OneVue Sense®
Environmental Monitoring by Primex

White Paper

Complying with CDC Vaccines For Children (VFC) program regulations:

Choosing the correct temperature data logger for pharmacies.

Continuous monitoring of vaccines, blood products, and temperature-critical medications is vital to preserving potency and protecting patients.

Introduction

The ever-present need for pharmacies to comply with U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) regulations, tight budgeting, and lean staffing have combined to create a "perfect storm" of risk for pharmacy directors. In particular, the CDC has set strict guidelines for the storage and temperature monitoring of refrigerated vaccines, especially for pharmacies participating in the Vaccines for Children (VFC) program.[1]

Fortunately, technology presents several cost-effective temperature data logging solutions to protect your patients, your status, and your bottom line. Whether using simple data gathering devices or a full-featured temperature monitoring and management solution, the end goal is to guarantee that your vaccines and other drugs are continually stored within acceptable temperature limits.

In this white paper, we will explore different types of temperature data loggers and how each type can help ensure temperature and data gathering consistency, even at pharmacies with multiple locations.

The right temperature data logging solution will contribute to optimal patient outcomes, regulatory compliance, and time, labor, and cost savings.

In this white paper you will find…

- **Review of CDC VFC Recommendations**
- **Types of Digital Data Loggers**
- **Additional Implementation Considerations**

Review of CDC VFC Recommendations

For pharmacy directors, pharmacists, and pharmacy technicians, monitoring and logging temperature data is of vital concern, perhaps now more than ever.

Digital data loggers (also known as temperature sensors) have become essential to pharmacy operations, given the CDC recommendations for proper storage and handling of vaccines and temperature-critical medications.

Summary of CDC VFC Recommendations for Temperature Monitoring Devices[2]

- Use of digital data loggers for continuous temperature monitoring
- Calibrated monitoring devices with a Certificate of Traceability and Calibration
- Detachable probe in a bottle filled with a thermal buffer, like glycol
- Alarms to alert for out-of-range conditions
- User-programmed logging interval of every 30 minutes or less
- Accuracy to ±0.5 °C (±1.0 °F)
- If battery operated, a low-battery indicator
- Display of current and minimum/maximum temperatures

1 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit, January 2025, Washington, DC.

2 Ibid, page 11.

Continuous monitoring and data collection provides a temperature history essential for effective vaccine temperature management on a day-to-day basis. Additionally, continuous data loggers can be predictive in nature. For example, pharmacies with multiple locations can implement a quarterly review process to audit logged data for refrigeration units protecting a certain dollar amount of pharmaceuticals. This process can identify outliers and trends relative to temperature that could put your most sensitive medicines at future risk.

In short, reliable digital data logging devices that continuously monitor and capture ongoing temperature data are a sound business investment to protect valuable vaccines and other pharmaceuticals, reduce risk, improve your pharmacy operations, and deliver the highest quality care to your patients.

Choosing a Digital Data Logger

Many different types of data loggers exist today, ranging from basic stand-alone recording devices to sophisticated interconnected network devices. It is important for pharmacies to explore and understand the range of functionality offered by these different data logging devices before implementing a solution.

Basic Digital Data Loggers Offer Minimum Protection/Maximum Exposure

Ensure drug storage temperatures are continually monitored

Pros

Basic digital data loggers provide the minimum functionality at a relatively low cost. These logging devices have some amount of fixed or removable nonvolatile memory and a temperature probe that can be routed into the refrigeration unit being monitored. Typically, this type of data logger will have an LCD screen for real-time temperature monitoring.

Since temperature readings are saved to nonvolatile memory, a pharmacy or facility staff member must periodically extract the saved data via a data cable connected to a PC or by removing a memory card. A basic PC application, or sometimes a simple spreadsheet program like Microsoft Excel, is used to analyze the collected data.

Cons

Manual data download takes staff away from patient-centered activities and represents a "soft cost" that can add up in terms of staff time. On the other hand, if the data logger is left unattended for too long, the data may exceed the capacity of the memory card. If a reading is missed, the data is lost forever. It is also important to understand that basic data loggers may not support setting high- and low-temperature alarm thresholds.

Typically, basic digital data loggers don't have the capability to issue an alert or notification if the unit stops recording or a probe becomes disconnected. In the best case scenario, a local alarm may provide real-time alerting. If a storage unit temperature goes out of range when the pharmacy is unattended, there is a genuine risk of losses of costly vaccines, or worse, not being aware that you could be administering ineffective vaccines to patients.

Lastly, since the recorded data is simply raw temperature readings at a given time, users must manually create reports for data analysis. Often, data graphing and report generation modules are available at an additional charge, though advanced data analysis is not available at all for many basic data loggers.

