

PA Vaccines for Children (VFC) 2015 DIGITAL DATA LOGGER (DDL) POLICY

PA VFC program recommends the use of continuous temperature monitoring devices/DDL's, 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 (am and pm)
4. Take immediate action for Out of Range (OOR) temperatures

Data Logger Settings:

1. If not already preset, alarm limits for Min/Max temperatures should be:
 - Refrigerator Min 35°F/Max 46°F (Min 2°C/Max 8°C)
 - Freezer Min -58°F /Max 5°F (Min -50°C /Max -15°C)
2. Set recording duration intervals for every 30 minutes

Data Storage and Download Requirements:

1. Weekly downloads from the data logger are required to be completed. This downloaded data should be kept for at least 3 years
2. Keep temperature logs for at least 3 years
 - The PA VFC Program may randomly request this information for Quality Assurance (QA) requirements

Recommended Digital Data Logger Minimum Requirements:

1. Capable of displaying current, minimum, and maximum temperatures in Fahrenheit or Celsius
2. Must have user-programmable alarm thresholds
3. Must have an alarm for Out of Range (OOR) temperatures
4. Low battery indicator
5. Accuracy of +/- 1°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) of at least 30 minutes
9. Must be able to download data on to either a computer or website
10. Probe must be encased in a biosafe glycol thermal buffer
11. Must be NIST certified and calibrated per manufacturer's recommendations or at least every two years

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 and complete incident report
4. Call the Division of Immunizations directly
 - Report the incident for further instructions
 - Phone 1-888-646-6864 ask for the VFC QA nurse

Maintaining Temperatures and the Cold Chain:

1. Maintain proper temperature for vaccine storage
 - Refrigerator: 35° to 46° Fahrenheit / 2° to 8° Celsius
 - Average 40° Fahrenheit (5° Celsius)
 - Freezer: - 58° to 5° Fahrenheit /-50° to -15° Celsius
 - Average 0° Fahrenheit (-18° 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. Thermometers should be placed 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 5 days of incident. Instruction and Forms are available in Section 6F Provider Handbook