

ONSET®



Choosing a Vaccine Storage Temperature Logger: *5 Things to Look For*

Introduction



In the life science and healthcare industries the proper storage of temperature-sensitive products – specifically vaccines – is a fundamental and growing concern with respect to public health. Case in point: The Centers for Disease Control and Prevention (CDC) has asserted that few immunization issues are more important than the appropriate storage and handling of vaccines. According to the CDC, approximately 13.5 percent of all refrigerated vaccines are subject to accidental freezing during storage.

Effective vaccine management has many variables, including the type of refrigeration unit being used, how the product is loaded into the unit, the number and duration of door openings, and the ambient/exterior temperature of the refrigerator's location. All have an impact on the temperature of the vaccine in storage.

Since a refrigerator is “only as good as the temperature monitoring system inside,” the CDC emphasizes that an accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management. This time/temperature data is critical to determine the safety and efficacy of refrigerated drugs. Improper storage not only causes public health concerns but also can cost vaccine providers millions of dollars a year in spoiled product.

In view of these considerations, maintaining adequate and stable temperatures within vaccine refrigerators, freezers, and controlled storage units is a critical, driving necessity. And one that underscores the need for reliable temperature monitoring to ensure that temperature-sensitive pharmaceuticals are kept within specified temperature ranges.



Vaccine refrigerator. Credit: NIST

¹Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit

Monitoring Challenges

The amount of required temperature documentation for stored product has traditionally posed a real inconvenience for pharmacy managers, vaccine program coordinators/providers, hospitals, and medical clinics alike. By offering no automated processes outside of taking temperature measurements, typical USB data loggers—or older chart recorders and thermometers, in some cases—have proved inefficient and often burdensome.

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Standard Operating Procedures related to daily checks, manual documentation of minimum and maximum temperatures, and the removal/retrieval of temperature loggers when information is needed can hinder productivity and detract from a clinic staff's main focus – caring for patients. When using USB loggers, for example, users must physically remove the data logger from the refrigerator, connect the logger to a USB port on a computer and readout the data. Moreover, the task of creating and sharing a daily report is often still performed manually.

Until recently, providers with vaccine and pharmaceutical storage requirements had no cost-effective alternative offering a comprehensive solution tailored for their application requirements, along with significant improvements in automation through advancements in technology.



Advances in Data Logger Technology

BLE temperature loggers provide fast measurement and wireless transmission of data to mobile devices, while eliminating the need for dedicated equipment, computer software, or USB cables.

Advances in temperature-monitoring technologies, specifically the integration of built-in Bluetooth Low Energy (BLE) technology, enable users to overcome many of the logistical challenges specific to temperature-controlled storage monitoring. These advances streamline data collection processes and reduce many of the inefficiencies associated with traditional USB loggers. BLE temperature loggers provide fast measurement and wireless transmission of data to mobile devices, while eliminating the need for dedicated equipment, computer software, or USB cables.



Leveraging BLE, users can quickly configure and readout loggers wirelessly, set alarms, and easily check the logger status or view current, minimum, and maximum temperatures on their mobile devices. Users can also conveniently configure, readout, and manage data from up to 30 meters (100 feet) away. This provides seamless and efficient data access for pharmaceutical and clinical managers responsible for the storage and safekeeping of refrigerated vaccines, and is a particular advantage when having to deal with multiple refrigeration units.

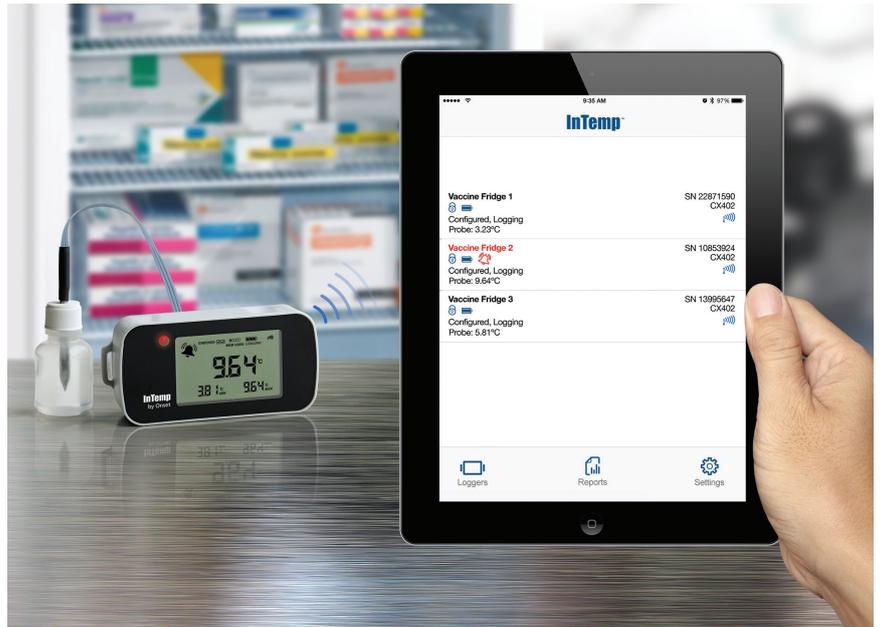
As an example, a user can download refrigerator temperatures remotely, without entering a room. This, in turn, eliminates the need to undergo any lab clearance protocols that may be required. And, because data retrieval can be accomplished without having to open a storage refrigerator, vaccines are protected from unnecessary ambient air intrusion.

