FAQ*: Storage and Handling Continuous Temperature Monitoring Devices – Digital Data Logger (DDL)*

Q: What is required for the new continuous temperature monitoring devices called digital data loggers?

A: As of January 1, 2018 CDC requires that each VFC provider use continuous temperature monitoring devices called digital data loggers (DDL) to monitor publicly funded vaccines during routine onsite vaccine storage, vaccine transport and mass vaccination clinics.

You can find more details regarding these devices in the latest version of the CDC Storage and Handling Toolkit.

Q. Are VFC providers required to review and record temperatures twice daily?

A: No, As of January 1, 2018, the temperature monitoring requirement has been updated for monitoring publicly funded vaccines.

1. VFC providers must record the MINIMUM and MAXIMUM temperatures at the start of each clinic day.
2. Review the current temperature prior to accessing and administering vaccines.
3. Record the time and date of each Min/Max reading
4. Record the name(or initials) of person who assessed the temperature reading
5. Download data (reports) from the DDL device and review weekly; preferably every Monday morning.
   a. If the provider office is closed or Monday is a holiday then the data is to be downloaded on the next business day.
   b. Data logger files do not need to be printed. The files need to be saved electronically in a location that can be accessed at any time by the provider.
6. The temperature logs are to be kept on file for at least three (3) years. Providers can print blank temperature logs from SCIAPPS

Q: How much do they cost?

A: DDLs are relatively inexpensive.   DDLs cost approximately from $85.00 to $150.00 each.

Q: Will I need any other equipment to use with the Digital Data Logger?

A: It depends on the type of DDL's that the provider purchases.   All vendors offer a cloud service to save data as a backup system.   Some DDL's require a docketing station to transfer information from the logger to the computer and/or cloud. Others may allow the provider to insert the USB directly from the logger into the computer.   Other DDL's may operate and send data directly to a cloud service in real time. Check with the manufacturer of the DDL prior to purchasing.

Q: Will I need a backup DDL device?

A: Yes, CDC requires a backup DDL per VFC site as of January 1, 2018. The backup DDL must meet the same CDC requirements for the primary DDL's at the site.

VFC provider must have at least <u>one</u> backup DDL with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed.

Q: Where can I get purchase a digital data logger?

A: Providers can start with the manufacturer of the previous calibrated thermometer in the provider vaccine storage unit(s) before January 1, 2018.   Give the manufacturer a call and inquire about DDLs.

Remember the device **MUST** meet the CDC required characteristics:

- Temperature probe
- Active temperature display that can be easily read from the outside of the unit
- Ability to continuously monitor temperatures and record when data is routine downloaded

The following are additional recommended features for these DDL's:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature indicator
- Low-battery indicator
- Accuracy of +/-0.5° C (+/-1° F)
- Memory storage of at least 4,000 readings
- Logging interval (or reading rate) recommended at a maximum time of every 30 minutes
- Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, Teflon®)

Q: Do I need training from the manufacturer that I purchase the Digital Data Logger?

A: Providers are strongly encouraged to receive training from the manufacturer where they purchased the DDL. The manufacturer should be able to train the provider's staff specifically Primary and Back Up vaccine coordinator on the following elements: DDL installation, DDL functionality, and retrieval of DDL temperature monitoring reports.

Q: Will VFC providers be able to re-enroll in during the 2018-2019 VFC Annual Enrollment/Re-enrollment without these devices being in place inside of the vaccine storage units?

A: Unfortunately, No. VFC providers must meet this this NEW VFC requirement. This is the reason for the early communication regarding this January 1, 2018 deadline.

VFC providers will be able to re-enroll once they can provide documentation that the devices are installed and measuring "in range" temperatures.

Q: How do I report an out of range temperature with the DDL?

A: Take these steps when reporting out of range temperatures:

- Quarantine the vaccine- Mark Do Not Use
  - If the temperatures in the primary unit are out of range, prepare to enact Emergency Transport Procedures—See Vaccine Management Disaster Recovery Plan DHEC 1225
- Download the temperature data from the data logger
  - Return the data logger to the vaccine unit
- Document any actions taken if an out of range exist on the temperature logs "Vaccine Storage Troubleshooting Record"
- Report to the Immunization Division IMMEDIATELY at 803-898-0460
  - Do not leave voicemails when reporting Storage and Handling Events.
  - If incident falls on weekend or holiday, please contact the Immunization Division on the next business day to report the temperature excursion. Immunization Division business hours are Monday through Friday 8:30am to 5:00pm.

Q: What are the configuration settings for the DDL's in South Carolina?

A: All DDL's must be set to the following parameters:

- Set the DDL to record temperatures in Celsius
- Logging intervals must be set to record temperatures every 15 minutes.
- Set the Hi/Low alarm limits for vaccine refrigerators and freezers:
  - Refrigerated vaccines
    - Hi alarm must be set at 8.1°C
    - Low alarm must be set at 1.9°C
  - Frozen vaccines
    - Hi alarm must be set at -14.9°C
    - Low alarm must be set at -50.1°C
- Set Hi/Low alarm to trigger after two consecutive readings above or below the Hi/Low alarm setting this is a total time of 30 minutes
- For instructional guidance refer to the brand specific DDL software installation and DDL vaccine storage unit configuration guide.

State Purchased Data Loggers: VFC 400

Q: Where can I locate training documents for the VFC 400?

A: Training materials are located on SCIAPPS – Scroll down page to the VFC 400 Vaccine Monitoring Digital Data Logger
https://www.scdhec.gov/Apps/Health/SCIAPPS/Public/VFCInfo

Q: I have downloaded data from the VFC 400 but it is not going to the VTMC (cloud)?

A: Please check the following:

- Ensure the DDL connections are connected to the docketing station
- Ensure the docking station is connected to the Computer
- FTP Server files are checked to automatically and on request
  - Refer to the PowerPoint "User Profile Configuration Set Up"

If the first two bullets have been verified then the provider's IT tech support will have to contact the vendor Control Solutions directly at 888-311-0636 to obtain information regarding granting access through to the provider's Firewall security.

If providers have any other questions please contact the VFC program staff 800-277-4687 or scvfc@dhec.sc.gov