

MODULE 5-C: Vaccine Storage and Handling Thermometers

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Temperature Monitoring Devices

Thermometers are a critical part of good vaccine storage and handling practices. A storage unit is only as effective as the temperature monitoring system inside. Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management. Every freezer and refrigerator unit used to store vaccine is required to have a certified calibrated temperature monitoring device. Investing in reliable temperature monitoring devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

The VFC vaccine coordinator and back-up coordinator are responsible for temperature monitoring equipment and certifications. If additional staff is responsible, those persons must be trained on temperature monitoring equipment and documentation.

Thermometer calibration information must be entered into Florida SHOTS for each storage unit before a VFC vaccine order can be placed.

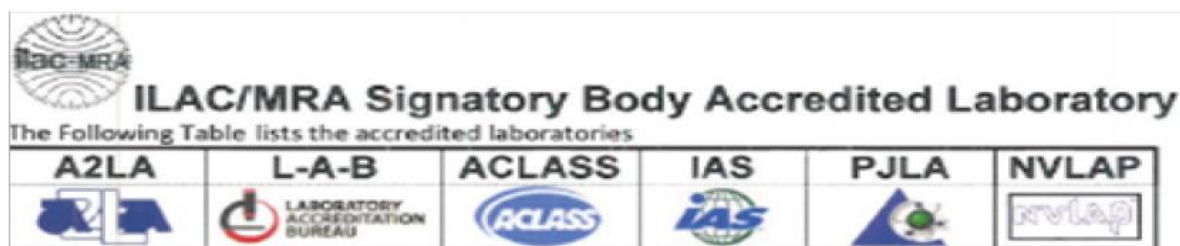
Types of Temperature Monitoring Devices

Calibrated Temperature Monitoring Devices

Providers are required to use calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (known as a Report of Calibration). Calibration testing and traceability that is performed by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) assures the user that testing performed meets the appropriate standard. Providers are responsible for maintaining up-to-date certificates of calibration.

ILAC/MRA accredited laboratories Certificate of Traceability must include:

- Clearly identifiable accreditation
- Name of device (optional)
- Model number
- Serial number
- Date of calibration (report or issue date)
- Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is $\pm 1^{\circ}\text{F}$ [$\pm 0.5^{\circ}\text{C}$])



Non-ILAC accredited laboratories and manufacturers must provide a Certificate of Traceability that includes the following elements:

- Name of device (optional)
- Model number
- Serial number
- Date of calibration (report or issue date)
- Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is $\pm 1^{\circ}\text{F}$ [$\pm 0.5^{\circ}\text{C}$])
- Measurement results of the device
- Statement that calibration testing conforms to ISO 17025.

Continuous Temperature Monitoring Devices

It is highly recommended that providers utilize a continuous temperature monitoring device for each storage unit. These devices can provide an indication of the length of time a unit has been operating outside the recommended vaccine storage temperature (excursion) and when an excursion occurred. Unlike a simple min/max thermometer, which provides only the information about warmest and coldest temperatures that were reached, the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals. They are capable of recording hundreds or even thousands of individual temperature readings.



Digital data loggers

Digital data loggers come with special software, which providers install on a computer. This software allows the user to set the frequency of the temperature readings, download data from the device, and calculate temperature averages, minimums, and maximums. In order to review the temperature history, the user must download data from the digital data logger on a regular basis. Some data loggers may have an audible alarm to alert the user to out-of-range temperature conditions. Other data loggers may have external lights that alert the user to out-of-range temperature

events; a green light indicates temperatures have remained in range and a red light indicates temperatures are out of range.

Data loggers should have the following specifications and functionality:

- Provides continuous monitoring information with an active display.
- Displays current temperature, as well as minimum and maximum temperatures (visible from the outside of the vaccine storage unit).
- Reset button for the maximum and minimum temperatures recorded in a period; Hi/Lo alarm for out-of-range temperatures.
- Low battery indicator.
- Memory storage for approximately 4,000 or more readings. (Data should be downloaded weekly and the logger cleared/reset to ensure adequate capacity).
- Device will not write over data—stops recording when memory is full.
- Detachable temperature probe (or a logger that allows the probe to remain in the unit undisturbed while the temperature is displayed and data is recorded via computer).
- User programmable logging interval (or sampling rate) 15 minutes or less (Florida SHOTS will only log readings every 15 minute).
- Accuracy of +/- 0.5 degree Celsius or +/- 1 degree Fahrenheit as certified by a current Certificate of Traceability and Calibration.

Please note: Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Data logger manufactures and distributors:

Vendor	Website
Control Solutions	www.vfcdataloggers.com
Berlinger USA, LLC	www.berlinger.ch/en/berlinger/main/ambient-tag/temperature-monitoring/fridge-tag2.html
Dickson	www.dicksondata.com/products/find/data-logger
Lascar Electronics	www.lascarelectronics.com/usb-data-logger.php?panelchooser=1&cat[]=63
Accsense	www.accsense.com

Temperature Monitoring Devices that are NOT Acceptable

Some devices can be difficult to read and most only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected. The following devices can

have significant limitations:

- Fluid-filled biosafe liquid temperature monitoring devices
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Household mercury temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that are not calibrated



Chart Recorder



Bi-metal stem thermometer



Fluid-filled biosafe liquid thermometer

Thermometer Placement

Prior to storing vaccines in a unit, it is important to determine where the most reliable and consistent temperature readings are and store your vaccines there. The probe is required to be centrally located with the vaccines in the refrigerator and the freezer.



Placement of Probe

Best practices for probe placement are as follows:

- Place the thermometer in the center of the compartment, away from the coils, walls, floor, and fan, in order to obtain a true reading of the temperature.

- In the refrigerator, place the thermometer on the middle shelf, adjacent to the vaccine, or hanging down from the upper shelf.
- In the freezer, suspend the thermometer from the ceiling of the compartment or place on a box or some other item, so that it is in the middle of the compartment, off of the floor.
- If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated.
- As of January 1, 2015, placing the thermometer in a central area of the storage unit with the vaccines is a requirement.

Thermometer Device Maintenance and Recertification

Certified-calibrated thermometers require periodic recertification and recalibration in order to remain accurate. Contact the manufacturer for instructions regarding recalibration procedures. When choosing a certified calibrated thermometer, consider the cost and frequency of required recalibration. Recalibration costs will vary by manufacturer, model, and type of thermometer. Keep documentation of recertification and recalibration for three years as part of the office records.

Calibration testing and traceability must be performed by:

- A laboratory accredited by an ILAC MRA signature body.
- An entity that provides documentation demonstrating the calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability.

Back-up Temperature Monitoring Device

As of January 1, 2015, VFC providers are required to have at least one back-up thermometer with a current certificate of calibration on-hand (not stored in unit along side current thermometer). This allows the back-up temperature monitoring device to be used in the event that something happens to the primary thermometer or if a thermometer needs to be sent out for recalibration.

The back-up temperature monitoring device should have:

- Current Certificate of Traceability and Calibration
- Detachable probe in a bottle filled with a thermal buffer such as glycol
- Different calibration testing schedule than the primary monitoring device

Temperature Alarms

Alarms are useful tools to alert staff to potential problems. However, any alarm is only as good as the people responding to it. Large vaccine losses and the need to revaccinate have occurred despite using alarmed, continuous monitoring systems. Issues around untrained staff who do not know how to read the monitor, unexpected events, poor monitoring and responses procedures, equipment failures, and improper maintenance have all been implicated in vaccine mishandling incidents.



Continuous monitoring temperature alarm/notification systems