



Pennsylvania Vaccines for Children (VFC) DIGITAL DATA LOGGER (DDL) POLICY

PA VFC program recommends the use of continuous temperature monitoring devices/DDLs, which must adhere to the following policy:

Continuous Monitoring Devices:

CDC recommends using a continuous temperature monitoring device for each storage unit. These devices can provide an indication of 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 information about warmest and coldest temperatures that were reached, the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals.

Temperature Monitoring:

1. Record time of recording and initials of person taking temperature.
2. Record current, minimum, and maximum temperature on paper temperature log with your VFC PIN number on the form. Blank forms are available in Section 6 Provider Handbook.
3. Record temperatures twice daily (a.m. and p.m.).
4. Take immediate action for out-of-range (OOR) temperatures and document on temperature logs.

Data Logger Settings:

1. If not already preset, alarm limits for min/max temperatures should be:
 - **Refrigerator** min 36.0° F/max 46.0° F (min 2.0° C/max 8.0° C)
 - **Freezer** min -58.0° F/max 5.0° F (min -50.0° C /max -15.0° C)
2. Set recording duration intervals (every 15 minutes is recommended, but intervals of up to every 30 minutes are accepted)

Data Storage and Download Requirements:

1. Weekly/monthly (recommended weekly) downloads from the data logger to a computer file are required to be completed. This downloaded data should be kept for at least three years and be accessible by staff members.
2. Keep temperature logs for at least three years
 - The PA VFC Program may randomly request this information for Quality Assurance (QA) requirements

Digital Data Logger Minimum Requirements:

1. Capable of displaying current, minimum and maximum temperatures in Fahrenheit or Celsius
2. Must have an active digital display that can be easily read from outside of the unit
3. Must have an alarm for OOR temperatures (recommend both visual and audible)
4. Low battery indicator
5. Accuracy of +/- 1.0° F (+/- 0.5° C)
6. Memory storage of a least 4,000 readings
7. Does not record over old data when log is full
8. User programmable logging interval or reading rate (every 15 minutes is recommended, but up to every 30 minutes is acceptable)
9. Must have user-programmable alarm thresholds
10. Must be able to download data on to either a computer or website
11. Must have current NIST certificate and calibrated per manufacturer's recommendations or at least every two years by an accredited laboratory and include:
 - Name of device (optional)
 - Model number
 - Serial number
 - Date of calibration (report or issue date)
 - Measurement results indicate passing with uncertainty = +/- 1.0° F (0.5° C)
 - Statement that calibration testing conforms to ISO 17025
12. Detachable probe to be encased in a biosafe buffered material
 - Biosafe glycol buffer highly recommended by VFC; also acceptable buffered materials (only if NIST certified):
 - A vial filled with liquid (i.e., glycol, ethanol or glycerin)
 - A vial filled with loose media (i.e., sand or glass beads)
 - A solid block of material (i.e., Teflon® or aluminum)

Cold Chain Failure Protocol/Out-of-Range Recordings:

1. Follow the VFC Cold Chain Failure Policy in Section 4 Provider Handbook.
2. Address the problem.
 - Document reason/action taken on temperature log.
3. Call the manufacturers if greater than 30 minutes OOR; complete incident report.
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4. Call the Division of Immunizations directly.
 - Report the incident for further instructions.
 - Phone 1-888-646-6864 and ask for the VFC QA nurse.

Maintaining Temperatures and the Cold Chain:

1. Maintain proper temperature for vaccine storage.
 - Refrigerator: 36.0° to 46.0° Fahrenheit/ 2.0° to 8.0° Celsius
 - Average 40.0° Fahrenheit (5.0° Celsius)
 - Freezer: - 58.0° to 5.0° Fahrenheit/-50.0° to -15.0° Celsius
 - Average 0° Fahrenheit (-18.0° Celsius)
2. Ensure working thermometers are used inside both refrigerators and freezers. NIST certified thermometers, calibrated per manufacturer's recommendations, are required for vaccine storage. Thermometer probes must be placed/secured in the center of each compartment.
3. Manually check and document temperatures twice a day on the temperature log regardless of whether a continuous reading or alarmed units are in use. Daily documentation should include the time when temperatures were checked and initials of staff checking the temperatures.
4. If vaccine temperatures are out of recommended ranges for less than 30 minutes during temperature logging, take immediate action to correct the problem and document the action taken on the temperature log or attach an explanation of action taken.
5. If vaccine temperatures are out of recommended ranges for more than 30 minutes the vaccine manufacturers must be called. Complete and submit the Vaccine Incident Report and Worksheet within five days of incident. Instruction and forms are available in Section 6F Provider Handbook.
6. Providers are responsible for the maintenance and NIST recalibration of all temperature monitoring devices/thermometers. Newly purchased units and recalibrations are at the expense of the provider site.