



**NYS Vaccines for Children (VFC) Program
Training Series
8: Selecting Temperature Monitoring Equipment**

New York State Department of Health
Bureau of Immunization

Hello and welcome.

This training is intended to provide guidance to New York State (NYS) Vaccines for Children (VFC) providers on purchasing temperature monitoring equipment.

NYS VFC Requirements for Temperature Monitoring Devices Effective January 1, 2018

1. A calibrated, continuous temperature monitoring device (data logger) with an **active temperature display** and continuous monitoring and recording capabilities where the data can be routinely downloaded in every storage unit housing publicly-funded vaccine
 - Must come with a valid (ILAC or ISO/IEC) certificate of calibration that confirms it measures accurately, within +/- 0.5°C (+/-1°F)
 - Active temperature display is a display that is located **on-site** and can be accessed and checked by staff on a regular basis. The display is required to indicate the current temperature inside of the unit and **ALSO display daily minimum and maximum temperatures.**
 - Continuous temperature monitoring = temperature reading taken at least every 30 minutes. **Device must have capability to produce a data output.**



Effective January 1, 2018, all providers receiving publicly-funded vaccine must use a calibrated, continuous temperature monitoring device with an active temperature display and continuous monitoring and recording capabilities where the data can be routinely downloaded. Every storage unit housing publicly-funded vaccine must have a continuous temperature monitoring device which is also referred to as a data logger.

The device must come with a valid (International Laboratory Accreditation Corporation (or ILAC) or International Standards Organization (or ISO) certificate of calibration that confirms it measures temperatures accurately. The device must measure temperatures within +/- 0.5°C (+/-1°F).

The device must have an active temperature display. An active temperature display is a display that is located on-site and can be accessed and checked by staff on a regular basis. The display is required to indicate the current temperature inside of the unit and ALSO display daily minimum and maximum temperatures.

Finally the device must have continuous temperature monitoring and recording capabilities with the capability to record a temperature reading AT LEAST every 30 minutes. The device must have the capability to produce a data output or report that indicates continuous logging.

NYS VFC Program Requirements (cntd.)

2. At least one back-up continuous temperature monitoring device on site with a valid certificate of calibration and meeting all primary device requirements

- For use when a primary device cannot be used, e.g.:
 - Calibration testing is required
 - Equipment failure
- Recommendations:
 - Store backup outside of the storage unit until needed
 - Calibration date different than primary monitoring devices

Visit www.health.ny.gov/vfc for more information on Back-up Data Loggers



VFC Providers are also required to have at least one back-up continuous temperature monitoring device on site that meets all of the same requirements as the primary devices. The backup device is used in case of equipment failure or when calibration testing of the current equipment is required.

The NYS VFC Program recommends the back-up temperature monitoring device be stored outside of the storage unit until needed, and the calibration date for the backup device be different than the one in use.

Visit the NYS VFC webpage for more information on back-up data loggers.

State-Supplied Continuous Temperature Monitoring Devices

- Fridge-Tag2L Data Logger supplied to all VFC providers
 - New enrollees should inquire with VFC program if interested in obtaining Fridge-Tag2L devices
 - Practices are not required to use the state-supplied Fridge-Tag2L devices
 - data logger in use must meet requirements
- Providers are responsible for purchasing additional data loggers
 - More than one storage unit (e.g., 2 refrigerators, 2 freezers, etc.)
 - backup devices
- Resources
 - <http://www.health.ny.gov/vfc> under section “Data Loggers”



In 2017, the VFC Program supplied all current VFC Providers with two state-supplied Fridge-Tag2L data loggers, free of charge. Providers who are newly enrolling in the program should inquire with the VFC Program if they are interested in receiving a state-supplied device.

VFC Providers are not required to use the state-supplied Fridge-Tag2L devices if they have a device that meets all of the requirements.

Providers are responsible for purchasing additional data loggers beyond the first two units provided. For example, large practices with more than one refrigerator or freezer.

All VFC providers must purchase backup continuous temperature monitoring devices. Additional resources on data loggers can be found on the VFC webpage at www.health.ny.gov/vfc under the section “Data Loggers”.

Continuous Temperature Monitoring Device Recommended Features

- Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperature.
 - placed centrally inside the storage unit away from ceilings, walls, vents, fans and coils.
- Audible high/low alarm for out-of-range temperatures
- Low battery indicator
- Records continuously with memory storage of at least one month of data (no less than 4,000 readings)
 - Data recording loops when memory is full (overwrites old data instead of stopping recording)



The NYS VFC program recommends that temperature monitoring devices have a detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperature. The thermal buffer should be placed centrally inside the storage unit away from ceilings, walls, vents, fans and coils.

