Louisiana Vaccines for Children Program Digital Data Logger Thermometer Guide

July 1, 2022 – June 30, 2023

Louisiana Department of Health
Office of Public Health
Immunization Program

General Requirements

The Centers for Disease Control and Prevention (CDC) and the Louisiana Vaccines for Children (VFC) Program within the state Department of Health, Office of Public Health, Immunization Program require that healthcare providers who receive VFC vaccines use calibrated ***digital data-logger*** **(DDL)** thermometers with a current and valid certificate of calibration issued by an appropriate entity[1]. All certificates must contain the following:

- Model number
- Serial number
- Date of calibration testing
- Measurement results indicating that the unit passed testing

Documentation that uncertainty is within suitable limits (recommended uncertainty +/-1^{o}F or 0.5^{o}C) is recommended but not required.

CDC ***requires*** that DDL thermometers have the following features:

- Temperature probe
- Active temperature display that can be easily read from the outside of the vaccine-storage unit
- Capacity for continuous monitoring and recording capabilities where the data can be routinely downloaded

At the same time, CDC ***recommends*** the following additional features for DDL thermometers:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures display
- Low-battery indicator
- Accuracy of +/-1^{o}F (0.5^{o}C)
- Memory storage of at least 4,000 readings

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[1]As defined by CDC, an "appropriate entity" will issue a certificate of calibration containing at least one of the following five items about calibration testing:

- Conforms to International Organization for Standardization (ISO) 17025 standards
- Was performed by an International Laboratory Accreditation Cooperation/Mutual Recognition Agreement (ILAC/MRA)-accredited laboratory
- Is traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class ($\leq$ 0.5^{o}C) or better
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

- User-programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes
- Use of a probe that best reflects the temperature of the vaccine (such as a buffered probe)

CDC and the Louisiana VFC Program also recommend that thermometers be placed in a central area of the storage unit directly with the vaccines in order to properly measure vaccine temperature. Thermometers should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit.

Listings of ILAC/MRA-accredited calibration laboratories may be obtained through the following participating organizations:

AIHA Laboratory Accreditation Programs, LLC (AIHA-LAP, LLC)
http://www.aihaaccreditedlabs.org

American Association for Laboratory Accreditation (A2LA)
http://www.a2la.org

ANSI National Accreditation Board (ANAB)
https://anab.ansi.org

International Accreditation Service (IAS)
http://www.iasonline.org

National Voluntary Laboratory Accreditation Program (NVLAP)
http://www.nist.gov/nvlap

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
http://www.pjlabs.com

Sample of ILAC MRA-Accredited Laboratories Near Louisiana

ASI Calibration Labs
http://www.asicallab.com
A2LA Certificate No. 1876.01
1644 Varner Dr.
Mobile, AL 36693
Telephone: (251) 660-9999

Traceable Products
http://www.traceable.com
A2LA Certificate No. 1750.01
12554 Galveston Rd., Ste. B230
Webster, TX 77598
Telephone: (281) 482-1714

Global Instrumentation Services, LLC
http://www.globalinstserv.com
ACLASS/FQS Certificate No. L2268
519 N. Sam Houston Pkwy. E., Ste. 125
Houston, TX 77060
Telephone: (888) 277-7450

Continuous Monitoring

In following the CDC's guidance, the Louisiana VFC Program requires the use of a *continuous monitoring* DDL for units that store VFC vaccine. This is a DDL with the ability to record/graph temperatures over time. It should be noted, however, that a high/low recording thermometer is not the same as a continuous-monitoring thermometer. High/low devices offer only basic information about the maximum and minimum temperature a thermometer has reached, while continuous-monitoring devices are capable of digitally storing *all* past temperatures for future reference.

Internal vs. external temperature probes

Both the CDC and the Louisiana VFC Program *strongly recommend* the use of DDLs with an *external probe in glycol*. Research conducted by the National Institute of Standards and Technology (NIST) concluded that:

> **"Data loggers featuring an external probe kept in a glycol-filled bottle provide effective, continuous temperature monitoring of stored vaccines. This setup mimics the conditions and properties of stored vaccines. Provided that a structured validation protocol is followed, digital data loggers of this type can be used to stably monitor vaccine temperature for many months or years. By contrast, loggers featuring sensors designed to record air temperature proved unacceptable for use as vaccine temperature monitors."**[2]

High/Low Alarm

A DDL should have a high and low alarm that alerts the provider any time a refrigerator or freezer temperature goes outside the recommended range.

