Temperature Monitoring Toolkit: How to Protect Valuable Pharmaceuticals

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When you are responsible for keeping pharmaceuticals and vaccines cold, disaster is always looming…especially when you aren't at work to keep an eye on them. A refrigerator full of vaccines can be worth $20,000.

They can be ruined if the exact temperature is not maintained while in storage. In addition, you face other "costs" like compromised health from using inactive vaccines or "bad" pharmaceuticals.

Storage and handling can be confusing, as there are rules from many different regulating bodies including the Centers for Disease Control (CDC), the Vaccines For Children (VFC) program, and state and local health departments. This eBook draws on Sensaphone's 30+ years of developing technology to monitor critical assets. By learning the basics about safe storage, you can be certain that your products are never compromised and that you have the documentation to prove it.

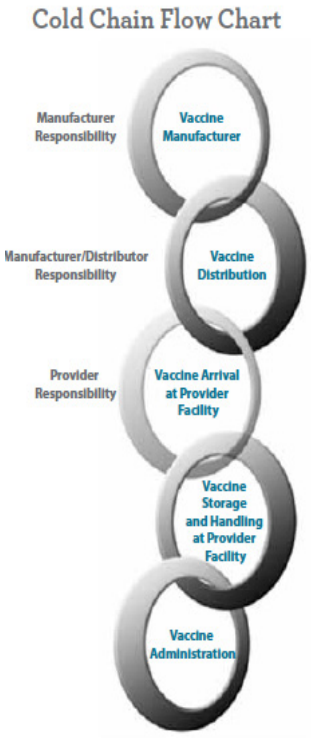
Cold chain: What is it, and why is it critical?

The Cold Chain Flow Chart is an illustration depicting the importance of keeping vaccines and other medical products at a consistent cold temperature from manufacturing through distribution, and storage to end use.

It clearly illustrates the need to keep all "links" in the chain unbroken to maintain product integrity. These products typically spend most of their time in storage waiting to be used, so the storage link is critical in the chain.

Failure to maintain the correct temperature can reduce a product's potency, which can't be restored. Drugs and vaccines can be ruined from excessive heat, cold or light, and you usually can't tell a ruined product from a good one. This means that the only real way to safeguard these assets is to be proactive about maintaining the correct temperature.

The CDC is specific about vaccine storage procedures in its *Vaccine Storage and Handling Toolkit*. It emphasizes the importance of constantly monitoring the temperature of storage units and taking immediate corrective action when the temperature goes outside the recommended range. If a facility can't be certain that vaccines or pharmaceuticals remained within the range, they are advised to discard them. The cold chain must remain unbroken.



Potential consequences for pharmacies and vaccine providers

The CDC and local immunization programs are sending strong warning messages to hospitals and clinics to discard compromised vaccines. If the compromise happens while the vaccines are in storage at a hospital or clinic, that facility has to pay for the loss. Ultimately, a practice will be held responsible for the thousands of dollars in loss if the log files and inventory are not properly recorded and documented. That can hit their bottom line hard.

For this reason, the pressure is on for vaccine providers to take the appropriate measures to store vaccines at the proper temperature and maintain that temperature until they are administered. They also need a system in place that documents their temperature history with hard data.

Human error occurs when vaccine refrigerators and freezers are left un-monitored. Perhaps the staff was too busy to record log files or accidentally left a door ajar. Beyond human error, mechanical and power failures can happen at any time. Whatever the cause, when the integrity of the vaccines is compromised, your state health inspector may issue a request to dispose of all the vaccines that cannot be proven compliant under the CDC safe practice and handling procedure. A documented system is the only way to ensure continuous data logging, alarm logs, audit trails and reports.

Think of storage and monitoring equipment as an insurance policy to protect patient health facilities against costly vaccine replacement, administration of compromised vaccines, and other consequences.