Continuous temperature monitoring devices should also come with an audible alarm to alert you to any out of range temperatures. Many devices come with a visual alarm but these can be easily overlooked or ignored.

The continuous temperature monitoring device should have a low battery indicator so that you are aware in advance if the device needs a battery change.

The device should record data continuously and have a memory storage of at least one month of data (or at least 4,000 readings). Also, the device's data recording should loop when the memory is full, and continue to overwrite old data instead of stopping recording.

Questions?

- Refer to Temperature Monitoring Requirements Document
 - https://www.health.ny.gov/prevention/immunization/vaccines_f_or_children/docs/temp_monitor_device_guidance.pdf
- Contact VFC Program
 - dataloggers@health.ny.gov or 1-800-543-7468



If you have additional questions about temperature monitoring requirements, refer to the temperature monitoring requirements document by visiting the link on this slide. You can also send an email to the NYS VFC Program's dedicated mailbox at dataloggers@health.ny.gov or call the NYS VFC Program at 1-800-543-7468.

Why Data Loggers?

- Alarm helps identify excursions quickly
- Shows how often and how long temperatures were out of range
 - Eliminates the “unknown” with temperature excursions
 - May prevent unnecessary vaccine disposal
- Early identification of problems with a storage unit
 - Potentially before any vaccine loss
- **Data Loggers DO NOT replace twice daily temperature checks**
 - Temperatures still need to be checked and recorded by staff twice daily
 - Refer to Temperature Monitoring Procedure training for more information



There are a number of reasons why data loggers are a useful tool for VFC Providers.

First, most data loggers come equipped with an alarm which can help to identify temperature excursions more quickly.

Next, data loggers continuously monitor and record temperatures in refrigerators and freezers and store the data in the device's memory so that it can be downloaded and accessed later. Review of the data can indicate how often and for how long temperatures may have been out of range. This can better aid the manufacturer to determine whether the vaccine is still viable. In cases such as power outages where temperatures would have otherwise been unknown, vaccine may actually be saved from being discarded.

Finally, data loggers are a wonderful tool to provide early identification of storage unit issues, such as a malfunctioning or failing unit. Since data is being collected continuously, providers can review the data and note any patterns or trends that may be indicative of a less obvious problem.

Keep in mind that the use of data loggers does not replace the twice daily manual temperature checks that the NYS VFC provider is required to perform. Temperatures still need to be checked and recorded by office staff twice daily and documented in the New York State Immunization Information System or NYSIIS temperature log.

More information on the temperature monitoring process can be found in Training #9 of this series.

Data Logger Features

- Pre-programmed temperature reading schedule
- Computer interface via USB/Wi-Fi/Bluetooth
 - Software allows review of data in table or graph format
 - Cloud monitoring systems
 - » Do not replace twice daily temperature checks
 - » Display still required
- User-programmable preferences:
 - Reading interval (at least every 30 minutes)
 - Alarms: Audible recommended
 - Alarm thresholds: time and temperature
 - Additional preferences
 - » location of saved data
 - » file formats
- » Some do not require software

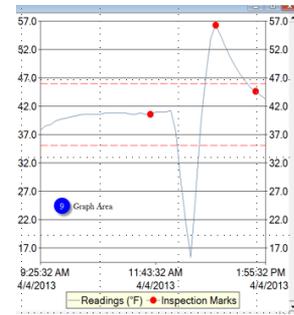


Image obtained from the Nevada State Immunization Program's LogTag@TRED30-7R Training Guide, 2013



Data loggers available for purchase have a large variety of features.

Data loggers collect data automatically on a programmed schedule, for example every 5, 10 or 15 minutes. Each reading is recorded as a data point including the temperature, date and time.

Data loggers have limited data storage and display capability. You may wish to interface with a computer to set up operating preferences, download data, and view more detailed data. Data loggers can connect to your computer for data downloads in various ways including USB or wireless connections such as WiFi or Bluetooth. Data logger software allows for the review of data in a table or graph format.

USB is the more common method but requires that you unplug the device from the probe to then plug into a computer to view the data.

Wireless systems do not require that the device be disconnected from the probe or moved away from the storage unit to view or download the data. However, some wireless data loggers require users to have access to a wireless network (WiFi) therefore installation may require assistance from technical staff.