When evaluating BLE temperature loggers, it is important to be aware of the key automated features and distinct user benefits that are available. Understanding these differentiators—and how they impact monitoring practices for temperature-controlled products—can help facilitate the most informed decisions and reduce the time and expense associated with manual approaches.

Following are five important features/capabilities to consider when evaluating data loggers for temperature-controlled storage applications.

1. Bluetooth Operation

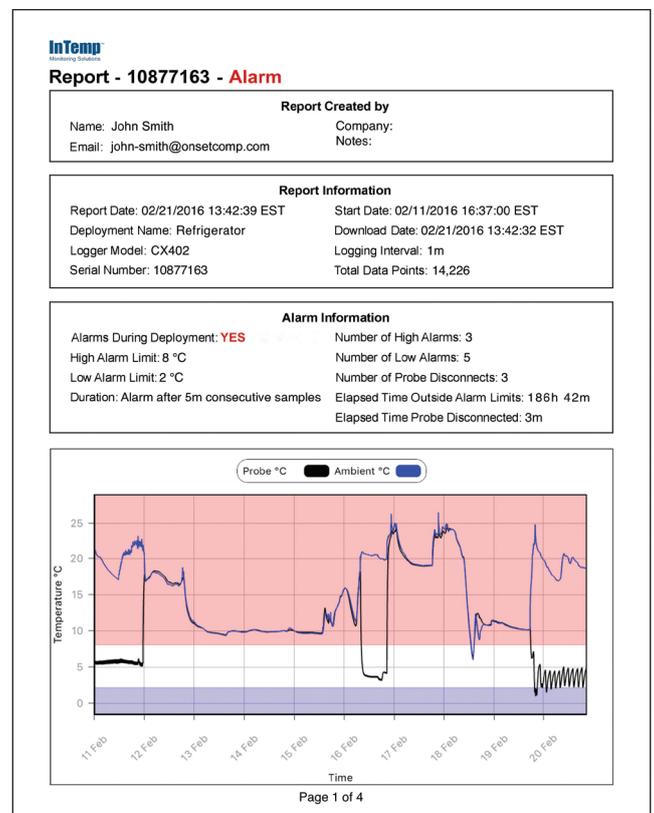
Advances in wireless technology have greatly improved the ease and efficiency with which data can be collected, organized, and shared utilizing mobile devices. By offering greater visibility on a more frequent basis, without the need to consistently detach a logger, Bluetooth Low Energy (BLE) is particularly conducive to data logging. In particular, BLE temperature loggers and their associated apps make record-keeping requirements easier, quicker, and more convenient than ever before.



In contrast to USB data loggers, which require cable connections to retrieve and offload data, and strip chart recorders, which offer imprecise views of the data, BLE technology provides the capacity for users to readout data automatically to an accompanying app running on a mobile device. This eliminates having to remove the data logger from its monitoring location, thereby minimizing hassle and gaps in temperature data. It also allows for quicker action in the event of temperature excursions.

With information stored electronically, users no longer have to log monitoring data manually. This, in turn, can simplify and digitize the common daily checking process. Digitizing the documentation of temperature levels (traditionally done by hand) also greatly reduces the chance of human error, fostering improved monitoring accuracy and more reliable temperature data.

Additionally, as Good Distribution Practices are integrated into other areas of the supply chain, such as last mile distribution, BLE can help contribute to more secure electronic records. The security encryption of a BLE device ensures that only designated individuals can access data and PDF files, providing secure traceability for regulatory audit purposes.



Sample report generated using an InTemp CX402 Temperature Logger

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2. Powerful Mobile Software

When evaluating temperature loggers, it is important to understand the features of the accompanying mobile app. Be sure the app makes the initial logger setup easy and efficient, allows users to choose from a range of preset configurations (ones for clinical refrigeration or ambient storage monitoring, for example), and enables users to create custom configurations for other applications as necessary.

