

# MDHHS Digital Data Logger Tip Sheet

This handout provides guidance on the use of a Digital Data Logger (DDL) as a continuous temperature monitoring device. Proper use of storage equipment is important to ensure vaccines are safe and effective. The Michigan Department of Health and Human Services (MDHHS) follows recommendations set forth by the Centers for Disease Control and Prevention (CDC) on DDLs.

For all VFC provider requirements, please review the Michigan Vaccines For Children (VFC) Provider Manual at [www.michigan.gov/vfc](http://www.michigan.gov/vfc).

Always check temperatures from a VFC-approved DDL .

**NOTE:** Routine monitoring will identify out-of-range temperatures quickly and allow you to take immediate action, preventing loss of vaccines and potential revaccination of patients.

## Features Your Digital Data Logger Should Have

CDC and MDHHS recommend DDLs with:

- Detachable probe in a buffered material (e.g., glycol, glass beads, sand, or Teflon)
- Continuous temperature monitoring and recording capabilities where the data can be routinely downloaded and analyzed for review
- Temperatures should be easily readable from the outside of the unit
- Alarm for out-of-range temperatures
- Display current temperature, plus minimum & maximum (min/max) temperatures on an active display screen
- Be within +/- 1°F (+/- 0.5°C) accuracy
- Low battery indicator
- Logging interval (or reading rate) that can be programmed by the user to record at least every 30 minutes
  - If no interval setting of 30 minutes, use an interval less than 30 minutes (every 5 minutes is highly recommended)

## Your Digital Data Logger

- Maintain the National Institute of Standards and Technology (NIST) traceable Certificate of Calibration and all manufacturer guidance documents
  - Calibration testing should be done every two to three years or according to the manufacturer's suggested timeline. Current and valid Certificate of Calibration Testing should include:
    - Model/device name or number
    - Serial number
    - Date of calibration (report or issue date)
    - Confirmation that the instrument passed testing (or instrument in tolerance)
    - Recommended uncertainty of +/-0.5°C (+/-1°F) or less
- Each facility should have a recommended DDL for:
  - Each vaccine storage unit
  - Each emergency transport unit
- VFC providers must have an extra **backup digital data logger** readily available (with a different calibration testing schedule) in case a primary device malfunctions or is out for calibration testing
- Ensure a supply of extra batteries is on-hand
- Follow manufacturer guidance for setting up your DDL

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Resources: CDC Storage and Handling Toolkit at: [www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html)

MDHHS guidance for storage and handling can be found at: [michigan.gov/vaccinequicklooks](http://michigan.gov/vaccinequicklooks) and [www.michigan.gov/vfc](http://www.michigan.gov/vfc).

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- You may need to use the USB port on your computer to setup your DDL
- Name the logger based on the unit in which it is placed (e.g., Unit #1 Freezer, backup)
- During the setup process you will set the temperature scale, frequency of recording the temperature, data logger display, and select alarms; follow manufacturer guidance during your setup process
- Some Pharmaceutical Purpose-Built Units may have a temperature device like digital data loggers (DDLs). Before utilizing for primary temperature monitoring/documentation, this must be approved by the Local Health Department (LHD). If not approved, a separate DDL must be utilized
- For an Ultra-Cold freezer, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures

## Placing Your Digital Data Logger in the Storage Unit

- The DDL monitor is placed on the outside of the refrigerator or freezer; the probe is placed in the storage unit, centrally located with the vaccines
- Pharmaceutical storage units may have a built-in port which may dictate probe and cable placement
- If storage unit does not have a built-in port or qualifying built-in port for temperature monitoring:
  - The cable should enter refrigerator/freezer on the hinge side, high in the corner
  - Monitor the cable to ensure frost does not build up

## Checking the Temperature on Your Digital Data Logger

At minimum, assess and record both the current temperature and the minimum/maximum (min/max) temperature in the AM when the clinic opens. Then assess and record the current temperature again 30-60 minutes before leaving for the day. Providers must act on all out-of-range temperatures. If a reading is missed, leave a blank entry in the log. Such entries should be distinguished from entries in which the DDL failed to display a reading.