Some continuous temperature monitoring systems report data directly to a cloud server that can be accessed by logging into a website or even a mobile app. A cloud server is a centralized data storage location on a web server that is usually hosted by the data logger vendor. These types of systems may provide notification to the provider if an excursion occurs but remember that they do not replace the manual twice daily temperature checks, so a display on the outside of the unit is still required.

Some typical user-programmable preferences are:

The device's logging interval. For example, the user can specify that the device record a temperature every 30 seconds, 5 minutes, 15 or 30 minutes, etc. The NYS VFC program requires that the device selected has the ability to record a temperature at least every 30 minutes.

Data loggers typically have a visual or audible alarm. The user can specify what temperatures signal an alarm on the device. Visual alarms typically consist of a flashing green light for good and a red light for problems. These types of alarms are often overlooked or ignored. Therefore, devices with audible alarms are recommended over visual only alarms.

Some data loggers allow the capability to delay alarm temperature thresholds. For example, an alarm would only be activated if the temperature exceeds 46 Fahrenheit for more than 60 minutes.

Data Logger software can also be used to set additional preferences specified by the user. This can include data preferences such as the location to which data downloads are saved, file type formats, and more.

Keep in mind that some data loggers do not require software to be installed.

Temperature Monitoring Alarms and Alert Systems

1. Device with local alarm that notifies staff within vicinity of storage units
 - Equipment failure or door ajar via a visual or audible alarm
 - Audible alarm recommended versus device with visual-only alarm
2. Advanced systems that provide off-site notification
 - System contacts the specified person(s) by phone, text or email when out of range temperatures are identified
 - Recommended for large volume facilities
 - Alerts appropriate staff during event (e.g., weekend or off hours)
 - Emergency Plan
 - Ensure offsite systems have up to date contact information and that staff are informed of their emergency responsibilities

As mentioned previously, some continuous temperature monitoring systems come equipped with alarms or notification systems to alert you if there is a temperature excursion.

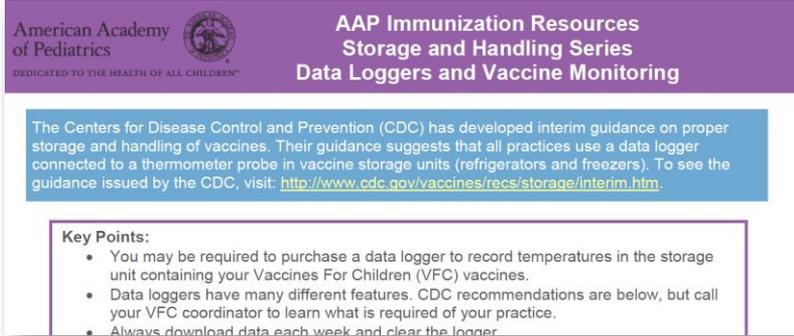
The simplest type of alert systems are temperature monitoring devices that notify persons that are in the vicinity of the storage units if there is a problem such as an equipment failure or the door was left ajar. These local systems alert staff via a visual or audible alarm on the device or both.

More advanced off-site notification systems are useful after office hours to notify one or more staff persons in case of temperature excursions. These systems can be set up with a primary contact as well as backup staff. The contacts may be vaccine coordinators or the provider of record and would receive a telephone call or other type of notification such as an email or text in the event of a temperature excursion.

Alert systems may be beneficial for large volume facilities as they are able to alert you to a temperature excursion during the event (for example during off-hours such as weekends or holidays) so the situation can be corrected in time to prevent the loss of vaccine.

Include information on any temperature monitoring systems in your Emergency Plan. Ensure that the system has current contact information and that the contact staff are aware of and able to fulfill their responsibilities to activate the Emergency Plan when needed.

AAP Data Logger Guidance



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

AAP Immunization Resources
Storage and Handling Series
Data Loggers and Vaccine Monitoring

The Centers for Disease Control and Prevention (CDC) has developed interim guidance on proper storage and handling of vaccines. Their guidance suggests that all practices use a data logger connected to a thermometer probe in vaccine storage units (refrigerators and freezers). To see the guidance issued by the CDC, visit: <http://www.cdc.gov/vaccines/recs/storage/interim.htm>.

Key Points:

- You may be required to purchase a data logger to record temperatures in the storage unit containing your Vaccines For Children (VFC) vaccines.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required of your practice.
- Always download data each week and clear the logger.

https://www.aap.org/en-us/Documents/immunization_dataloggers.pdf

The NYS VFC Program cannot recommend specific products.