Min/Max Display

A large, easy-to-read display is very useful when monitoring vaccine temperature, including the twice-a-day readings expected of providers. Digital data loggers that use confusing symbols/icons as well as small, hard-to-read displays should be avoided. A DDL should also have the ability to display (and reset) minimum/maximum temperatures between readings.

Accuracy

Thermometers should have a high accuracy of **+/- 1ºF (+/- 0.5ºC)**. This information should be contained in the device's certificate of calibration.

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[2]Chojnacky, M.; Miller, W.; and Strouse, G. *Data Logger Thermometers for Vaccine Temperature Monitoring*, http://nvlpubs.nist.gov/nistpubs/ir/2012/NIST.IR.7899.pdf.

Low-Battery Indicator

Notification of low-battery status is essential for accurate vaccine-temperature recording. Such notification gives a provider advanced warning and ensures that vaccine monitoring is not interrupted or incomplete.

Software

Temperature data from a DDL can be downloaded to a computer using special software or retrieved from a website. The software or website may also allow a provider to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine safety, so it is important for a provider to decide whether independent software or a website program will work best.

Wireless and Cloud-Based Systems

Wi-Fi and Ethernet-based systems are relative newcomers to the field of continuous temperature monitoring but are gaining popularity. While more costly than stand-alone units, the increase in convenience and accessibility makes them a smart purchase. Some of the newer systems send temperature data directly to a cloud storage site which can be accessed in real time from any computer in the world. Real-time feedback is especially useful when addressing time-sensitive vaccine excursions. Providers will likely need a competent IT staff person (or an employee with strong technical skills) to help implement such a system.

Back-Up Continuous Monitoring Data Loggers

CDC and the Louisiana VFC Program ***require*** having at least one calibrated back-up DDL thermometer (i.e., a DDL thermometer not being used to monitor any other vaccine storage unit) with a current, valid certificate of calibration in case the primary, in-use DDL breaks, malfunctions, or needs to be sent to the laboratory for calibration.

A back-up DDL thermometer should have the same features as the primary device (for example, a detachable probe in a buffered material such as glycol). In addition, the CDC and the Louisiana VFC Program *recommend* that the back-up DDL have a different calibration schedule from that of the primary device so that the back-up is available when the primary DDL is sent for calibration.

Equipment Options

Based on the above guidelines, the following is a brief list of equipment options that meet or exceed CDC and Louisiana VFC Program requirements and/or recommendations. This list is by no means exhaustive and merely provides examples of continuous-monitoring DDLs to consider when purchasing.

Disclaimer

*As a state-government entity, the Louisiana VFC Program does **not** endorse any specific brand or product. The terms and conditions of a purchase are ultimately between a provider and its vendor.*

Manufacturers and Vendors

Providers have many options when it comes to purchasing DDLs. The following are examples of manufacturers and vendors:

Control Solutions, Inc.: http://www.vfcdataloggers.com
MicroDAQ, LLC: http://www.microdaq.com
CAS DataLoggers: http://www.dataloggerinc.com
ThermoWorks: http://www.thermoworks.com
Thermco Products: http://www.thermcoproducts.com
Traceable Products: http://www.traceable.com
Dickson: http://www.dicksondata.com
LogTag North America, Inc.: http://www.logtagrecorders.com/us/
InTemp® by Onset: http://www.onsetcomp.com/intemp/
Lascar: http://www.lascarelectronics.com
DeltaTrak: http://www.deltatrak.com

Sample Digital Data Loggers

InTemp® VFC Bluetooth Low Energy Temperature (with Glycol) Data Logger (CX402-VFCxxx)

This DDL communicates wirelessly via Bluetooth Low Energy to mobile devices. Using the InTemp app, users can easily view data, check logger status, set alarms, and create and share secure PDF reports for streamlined reporting and regulatory compliance. All loggers feature a built-in LCD display to view current and daily minimum and maximum temperatures, advanced audible and visual alarm capabilities for notification of temperature excursions, an internal sensor for ambient temperature monitoring, and a 3-year NIST Certification of Calibration (probe only, not ambient temperature sensor).