Figure 1
Basic Data Logger Examples

Dickson SM320

VFC 600

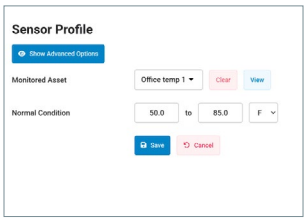
Networked Data Loggers Are a Smart Upgrade

Networked data loggers represent a more sophisticated approach to continuous data logging. Wired or wireless sensors continuously monitor and log temperature data, then connect through the network to periodically upload the stored data to a software application on an on-premise, hosted, or cloud-based server. If the network is unavailable or out of commission, the data logger will continue logging data until the connection is restored before uploading all of the stored data at once.

With the more advanced systems, browser-based software is used to configure high/low thresholds, set logging and transmitting intervals, analyze collected data, generate reports, and manage the distribution of alarms via email, text message, or phone support. Detailed report generation provides essential support for regulatory audits and monitoring compliance with your pharmacy's internal quality standards. Robust reporting is typically limited to the higher-tier network data logger solutions and includes report generation templates not typically available with many stand-alone basic data logging devices.

Figure 2
Networked Data Logger and Software Example

OneVue Sense Temperature Sensor



OneVue Sense Software Platform Temperature Thresholds

Some networked data loggers use gateway or repeater devices to create a wireless mesh network utilizing the 900 MHz radio frequency to communicate with the data loggers. Often, these systems feature proprietary technology, which could result in service issues in the future. With more sophisticated systems, the wireless data loggers use standards-based technology and connect directly to the standard 802.11 network in the pharmacy via Wi-Fi or Ethernet to transmit and record monitoring data. The two systems have several other significant differences, chief among them being wireless security and available power options.

Wireless Security

Security is always an important aspect to consider for any wireless system. Since the collected data is sent wirelessly to the software, ensuring that any potential system has proper encryption and data security is vital. A data logging system should not only support Wi-Fi security (WEP/WPA/WPA2), but also provide support for RADIUS authentication (EAP-FAST/PEAP/EAP-TLS), often employed by IT organizations in network deployments.

With gateway/repeater type data logging systems, sensors push data to gateways for upload to the software. Each data logging sensor can send its own data and repeat other sensors' signals to push data to the gateway. The data gathering process works completely independently of the existing pharmacy network. The gateway accesses the pharmacy IT network via an Ethernet connection to send the data to the software. In other words, these systems effectively use two types of network protocols to capture temperature monitoring data. When choosing a data logging solution of this type, it's important to understand the security features of both the sensors and the gateways to ensure data integrity and minimal impact to the existing network infrastructure.

For a wireless network-based data logging system, the sensors connect to the existing pharmacy IT network to transfer and record data using wireless Wi-Fi or wired Ethernet connections. Sensors have built-in security and authentication protocols to ensure data integrity and safety. Data packets are small, and connection times are short to put minimal load on the network.

It is still crucial to ensure the system you choose has the latest, most advanced protocols to maintain the security of your data.

Power Options

An additional aspect to consider is the power source of each data logging device. Most wireless data loggers are powered via an AC adapter with an internal backup battery to enable continued logging during a power outage. Some solution providers go beyond that basic to provide multiple power options, including AC, battery, and in some cases, even Power over Ethernet (PoE) for Ethernet-based solutions.

Allow pharmacy staff to take timely, appropriate actions to minimize losses

Gateway/repeater systems often require an Ethernet connection to the gateway to transfer data to the web-based software. The gateways must be placed in the pharmacy in a position that will allow it to accept the signal from the sensors and have a connection to an Ethernet line.

The way the data is captured and stored is extremely important when selecting a data logging solution, and these additional elements of the CDC guidelines are vital to keep in mind when deciding.

Additional Implementation Considerations

Calibrated devices with a Certificate of Traceability and Calibration

To ensure accuracy of your temperature readings, the CDC recommends only using devices that have been tested and approved by an ILAC/MRA-accredited laboratory.

Use of a thermal buffering solution, like glycol, to minimize nuisance alarms

Vaccines and other pharmaceuticals have been found to be more resistant than the air temperature to the temperature fluctuations caused by opening the refrigerator or freezer door or the defrost cycle. Placing a temperature probe in a thermal buffer provides a more accurate reading of actual vaccine temperatures.

Digital display on the outside of the data logger to show current temperature

A digital display allows pharmacy staff to read temperatures without having to open the refrigerator or freezer door, which can cause a temperature fluctuation.

Alarm that alerts out-of-range conditions

Virtually all data loggers have a visual or audible alert at the device when an out-of-range condition is detected. More sophisticated solutions can also send alerts via email, text message, or phone call to help ensure vaccines can be properly protected when an alarming temperature excursion occurs.

Accuracy to ±0.5 °C (±1.0 °F)

Make sure the device and probes you select have been calibrated to provide the minimum accuracy recommended by the CDC.

