

# New York State Vaccines for Children (NYS VFC) Program

## Temperature Monitoring Device Guidance

### Requirements

NYS VFC providers are **required to:**

- **Manually check the temperatures of all refrigerator and freezer units where VFC vaccine is stored twice daily;** when the clinic opens and when it closes for the day. This requirement applies regardless of the type of temperature monitoring device being used because of the possibility of equipment failure.
- **Use a calibrated temperature monitoring device with a current Certificate of Traceability and Calibration Testing<sup>i</sup>** (also known as Report of Calibration) in each refrigerator or freezer used to store VFC vaccine. All temperature monitoring devices require recalibration according to the manufacturer's specifications, but not to exceed two years. Temperature monitoring device probes should be placed in a central area of the storage unit with the vaccine. If the unit is purpose built for storing vaccines or medical supplies, placement of the buffered probe can be adjusted, effective March 2016<sup>ii</sup>.
- **Have at least one back up temperature monitoring device with a current certificate of calibration** in case of equipment failure or calibration testing of the current equipment is required. The NYS VFC Program recommends the backup temperature monitoring device be stored outside of the storage unit until needed, and the calibration date for the backup device be different than the one in use.

### Recommended Data Logger Functionality

The NYS VFC Program recommends using a digital data logger<sup>iii</sup> for continuous temperature monitoring and recording. The device can provide an indication of the length of time a unit has been operating outside the recommended vaccine storage temperature, and when exactly the excursion occurred, which may prevent disposing of vaccine unnecessarily. A data logger with all of the following features is advised:

- Digital display on outside of storage unit to allow reading temperatures without opening unit door
- Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperature
- Display that shows current temperature, as well as the minimum and maximum temperatures (indicates the coldest and warmest temperatures recorded since device was last reset)
- Audible high/low alarm for out-of-range temperatures
- Accuracy of  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ )
- Low battery indicator
- Memory storage of at least 4,000 readings; the device should not rewrite over old data and should stop when memory is full
- User programmable logging interval or reading rate of at least every 15 minutes

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<sup>i</sup>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 such as the American Association for Laboratory Accreditation. A list of ILAC/MRA laboratories is available in the [CDC's Storage and Handling Toolkit](#). An alternative is calibration performed by a non-accredited laboratory that demonstrates calibration testing performed meets 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>. Before purchasing a device or sending temperature monitoring devices for calibration, check with the laboratory/calibration company to verify the required information will be included on the certificate. 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 should be replaced.

<sup>ii</sup>It is generally recommended that temperature monitoring device probes be placed centrally within each storage unit, near the vaccine, to ensure that the probe is recording the temperatures closest to the vaccine vials. Purpose-built units have fan-forced air circulation or multiple cool air vents to promote temperature uniformity throughout the unit. Probes can be adjusted in purpose-built units **ONLY** if the purpose-built unit has either 1) a built-in thermometer OR 2) a dedicated port for the probe that dictates placement of the probe.

<sup>iii</sup>The American Academy of Pediatrics has created a list of data logger manufacturers and distributors, and of alarm phone dialer manufacturers that may aid you with selecting a device; visit [https://www.aap.org/en-us/Documents/immunization\\_data\\_loggers.pdf](https://www.aap.org/en-us/Documents/immunization_data_loggers.pdf). NYSDOH cannot endorse or recommend specific products or brands. However, if you have questions about a temperature monitoring device, before making a purchase contact the NYS VFC Program at 518-473-4437.