FEATURES:

- Easy-to-read display with current and daily min/max temperatures
- Real-time alerts and automatic data downloads with optional CX Gateway device
- Bluetooth transmission of data and alarm states
- Logger setup and download of data in seconds – without a PC or cable
- ±0.5°C accuracy for reliable temperature readings
- Battery-powered to guard against local power loss
- Several Glycol bottle sizes with probe and cable length options
- Includes 3-year ISO 17025 compliant calibration, per CDC guidelines

For more information, visit: http://www.onsetcomp.com/intemp/

Control Solutions VFC 400 Vaccine Monitoring Data Logger

With a calibrated accuracy of ±0.3ºC over a measurement range of -40ºC to 40ºC, this DDL measures and stores up to 15,905 temperature readings from a remote temperature probe. The display is designed to show "at a glance" if temperature violations have occurred during the current day and up to the previous 29 days. The display also shows the current temperature reading, the current time, recording status, and battery status. The alarm is triggered if temperature readings are outside pre-set alarm limits.

FEATURES:

- NIST Traceable Certificate of Calibration compliant to ISO/IEC 17025:2017
- Audible and visual alarm for out-of-range temperatures
- Displays low-battery indicator, current temperature, minimum and maximum temperature, alarm, duration of alarm, time, recording, stopped, and summary of days collected
- User-programmable logging rate from every 30 seconds to hourly
- High-quality gold-plated remote sensor connector

For more information, visit: http://www.vfcdataloggers.com

Excursion-Trac™ Traceable® Refrigerator/Freezer Datalogger Thermometers (single-probe model (Manufacturer Item No. 6430) shown)

Excursion-Trac™ Traceable® refrigerator/freezer DDL thermometers meet the CDC requirements for vaccine storage and monitoring, maintain 525,600 temperature observations, and allow recorded data (CSV file) to be transferred from thermometer to PC or Mac using a USB flash drive (not included).

FEATURES:

- Hi/Lo alarms and Time/Date stamps
- Smart-Alarm™ signals out-of-range conditions
- Monitors readings overnight, on weekends, or for any time period with rolling data log
- Temperature range of –58 to 158°F (–50 to 70°C)
- Bottle probes sealed in a miniature bottle filled with nontoxic glycol
- Traceable® Certificate which assures accuracy from the manufacturer's ISO/IEC 17025:2017 (1750.01) calibration laboratory accredited by A2LA

For more information, visit: http://www.traceable.com

Additional Equipment

The following are additional equipment a provider may consider when assessing its vaccine-storage needs.

Alarm Telephone Dialers

These devices, though a relatively old technology, may be useful to providers with limited internet connectivity or recurrent power outages. They are sold by several manufacturers in varied models, styles, and prices to choose from.

Alarm telephone dialers are designed to call pre-determined telephone numbers when temperatures go out of range and are a simple and reliable alarm option, provided the system is accurate. Maintaining a temperature reading that mirrors a current calibrated continuous-monitoring DDL is imperative to the usefulness of a dialer.

Providers have many options when it comes to purchasing dialers. The following are examples of manufacturers:

Sensaphone: http://www.sensaphone.com
Dickson: http://www.dicksondata.com
United Security Products: http://www.unitedsecurity.com
Security Product Solutions: http://www.securityproductsolutions.com

Emergency Power Generators

Disruption in the power supply is one of the most frequent causes of costly vaccine loss, since it does not take long for a refrigerator or freezer to warm up due to a power outage and thus compromise vaccine integrity. Healthcare providers (especially those in rural or coastal areas, or those storing large vaccine inventories) should seriously consider having an emergency power generator in place should an emergency occur. If a provider already has such a unit in place, it must make sure a vaccine refrigerator and freezer are connected to that power circuit.

According to the CDC, emergency power generators should be tested quarterly and receive maintenance at least annually (check manufacturer specifications for test procedures and maintenance schedules). In addition, sufficient fuel should be kept on hand to continuously run the generator for at least 72 hours.[3]

There are many manufacturers and vendors selling generators. Below are a few examples:

Generac: http://www.generac.com
Cummins: https://www.cummins.com/generators-power-systems
Kohler: http://www.kohlerpower.com/en/residential/generators
Briggs & Stratton: http://www.briggsandstratton.com/na/en_us/buying-guides.html

Louisiana VFC Program Contact Information

For more information on data-logger thermometers or any other matter concerning VFC requirements or recommendations, please contact the Louisiana VFC Program at (504) 568-2600.

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[3]Centers for Disease Control and Prevention. *Vaccine Storage & Handling Toolkit*, http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.