire 5.5 cubic feet of storage space.
- Unprecedented temperature stability of 0.2 °C for each location.
- Sample temperatures never lower than 3 °C with a 4 °C set point.
- All recorded samples remained in-spec even during extended door openings.

Additional CDC storage guidelines

- Store vaccines in stand-alone refrigerators [never use a dorm-style refrigerator].
- Use a digital data logger with a current and valid certificate of calibration testing.
- Placement of water bottles on top shelves to improve temperature stability through door opening events.
- Don't store vaccines or valuables on top shelf or in door.

Weighted Slug Pull-down Test, 4 °C Set Point



* Matthias DM, et all. Vaccine 25 (2007) 3980-3986

Phononic performance testing

To measure the temperature profile of the Phononic 5.5, a series of test protocols were performed and this application paper shares the results.

Testing methodology

While there isn't an industry standard for testing pull-down, recovery, temperature stability, or uniformity of refrigerators or freezers used in pharmacy or laboratory applications, Phononic followed industry practices when conducting this study. For the sake of this testing protocol, Phononic is exclusively focused on vaccine storage and has created testing protocols to meet new, impending guidelines. To accurately measure the microclimates throughout the refrigerator, two different setups were employed to simulate an empty chamber and a chamber with samples.

Protocol 1: pull-down test, 4 °c set point

To measure the pull-down capacity of an empty refrigerator, Phononic distributed 15 weighted brass slugs equipped with T-type thermocouples throughout the storages areas of the refrigerator (see Figure 1). Brass slugs were chosen instead of samples to accurately simulate field conditions where products are not loaded until 24 hours after installation. The unit was powered on in an ambient environment of 25 °C and allowed to pulldown and operate at the 4 °C set point temperature for 10 hours. Temperature measurements were recorded every 10 seconds for the duration of the test. Graphs represent the actual temperature reading for all 15 weighted slugs.

Results

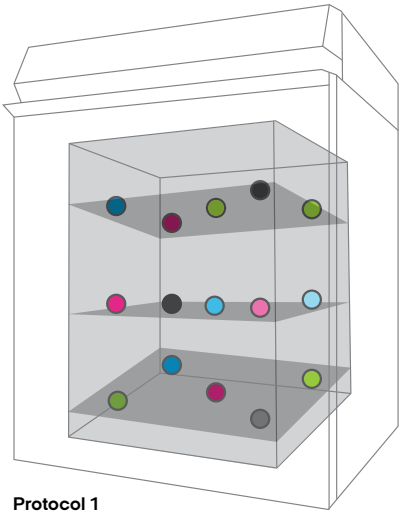
- Temperatures are +/- 1 °C from the center temperature reading of 4 °C.
- In a given sample location, the temperature of the slug varies no more than 0.2 °C once the refrigerator reaches steady state.

Protocol 2: Measuring product sample integrity during frequent door opening events

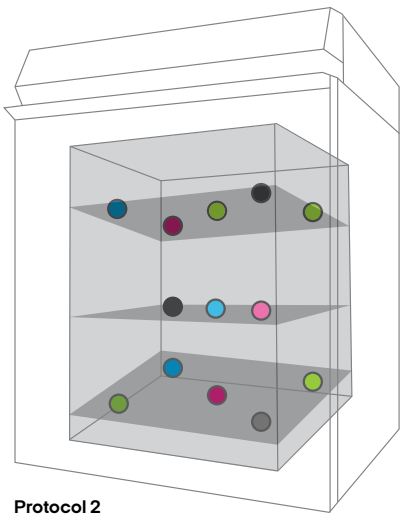
To measure the conditions in a frequent door opening environment, Phononic loaded a chamber with 13 boxes containing a 2 mL glycol vial with 1 mL of saline solution equipped with bare T-type thermocouples (to simulate product samples). The 13 boxes were distributed (Figure 2) to provide a complete picture of microclimates formed throughout the entire chamber. Once the Phononic 5.5 stabilized for 12 hours, we initiated a series of timed door opening studies to include 8-second, 30-second, and 3-minute door opening events. We repeated the door opening events every 10 minutes to simulate a high use environment.

Results

- Throughout the entire protocol, sample temperatures remained in control well within the target 2 °C – 8 °C range. Furthermore, no risk of freezing temperatures was identified, including the long door opening hold.

