



New York State Vaccines for Children (NYS VFC) Program

Temperature Monitoring Requirements

As of January 1, 2018, NYS VFC providers are **required to:**

1. **Use a calibrated, continuous temperature monitoring device (or digital data logger)** with a current Certificate of Traceability and Calibration Testing¹ (also known as Report of Calibration) to monitor temperatures in each refrigerator or freezer used to store publicly-funded vaccine.
2. Have at least **one back-up continuous temperature monitoring device** with a current certificate of calibration in case of equipment failure or for use when calibration testing of the current equipment is required.
 - a. The back-up temperature monitoring device should be stored outside of the storage unit until needed, and the calibration expiration date for the back-up device should be different than the one in use.
3. **Manually check and document the temperatures of all refrigerator and freezer units where publicly-funded vaccine is stored twice daily; when the office opens and when it closes for the day and enter those temperatures into the New York State Immunization Information System (NYSIIS) Temperature Log.** This requirement applies regardless of the type of temperature monitoring device being used because of the possibility of equipment failure.
 - a. Beginning in January 2018, NYS VFC Providers will **also be required to check the minimum and maximum (min/max) temperatures at least once per day**, preferably when the office first opens. The daily min/max reading must be recorded in the NYSIIS Temperature Log.
4. **Call the NYS VFC Program (1-800-543-7468) whenever a temperature excursion² has occurred.**

Required Device Functionality

- Continuous temperature monitoring capability = temperature reading recorded at preset intervals (at least every 30 minutes) and must have the capability to produce a data output (to be given to the NYS VFC program and/or vaccine manufacturer in the event of a temperature excursion)
- Accuracy or documented uncertainty of $\pm 1^\circ$ Fahrenheit ($\pm 0.5^\circ$ Celsius)
- Digital display on outside of storage unit to allow reading temperatures without opening storage unit door
- Display must indicate current as well as minimum and maximum temperatures

Recommended Device Features

- Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperature
 - The thermal buffer should be placed centrally inside the storage unit away from ceilings, walls, vents, fans and coils.
- Audible high/low alarm for out-of-range temperatures
- Low battery indicator
- Records continuously with memory storage of at least one month of data (no less than 4,000 readings)
- Data recording loops when memory is full (overwrites old data instead of stopping recording)

Questions? Contact the NYS VFC Program at 1-800-543-7468 or dataloggers@health.ny.gov

¹ Calibration of temperature monitoring devices should be performed by a laboratory that is accredited by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body or by a non-accredited laboratory that demonstrates meeting International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 international standards for calibration testing and traceability. The California VFC Program has created a checklist of accredited and non-ILAC accredited certificate requirements, visit <http://eziz.org/assets/docs/IMM-1119.pdf>. If calibration testing indicates the temperature monitoring device is no longer accurate within $\pm 1^\circ\text{F}$ ($\pm 0.5^\circ\text{C}$), the device needs to be replaced.

²An event in which vaccine is exposed to temperatures outside of the acceptable range.