The American Academy of Pediatrics (AAP) has developed a data logger and vaccine monitoring guidance document which includes a listing of data logger manufacturers that may aid your practice in selecting a device. The document also includes additional guidance on alert systems.

The NYS VFC program cannot endorse or recommend specific brands or products. However, if you have questions about whether a specific temperature monitoring device meets current requirements, call the NYS VFC program at 1-800-KID-SHOT or email dataloggers@health.ny.gov for more information.

Vaccine Storage Units with Built-in Temperature Monitoring

- To meet VFC requirements:
 - Valid calibration
 - Must be a continuous temperature monitoring device
 - Must produce a data output
 - The thermometer must have a display for reading temperatures and display current and min/max temperatures
 - You must maintain valid calibration
 - In the event of unit repair, the thermometer may need recalibration.
- Readings may differ somewhat if using more than one device
 - Due to:
 - Thermal buffering
 - Probe location
 - Temperature sensor type (thermistor, thermocouple)



Some vaccine storage units may come with built in calibrated temperature monitoring devices. These units can meet both the storage unit and temperature monitoring device requirements, as long as the temperature monitoring device meets the NYS VFC program's criteria for calibration, is a continuous temperature monitoring device and has a display for reading temperatures. The display must be able to indicate the current and min/max temperatures inside the storage unit and the device must be able to produce a data output.

It is best if the display is located on the outside of the unit.

If you decide to purchase units with built-in temperature monitoring and then use another temperature monitoring device to check temperatures, please note that there may be up to a 2 degree Fahrenheit difference in temperature between different devices. This is related to several factors including whether or not the probe has a thermal buffer, probe location (side wall of unit, back of unit vs. center), and type of temperature sensor used.

Key Messages: Selecting a Temperature Monitoring Device

- Requirements:
 - Calibrated, continuous temperature monitoring device in each unit that stores publicly-funded vaccine
 - Contact VFC Program for information on state-supplied data loggers at 1-800-543-7468 or dataloggers@health.ny.gov
 - At least one back-up continuous temperature monitoring device with different calibration date than primary devices
- Alarm systems that provide offsite notification helpful for large inventories
- Manual twice daily temperature checks and entry of temperatures into NYSIIS is still required regardless of the type of system in use
- Additional info on requirements
 - Refer to [Temperature Monitoring Requirements](#) document
 - Contact VFC Program



The key messages for this training module are:

The NYS VFC program requires that providers have a calibrated, continuous temperature monitoring device in each unit that stores publicly-funded vaccine. The temperature monitoring device can be built into the unit as long as it meets data logging and calibration requirements.

Contact the NYS VFC program for more information on state-supplied devices.

VFC Providers are also required to have at least one back-up continuous temperature monitoring device with a different calibration date than your primary devices.

Alarm systems that provide offsite notification may be useful, particularly to practices with large vaccine inventories.

As a reminder, manual twice daily temperature checks and entry of temperatures into NYSIIS are still required even if you have a data logger or continuous temperature monitoring system with alarms or off-site notifications.

If you have questions about data loggers or temperature monitoring requirements refer to the guidance document in the link on this slide or call or email the VFC program.

Resources

NYS Vaccines for Children (VFC) Program

Temperature Monitoring Requirements

http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/temp_monitor_device_guidance.pdf

Data Loggers

https://www.health.ny.gov/prevention/immunization/vaccines_for_children/storage_and_handling.htm#dataloggers

Centers for Disease Control and Prevention (CDC)

Vaccine Storage and Handling Toolkit, page 15

<http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

American Academy of Pediatrics (AAP)

Data Loggers and Vaccine Monitoring

https://www.aap.org/en-us/Documents/immunization_dataloggers.pdf

National Institute of Standards and Technology (NIST)

Accurate Cold Chain Temperature Monitoring Using Digital Data Logger Thermometers

<http://www.nist.gov/pml/div685/grp01/upload/NIC-2012-Accurate-Cold-Chain-Temperature-Monitoring-Using-Digital-Data-Logger-Thermometers.pdf>



Here is a listing of available resources.

Additional Training for NYS VFC Providers

**Next: NYS VFC Program Training Series #9: Temperature
Monitoring Device Calibration**



There are a number of additional trainings available.

The next training in this series is #9 Temperature Monitoring Device Calibration.