### AM Check:

- **Check and record** current temperature (with decimal point, including the tenth's place (i.e., 40.1F), do not round up or down), initials, and **exact** time; assess if temps are in range
- **Check and record** min/max reading, assess if all temps are in range; if min/max is out-of-range, an excursion occurred at some point since the last check—you must act immediately; follow your Emergency Response Plan; do not use the vaccine until viability is determined by the manufacturer

### PM Check:

- **Check and record** current temperature (with decimal point, including the tenth's place (i.e., 40.1F), do not round up or down), initials, and **exact** time; assess if temps are in range; if out of range act immediately; follow your Emergency Response Plan

**How to check min/max:** Check min/max every AM; this allows you to notice out-of-range temperatures that may have occurred after-hours or on weekends; min/max documentation is required for all VFC providers.

- **VFC-5000 (black USB data logger):** Press button near display screen to show reading with ▲ next to it—this is your max. Press button again to see reading with ▼ next to it—this is your min. **Hold down the button** until you see “CLR”. This clears min/max so that you begin tracking a new min/max for tomorrow's check. Clearing min/max does not erase data—it will remain on downloaded data
- **VFC-400 (red & white data logger):** Press “Review/mark” and reading will say “max” next to it in upper right corner to indicate your “max” temp. Press “Review/mark” button again and reading will say “min” next to it in

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upper right corner to indicate your “min” temp. This min/max resets automatically after midnight—therefore it doesn’t need to be “cleared” daily but needs to be documented daily. For days prior to the midnight clearing, toggle back by pressing “Review/mark” (T -1, T-2) to ensure no excursion occurred. These devices display an “X” when a temperature is outside of the configured limits. They also have audible alarm capabilities

- **Electronic or wireless monitoring programs (TempTrak, Isensix):** Log into system and record temps. If electronic logging of temperatures does not include all required elements, they should be documented on a handwritten temperature log. These systems typically are equipped with alarm notification systems

**Out-of-range temperatures:** ANY out-of-range temperature is considered an excursion and requires immediate action. For guidance, see “MDHHS Guidance for Responding to Temperature Excursions.” Do not use vaccine exposed to out-of-range temperatures until you have received guidance from vaccine manufacturers and/or the LHD advises you to do so.

## Downloading Your Digital Data Logger

- Downloaded data should be reviewed and saved **weekly to your computer**; immediate download and review must also occur anytime an out-of-range temperature is identified
- Download according to software associated with your device manufacturer (Control Solutions, LogTag, etc.)
- When downloading data, remove the data logger from outside the storage unit to download on computer
  - Probe should stay inside storage unit
  - Save and name the logged data (e.g., Freezer 2 January 2, 2019)
  - Review the data for out-of-range temperatures
- Ensure alarms are set correctly to notify you of any out-of-range temperatures
- Ensure intervals show that the DDL is recording at least every 30 min (best practice is every 5 min)
- All temperature data should be stored for at least 3 years, **including** temperature logs and .txt files

## Key Points to Remember

- VFC providers must send temperature logs to the health department monthly, whether an order is placed or not
- VFC providers must follow the guidelines within the Michigan VFC Provider Manual at: [www.michigan.gov/vfc](http://www.michigan.gov/vfc)
- DDLs and all thermometers must be calibrated with a Certificate of Traceability and Calibration Testing that is not expired
- Follow manufacturer recommendations for required calibration
- Consider an alarm/notification system; these systems alert staff to temperature changes, however, cannot be used to monitor daily temperatures (Most DDLs do not phone staff to alert them of out-of-range temperatures)
- In case of temperature excursion, download the DDL to review temperatures reached and duration of excursion; this is necessary when calling vaccine manufacturers for viability concerns
- Always refer to the manufacturer’s product information for the most up-to-date storage equipment guidance
- Know the resources; review MDHHS guidance & CDC’s Storage and Handling Toolkit for current information; utilize CDC trainings “[You Call the Shots](#)” and “[Keys to Handling Your Vaccine Supply](#)” or MDHHS Immunization Nurse Education (INE) “Vaccine Management Module”

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