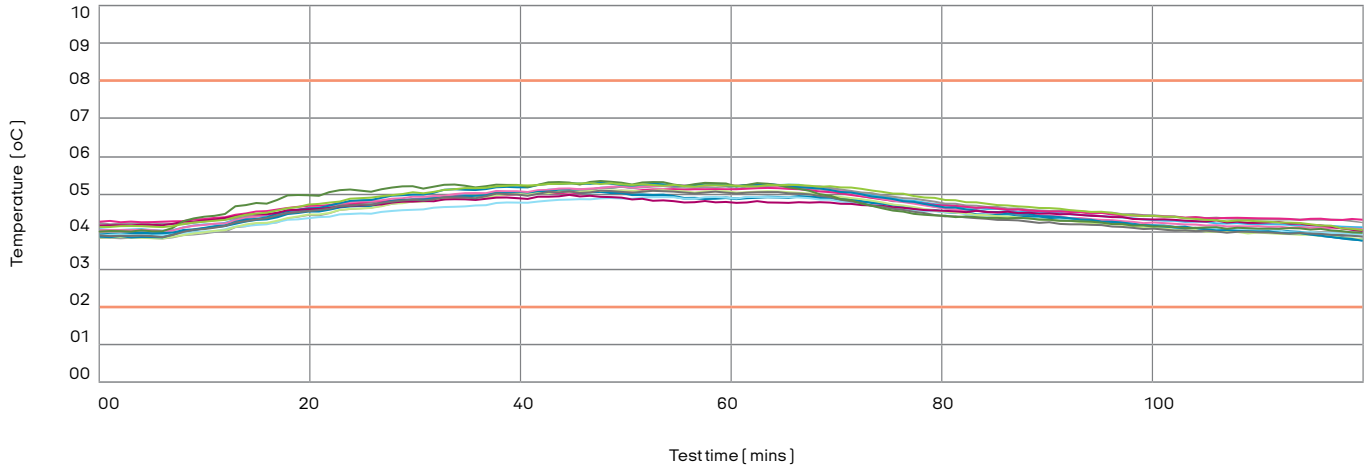


Protocol 1

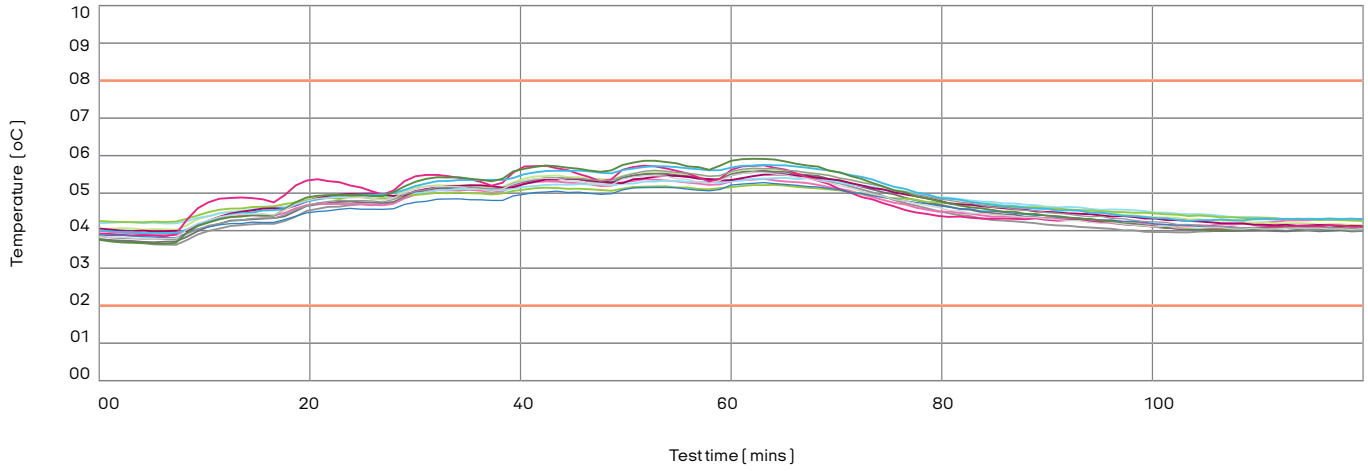


Protocol 2

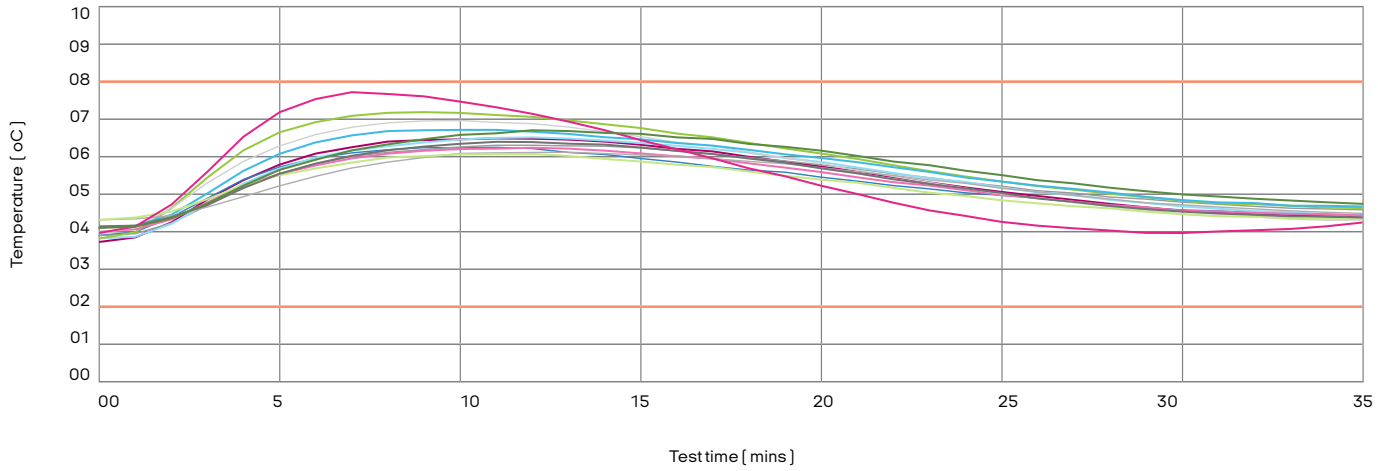
8 Second Door Opening Every 10 Minutes for 1 Hour, 4 °C Setpoint



30 Second Door Opening Every 10 Minutes for 1 Hour, 4 °C Setpoint



3 Minute Door Opening, 4 °C Setpoint



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Phononic is reimagining cooling and heating in ways never thought possible. Its breakthrough solid-state technology is transforming industries and creating new markets with innovative solutions that disrupt antiquated business models and incumbent technologies. Phononic is the critical element of innovation needed to radically change what it means to be efficient, effective and sustainable. The company has been named to the 2016, 2017 and 2019 CNBC Disruptor 50 lists, received the US EPA's 2017 Emerging Tech Award, R&D 100 Award and more.

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