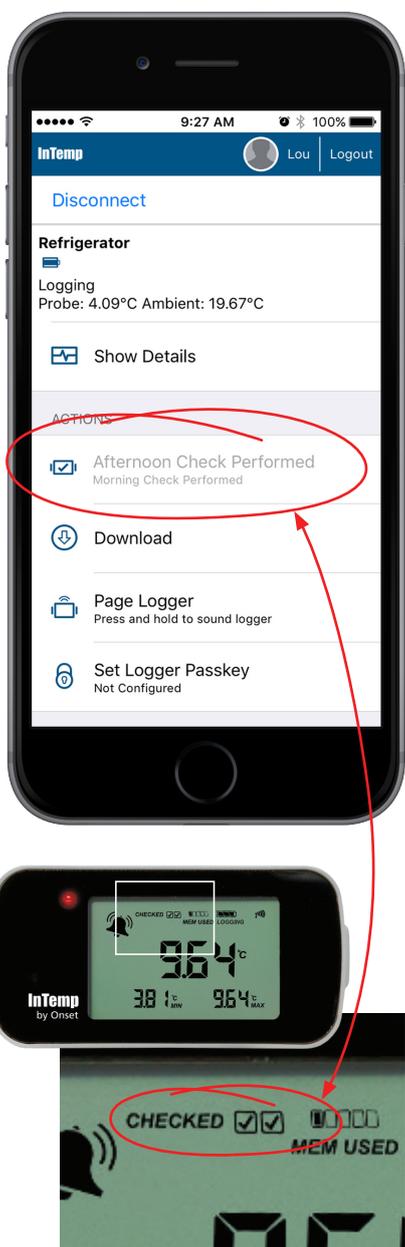
The app should also allow users to download and send data in one simple step and easily share automated reports. This enables personnel responsible for storage monitoring to meet regulatory compliance requirements much more quickly, reliably, and effectively.

Make sure the app supports the secure transmission of PDF and Excel files, and provides flexibility with respect to where data can be transmitted so information can be shared easily with numerous units or departments. Users should have the ability to standardize across multiple labs and communicate information to central sites. Collected data should be easily exported into Excel for advanced analytics, and it should be easily accessible for audits so the audit preparation process is more efficient.

Finally, to keep things secure, look for an app that enables users to set encrypted passkeys that other mobile devices will require for connection to the logger.

3. “Daily Check” Features

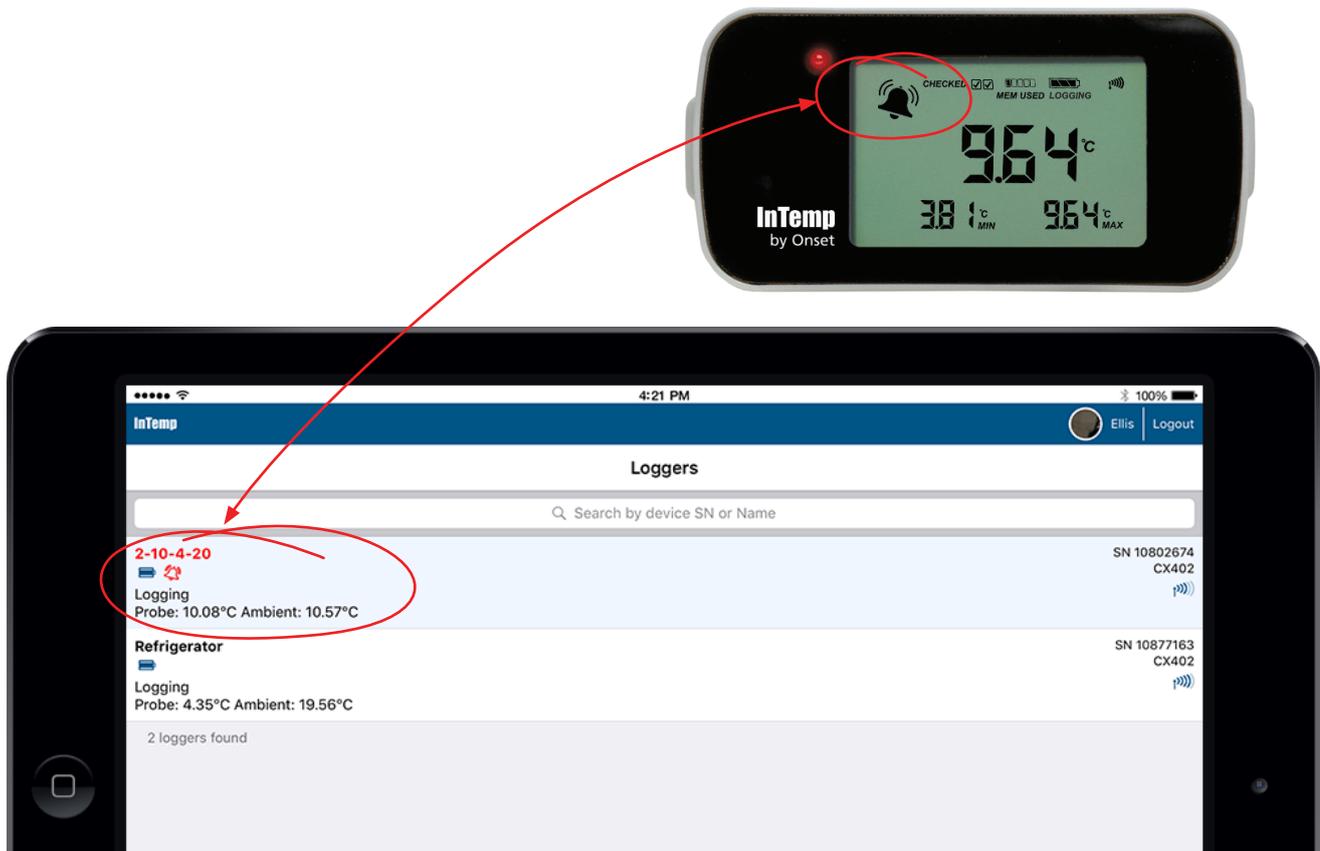
If the monitoring application requires users to perform daily or twice-daily checks of the logger, it’s advantageous to look for a temperature logger designed to streamline these tasks. Some loggers enable the accompanying mobile app to connect to the logger to perform checks. Once a check is completed, it can be recorded as a logged user-action and should be visible on the logger screen and in the reports. This helps users keep track of temperature checks throughout the day, while providing documentation that the checks were performed and of who performed them.