Display of current and minimum/maximum temperatures

A record of the minimum and maximum temperatures allows pharmacy staff to demonstrate that vaccines have been continuously kept within acceptable ranges.

Low-battery indicator

An indicator light on the data logger ensures there's no gap in temperature monitoring by alerting pharmacy staff before batteries die. More sophisticated data logger solutions and their software can detect a low battery state and send pharmacy staff an email, text message, or phone call alert.

Memory storage of at least 4,000 readings

Your selected data logger must be able to hold readings until someone is able to download them. This feature is essential in the case of a power failure to retain historical data.

User-programmable logging interval

Most data loggers can be set to read temperatures several times a day, if not several times an hour. Some networked data logger solutions also have the ability to set custom reporting intervals that are independent of the logging interval.

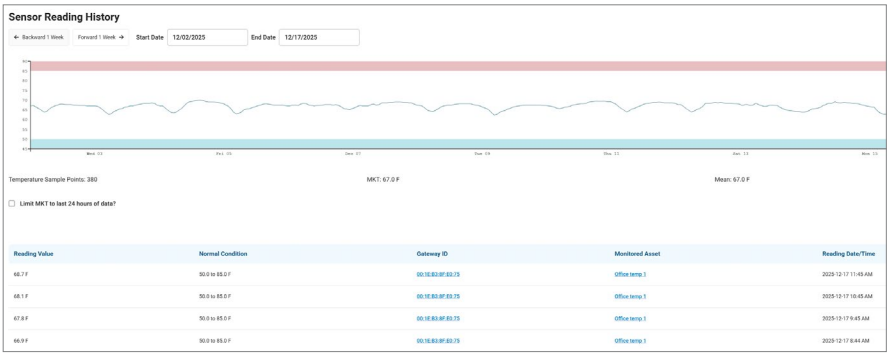


Figure 3
OneVue Sense Software example of weekly and hourly temperature readings.

Example
The sensor (logger) can be set to log data per the logging period, but will only connect to the network and send the data per the set reporting interval. If temperatures exceed high or low thresholds at any time, the data logger sensor will report this immediately to the management software and enable its local alarms (red flashing LED and buzzer if enabled). The management software will then send the email, text message, and/or phone call alerts based on a predefined notification list.

Primex Wireless Networked Data Loggers

- CDC- and VFC-compliant temperature monitoring
- NIST-traceable temperature probes (with two-point VFC-compliant calibration report)
- Support for two probes for redundancy or multiple monitoring points
- Glycol- and wax-based thermal buffering options
- 802.11 b/g/n connectivity with no additional gateways or repeaters required
- SSL-encrypted data packets, WEP/WPA/WPA2 wireless encryption support
- Support for EAP-FAST, PEAP, EAP-TLS, and EAP-TTLS authentication methods
- Ethernet option available (supports 10/100 Ethernet and PoE 802.3af)
- AC, battery, or PoE powering options (battery backup when externally powered)
- User-configurable logging and reporting intervals
- User-configurable high/low thresholds and span settings (web browser access)
- LCD screen with support icons (probe error, low battery, signal/connection status)
- Status LEDs (green, yellow, red) providing visual feedback and alerting
- Onboard audible buzzer for local audio alerting (on/off configurable)
- FDA-registered devices

OneVue Sense® Temperature Sensors Exceed All Critical Selection Criteria

OneVue Sense temperature monitoring sensors exceed the requirements of the VFC program and provide a scalable, robust platform for various monitoring applications.

OneVue Sense networked Temperature Sensors use NIST-traceable probes and include a calibration report with each probe. Thermal buffering solutions based on glycol (vaccines) and wax-based (solids) are available for all probes.

OneVue Sense networked Temperature Sensors include management software that can be deployed on-premise or securely cloud-hosted. It supports the latest reporting and alerting methods to ensure threshold breaches are identified and reported in real time. Users can access the OneVue® reporting software dashboard from any device with a web browser.

Flexible Integration into Your Existing and Future IT Infrastructure

No new infrastructure is required to implement OneVue Sense Temperature Sensors. The system incorporates the latest, most secure communication and authentication protocols to perform efficiently within the existing 802.11b/g/n environment. OneVue Sense Temperature Sensors can also be configured with a fixed logging period and a separate reporting period to minimize network time.

Conclusion

There are hundreds of data logging products on the market today. Before embarking on a new initiative or seeking an upgrade for your current temperature monitoring program, it's important to understand the requirements of the CDC, FDA, State Board of Pharmacy, and any other authorities having jurisdiction over your operations. The features of the solution you choose are important to your ability to operate efficiently and in compliance, but the ultimate and overarching goal is patient safety.

965 Wells Street
Lake Geneva, WI
53147

Phone: 855-602-2934
Hours: 7:00am – 5:00pm CT
Email: info@primexinc.com