Vaccine recalls due to inappropriate storage lead to:

- Extra doses for patients
- Damage to public confidence in vaccines
- Increased costs for providers
- Liability for a provider's practice

CDC RECOMMENDATIONS ON THERMOMETERS USED TO MONITOR VACCINE TEMPERATURE

Thermometers should:

1. **Be digital if a remote monitoring system with sensor is not being used**
2. **Have a remote probe and be suitable for application's temperature range**
3. **Be submerged in glycol or glass beads**
4. **Be calibrated with a Certificate of Traceability**
5. **Be calibrated by an accredited lab**
6. **Have an accuracy of +/-1 °F**
7. **Have an alarm, min/max display and reset button**

Recommendations for storing cold pharmaceutical products

Recent studies published in the *World Journal of Pharmacy and Pharmaceutical Sciences* emphasize the importance of proper storage of pharmaceuticals until they reach consumers. This is because any loss of potency during storage may influence the efficacy and safety of pharmaceuticals. Like vaccines and other medical assets, pharmaceutical products require controlled storage and transit conditions to ensure that their quality and efficacy is not compromised. In fact, the *Journal* cites proper drug storage among a pharmacist's most important responsibilities.

"Storage is an important aspect of the total drug control system," said Kausar Shafaat in his published work *An Overview: Storage of Pharmaceutical Products*. "Proper environmental control including temperature, light, humidity, conditions of sanitation, ventilation and segregation must be maintained wherever drugs and supplies are stored."

High temperature and relative humidity are the most important factors involved in drug degradation. Refrigerators need to be carefully monitored to ensure that the stock is always in appropriate and auditable environmental conditions. The storage environment needs to be temperature-mapped and have relevant controls in place to avoid extremes in temperature.

World Health Organization's *Guide to Good Storage Practices for Pharmaceuticals*

- Recorded temperature monitoring data should be available for review.
- The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.
- All monitoring records should be kept for at least the shelf-life of the stored material plus one year.
- Temperature mapping should show uniformity of the temperature across the freezer or refrigerator.
- Equipment used for monitoring should be calibrated and regularly checked.

Although the Joint Commission does not specifically require temperature logs for refrigerators and freezers, it does require that medication be stored according to manufacturer's recommendations and that facilities maintain and monitor equipment performance. Facilities must regularly track temperatures and note deviations from the required ranges for all stored drugs. Facilities must also have a process for disposing of medication from refrigerators and freezers that have deviated from the recommended temperature ranges.

CASE STUDY:

STORMONT VAIL HEALTH

"Temperature is the most important consideration when storing drugs," said Michael Shaughnessy, maintenance mechanic specialist with Stormont Vail Health of Topeka, Kansas, which was recently named one of the nation's 100 Top Hospitals. Shaughnessy relies on Sensaphone monitoring devices for pharmaceutical storage throughout the hospital system, having used them for over ten years to monitor refrigerators and freezers holding pharmaceuticals. The devices also monitor ambient temperatures in research drug areas.

Because the Midwest region is prone to severe storms, the facility also monitors the power of their cold storage units. They currently have 53 base units monitoring 132 zones for temperature and power. If a device detects a deviation in temperature, it sends telephone alerts to four people.

"The monitoring systems have always worked well to alert personnel to temperature fluctuations – whether from a door left open, equipment malfunction or power outage." The monitors provide immediate notification so the appropriate people can take fast action to protect the quality of the medications and safeguard patient care.

> **"The systems have always worked well to alert personnel to temperature fluctuations – whether from a door left open, equipment malfunction or power outage."**
>
> *– Michael Shaughnessy, maintenance mechanic specialist, Stormont Vail Health*

An overview of medical-grade refrigerators and freezers

Regulatory bodies like the CDC don't recommend specific storage equipment, but they do provide guidelines for refrigerators and freezers.

CDC recommendations on cold storage units

- Use stand-alone units that either refrigerate or freeze – not both.
- If using consumer-grade units, use freezerless or refrigerator only of dual-zone units. Remove all drawers.
- Pharmaceutical-grade refrigerators are ideal – full sized or unde the counter.
- Make sure refrigerators and freezers can't be unplugged.
- Stabilize the temperature with water bottles and frozen coolant packs.