4. Alarm Capabilities

In temperature-controlled storage monitoring applications, it's critical that the data logger being used is able to notify personnel in the event of a temperature excursion or a disconnected temperature probe. Look for temperature loggers that have the ability to notify you of events like these in a variety of ways. Some models provide a blinking indicator on the logger LCD screen, an alarm icon on the LCD and corresponding mobile app, and even an audible alarm that will beep until corrective action is taken.

It may also be worthwhile to check into the logger's advanced alarm capabilities. For example, certain products allow users to choose to have alarms tripped cumulatively – when the amount of time the sensor is out of range over the course of the development is equal to the selected duration – or consecutively, in which case the alarm only trips if all sensor readings were at or above a specific threshold for a continuous period of time.



The images above indicate an alarm state as a result of breaking the preset high temperature threshold.

5. Large Temperature Display

Look for models that display all temperature values on a single screen vs. ones where you have to use buttons to toggle your way through a series of screens.

With traditional USB temperature data loggers, half the battle is being able to easily view temperatures on the logger display.

Some of today's advanced temperature data loggers are equipped with a large LCD display to make it easy for users to view current and daily minimum and maximum temperatures throughout the day. Look for models that display all temperature values on a single screen vs. ones where you have to use buttons to toggle your way through a series of screens.



Additionally, some loggers can display checkbox icons on the screen when daily temperature checks are done, which can be particularly useful in applications where CDC guidelines for temperature monitoring need to be met.

Finally, the data logger should provide a visual indicator for alarm conditions if an excursion occurs, as well as indicators for battery level, storage capacity, and other diagnostics.

Beyond the considerations discussed above, it may also be advisable to consult a data logger supplier that offers a range of form factors/hardware configurations. This way, you can select a solution best suited to the particulars of your monitoring application.

Among the most common configuration in hospitals and clinics is a temperature logger connected to an external probe with attached Glycol bottle. By insulating temperature probes and delaying their thermal response times, the Glycol

bottle is meant to simulate the actual product being stored.

Some loggers also include an additional temperature sensor built into the housing to monitor ambient temperature outside the refrigerator, freezer, or storage area. These loggers eliminate the need to buy a separate logger to monitor room temperature, and can provide useful information about room conditions during an excursion event.

Data logger suppliers may also offer probe-only versions, which can be useful in situations where users need to track

actual refrigerator temperatures (without Glycol buffers) or in freezer applications. Suppliers may also offer loggers with internal temperature sensors only, designed for room temperature monitoring.



About Onset

Onset is a leading supplier of data logger and monitoring solutions used to measure, record and manage data for improving the environment and preserving the quality of temperature-sensitive products. Based on Cape Cod, Massachusetts, Onset has been designing and manufacturing its products on site since the company's founding in 1981.

Visit Onset on the web at www.onsetcomp.com.



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