



Department  
of Health

# Vaccines for Children (VFC) Program Training: Selecting Temperature Monitoring Equipment

Division of Vaccine Excellence  
Bureau of Vaccine Programs

SERIES 7



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Hello and welcome. This training is intended to provide guidance to New York State (NYS) Vaccines for Children (VFC) providers on selecting vaccine temperature monitoring equipment.

# TEMPERATURE MONITORING DEVICE REQUIREMENTS

**Must** use a calibrated, continuous temperature monitoring device called a digital data logger (DDL) to monitor publicly-funded vaccine. DDL requirements:

- Must continuously monitor temperatures (temperature reading taken **at least** every 30 minutes) for each unit that vaccine is stored (including use for each transport unit - emergency or non-emergency)
- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)\*
  - The probe should ideally be suspended centrally in the storage unit, away from ceilings, vents, fans, and coils. Never place the probe directly on a shelf, as this can lead to a false temperature reading.
- Must have the ability to create a log that can be downloaded and printed from the device for review
- Must have a digital display where current temperatures **and** daily minimum and maximum temperatures can be read and documented
- Must come with a valid [Certificate of Calibration](#) that confirms it measures accurately, within +/- 0.5°C (+/- 1°F)
- See [VFC Temperature Monitoring Device Guidance page](#) for further info and recommended DDL features.



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\*For accurate ultra-cold temperature monitoring, it is essential to use an air probe or a probe designed specifically for ultra-cold temperatures



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All providers receiving publicly-funded vaccine must use a calibrated continuous temperature monitoring device, also referred to as a digital data logger (or DDL).

It must have continuous temperature monitoring and be recording a temperature reading AT LEAST every 30 minutes. The device must have the capability to produce a printed report that indicates continuous logging.

The device must have a temperature display that is located on the device that 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 the daily minimum and maximum temperatures reached.

The device must come with a valid (International Laboratory Accreditation Corporation (ILAC), International Standards Organization (ISO), or International Electrotechnical Commission (IEC)) certificate of

calibration that confirms it measures temperatures accurately. The device must measure temperatures within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ ).

The DDL must have an audible high/low alarm for out-of-range temperatures and a low battery indicator to make you aware in advance if the device needs a battery change

The DDL must record continuously with memory storage of at least one month of data; data must be downloaded to keep logs of historical storage unit temperatures. This download should happen at least every two weeks to ensure temperature data is not lost when it loops and begins to overwrite old data. These temperature logs must be maintained for a minimum of 3 years, even if unenrolled from the program.

# BACK-UP TEMPERATURE MONITORING DEVICES

- Back-up data loggers will be used when calibration of primary devices is due, in case of an emergency, and if one of the primary device(s) malfunction.
- The back-up data loggers must meet all requirements outlined in the [Temperature Monitoring Requirements document](#).
- Providers enrolled in the Vaccines for Children Program are responsible for purchasing at least one back-up data logger per site.
- Must have one back-up DDL for refrigerator and one back-up DDL for freezer units OR may have one that may be configured for either storage unit type.
  - To purchase an additional Fridge-Tag back-up DDL programmable for either a refrigerator or freezer, please visit the Berlinger [website](#).
  - Store back-up outside of the storage unit until needed
  - Probe may be kept inside storage unit to have it readily conditioned
  - Calibration date must be different than that of primary monitoring devices



VFC Providers are also required to have a minimum of one back-up continuous temperature monitoring device on site for both refrigerator and freezer, or one that is programmable for refrigerator or freezer. Back up DDL's must meet 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 device has expired.

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 primary.

See the Temperature Monitoring Requirements document linked on this slide and on the resources document included with this training for more information on back-up data loggers.

# WHY DIGITAL DATA LOGGERS?



- Monitors vaccine temperatures continuously – even when practice is closed
- Helps identify temperature excursions quickly
- Displays frequency and duration of out-of-range temperatures
  - Eliminates the “unknowns” of temperature excursions
    - May prevent unnecessary vaccine waste
    - Early identification of any issues with storage unit(s), potentially before vaccine loss
    - Can potentially reduce the need for revaccination of patients and loss of patient confidence
- **Digital Data Logger Downloads DO NOT replace daily temperature checks**
  - Temperatures still must be manually checked by staff daily
  - Refer to Temperature Monitoring Procedure training for more information



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

Downloaded and saved logs can indicate how often and for how long temperatures may have been out of range. Vaccine Manufacturers use this data to determine whether the vaccine is still viable. In cases such as power outages where temperatures would have otherwise been unknown, vaccine can be saved from being discarded, or possibly reduce the likelihood of revaccination if action is taken quickly enough.

Data loggers are a wonderful tool to provide early identification of storage unit issues, such as fluctuating temperatures or a malfunctioning unit. Since data is being collected continuously, providers can review the data and note any excursions.