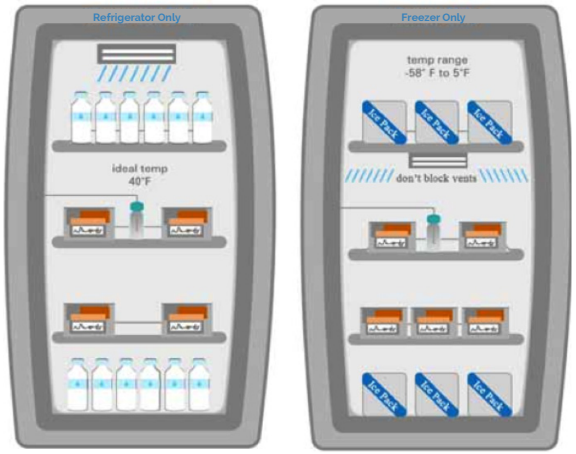
We suggest users set their system to monitor both the alarm panel on the refrigerator and the actual temperature inside the refrigerator. If the power goes out and they're only monitoring the alarm panel, the refrigerator can fail to trip the alarm, and the device won't be able to pass along the alarm. Monitoring both assures there are no issues with the refrigerator's electronics or the temperature inside. Ideally, the device would be plugged into the same circuit as the refrigerator to monitor power failure as well. Most medical-grade refrigerators have access ports to allow for third-party temperature probes.

Users can also drill a hole in the side, insert the probe and then seal the hole, or simply place the probe in the refrigerator and run the wire through the door opening. The gasket around the door should make a strong enough seal around the wire to keep the outside air from seeping in. We recommend the first option.

CDC recommendations on vaccine temperature range

- Store vaccines like VAR, HZV and MMR in freezers between -5 and 5 °F.
- Store vaccines like influenza and IPV in refrigerators between 35 and 46 °F.
- Never move vaccines between refrigerator and freezer to "cool them down" or "warm them up" faster.

The CDC recommends using water bottles in refrigerators and ice packs in freezers to help stabilize temperatures. For refrigerators, place water bottles on the top shelf, floor, and in door racks. For freezers, place ice packs along walls, back, and bottom of freezer and inside door racks.

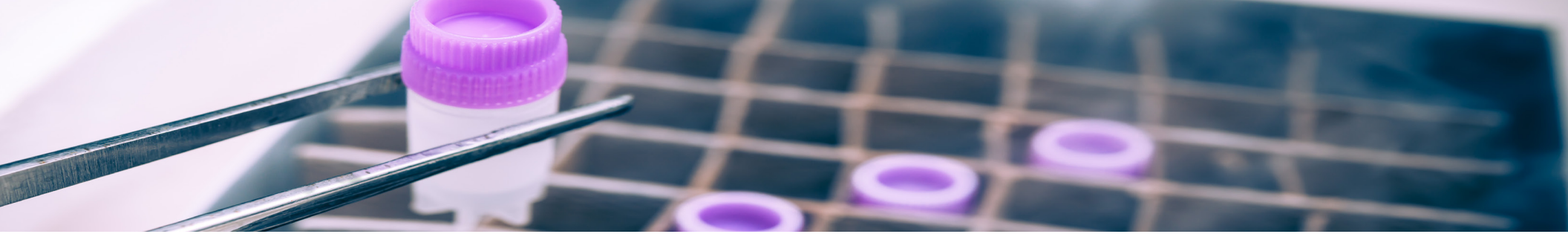


Temperature sensors, probes and buffers

SENSORS detect or measure temperature or other physical properties. They are wired or wirelessly connected to a more intelligent device that continually displays and records the temperature readings. That device is typically called a "data recorder" or a "remote monitoring system."

PROBES are sensors in rod form. They are inserted inside the environment being measured and connected to another device that records the temperature reading. A probe can be used with or without a temperature buffer.

BUFFERS are used with probes. The air temperature inside a refrigerator or freezer changes much more quickly than the temperature of vaccines and pharmaceutical products as a result of defrost cycles, opening of doors, and fans circulating the air. Inserting a probe into a bottle filled with a buffer of glycol solution or glass beads cushions it against temporary, non-threatening temperature changes, so alerts aren't sent needlessly.



Data logging vs. continuous temperature recording

We've already discussed the importance of keeping an ongoing record of temperatures in order to prove that items were stored correctly. What are your choices for doing so?

Continuous recording with a data logger

1) Install a data logger on each refrigerator and freezer.
2) Select a staff member to download data.
3) Upload data onto a computer to view and archive it.

A remote monitoring system that includes a data logger, but takes things a step further by automatically storing the data in a remote location that can be accessed by any desktop, tablet or phone. This means that personnel no longer need to be physically at the location of the refrigerators and freezers.

You can log data at user-customizable intervals, and you can log separate intervals when in an alarm state. The data is downloaded remotely through a website, either via a local network or cloud, where it can be printed or exported as a .pdf, Excel spreadsheet or .csv.

Remote monitoring systems also provide alarming functionality. When a temperature is logged that falls outside a preset range, the system sends a phone call, text or email to the designated contact, so that they can take preventive action.

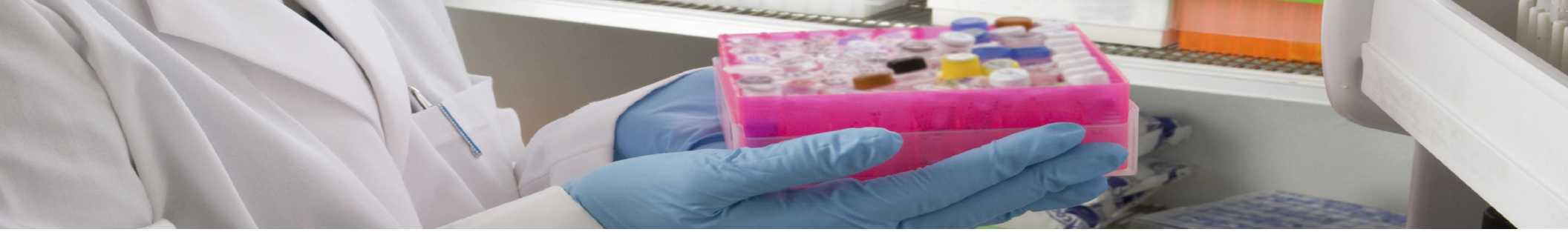
Remote monitoring systems help you verify that everything is constantly stored at the correct temperature. You get a cost-effective early warning system, detailed data logs and trending data to demonstrate compliance.

Today's more advanced systems also allow users to log both the highest and lowest temperatures over a set period of time – often a 24-hour period. This provides a snapshot to make sure the temps were within range that day – convenient when the person responsible for temperatures is not the same person designated to receive alarm notifications.

Continuous recording with a remote monitoring system

1) Install a device on the wall of the facility.
2) Connect it to the Ethernet or cellular network.
3) Install temperature sensors in refrigerators and freezers.
4) Connect the sensors to the device.

Data loggers and remote monitoring systems require a greater initial investment but cost far less when factoring in labor costs of manual recording and the "costs" of financial risk of compromised vaccines and other assets.



CDC RECOMMENDATIONS ON DATA LOGGERS AND REMOTE MONITORING SYSTEMS

- Digital display on outside of storage unit to allow reading temperatures without opening unit door.
- Detachable.
- Probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperatures. Vaccine temperatures have been found to be more thermostable than air temperature, which fluctuates with defrost cycles and opening and closing the unit door.
- Alarm to alert of out-of-range temperatures.
- Accuracy within +/-1 ˚F (+/-5 ˚C).
- Low-battery indicator.
- Continuous monitoring and recording capabilities to track and record temperatures over time .
- Display of current, minimum and maximum temperatures, which indicate the coldest and warmest temperatures recorded since device was reset.

CDC calibration recommendations

- Get a Certificate of Traceability and Calibration Testing.
- Testing should meet ISO/IEC 17025 international standards.
- Do calibration testing every one to two years.

Final Thoughts

Cold medical assets like vaccines, pharmaceuticals and research samples are expensive and sometimes irreplaceable. Their temperature has to be maintained during storage until they are ready to be used. Remote monitoring systems and data loggers protect these assets 24/7 and provide an audit trail documenting their correct storage. The devices are so inexpensive to install and maintain, you can't afford to be without this monitoring technology.

Have Questions? Need Advice?

Talk with a Sensaphone cold storage monitoring expert today at **877-373-2700**, **contact@sensaphone.com** or visit **sensaphone.com/industries/medical-cold-storage.**

About Us

Since 1985, Sensaphone® has designed and built its full line of innovative remote environmental monitoring systems and early detection products that quickly and effectively provide alerts to problems at your facilities. Over 400,000 systems are in use today around the world with the highest customer satisfaction rates in the industry.

Sensaphone is a family-owned business, and products are manufactured in the USA.

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901 Tryens Road, Aston, PA 19014
877-373-2700 • contact@sensaphone.com