Keep in mind that the use of data loggers does not replace the daily manual temperature checks that NYS VFC providers are required to perform. Temperatures still need to be checked and recorded by office

staff who will be able to detect patterns or trends that may be indicative of a less obvious problem.

## FRIDGE-TAG®2L DATA LOGGERS

- Fridge-Tag®2L Data Logger may be available free of cost to VFC providers, if available
  - New enrollees should inquire with NYS VFC program if interested in obtaining Fridge-Tag®2L devices
  - Practices are not required to use the State-supplied Fridge-Tag®2L devices; however, DDLs chosen must [meet all requirements](#)
- Providers are responsible for purchasing additional DDLs for primary use for each additional unit in which VFC vaccine is stored - larger practices may have 2 or more refrigerators and/or freezers, and need a DDL for each storage unit
- Resource: [Vaccine Storage and Handling Requirements - Vaccines for Children \(VFC\) Program](#)



Most years, the VFC Program supplies all enrolled Providers with two Fridge-Tag2L data loggers, free of charge, on a limited basis. Providers who are newly enrolling should inquire with the VFC Program to determine if there is an available 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. Staff should be able to operate and read all data loggers in use.

Providers are responsible for purchasing data loggers if the state supply is not available. Some, large practices may require more than one refrigerator or freezer for VFC vaccine and will need to purchase additional DDL's for each of those units.

All VFC providers must purchase backup continuous temperature monitoring devices. Additional information on data loggers can be found on the VFC website linked on this slide under "Data Loggers" section. This is also linked on the resource document included with this training.

# AMERICAN ACADEMY OF PEDIATRICS (AAP) DDL GUIDANCE



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

The Centers for Disease Control and Prevention (CDC) has developed guidance for storage and handling of vaccines. To see the current guidance issued by the CDC, view the [Vaccine Storage and Handling Toolkit](#).

### Key Points:

- CDC recommends that practices maintain a calibrated, temperature monitoring device (data logger) and manually record temperatures in each unit containing Vaccines For Children (VFC) vaccines. This should be done twice daily.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required in your state.
- Consider a phone-enabled or internet-aware alarm to alert you by phone/internet anytime temperature excursions occur. Multiple people should be on the notification list to ensure the best chance that appropriate action is taken to correct the problem.

[AAP Immunization Resources Storage and Handling Series](#)

The NYS VFC Program cannot recommend specific products.



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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.

While the NYS VFC program currently contracts with Berlinger USA to provide FridgeTag 2L DDLs to eligible providers, it is not required that they be used. Additionally, while Berlinger is currently contracted, 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- 800-543-7468 or email [NYVFC@health.ny.gov](mailto:NYVFC@health.ny.gov) for more information

## TEMPERATURE MONITORING ALARMS AND ALERT SYSTEMS

- Device with local alarm that notifies staff within vicinity of storage units
  - For example, staff are notified of equipment failure or door ajar (leading to fluctuation in temperatures) via a visual and/or audible alarm
  - Audible alarm recommended versus device with visual-only alarm
- Advanced systems can provide off-site notification
  - System contacts the specified person(s) by phone, text or email when out of range temperatures are identified
  - Alerts appropriate staff during a temperature excursion event (especially beneficial during hours when practice may be closed)
  - Recommended for large volume facilities
- Include information on temperature monitoring system(s) in your Emergency Vaccine Management Plan
- Ensure offsite systems have up-to-date contact information and that staff are informed of their emergency responsibilities



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 medical director 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 so the situation can be corrected in time to prevent the loss of vaccine. This can be especially helpful during off- hours such as weekends or holidays)

Include information on any temperature monitoring systems in your Emergency Vaccine Management 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.

# KEY MESSAGES

- Temperature Monitoring Device Requirements: Calibrated, **continuous** temperature monitoring device in each unit that stores publicly-funded vaccine
- Contact NYS VFC Program for information on availability of State-supplied digital data loggers (DDLs) at 1-800-543-7468 or [nyvfc@health.ny.gov](mailto:nyvfc@health.ny.gov)
- Back-up continuous temperature monitoring device(s) should have different calibration date(s) than primary devices
- Alarm systems that provide offsite notification are especially beneficial during hours when practice may be closed, and helpful for practices with large inventories
- Manual daily temperature recordings is a requirement regardless of the type of system(s) used
- DDL temperature logs must be downloaded at least every two weeks (and any time an out-of-range temperature is identified) and saved for a minimum of 3 years



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.

Contact the NYS VFC program for more information for the potential of 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 daily temperature checks are still required even if you have a data logger or continuous temperature monitoring system

with alarms or off-site notifications.

DDL temperature logs must be downloaded at least every two weeks (and any time an out-of-range temperature is identified) and saved for a minimum of 3 years

**THANK YOU!**



[nyvfc@health.ny.gov](mailto:nyvfc@health.ny.gov)



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Thank you for your participation in this training on selecting temperature monitoring equipment. As always, any questions can be sent to [nyvfc@health.ny.gov](mailto:nyvfc@health.ny.gov).