MnVFC Guide to Temperature Monitoring Devices

Minnesota Vaccines for Children (MnVFC) program requirements

▪ As of Jan. 1, 2018, all MnVFC providers are required to use a continuous temperature monitoring device in storage units that hold VFC vaccine.
▪ The temperature monitoring device can be a data logger or a continuous temperature monitoring system (e.g., TempTrak, Isensix).
▪ MnVFC providers must have a working, calibrated temperature monitoring device with a current and valid Certificate of Calibration in each vaccine storage unit. The Certificate of Calibration must be kept with your other MnVFC documents for three years. You will need to show this certificate at your MnVFC site visit.
▪ MnVFC providers must have one back-up temperature monitoring device, which is not in use, is readily available, and has a valid Certificate of Calibration.
▪ As of January 2018, this back-up device must be a data logger.
▪ If the back-up temperature monitoring device is not physically onsite, there must be a plan for how the back-up device will be accessed within a timeframe that will comply with the requirement to assess and record temperatures twice a day.
▪ Twice daily temperature checks including the time, temperature, and signature or initials of the person recording the temperature are still required to be documented.
▪ Minimum and maximum temperatures must be checked and recorded for each storage unit at the beginning of the day.

Features of continuous temperature monitoring devices

MnVFC providers are required to use a continuous temperature monitoring device (e.g., data logger or continuous temperature monitoring system). These devices can provide information on when the temperature went out-of-range, for how long, and what the temperatures were. Unlike a min/max thermometer, which provides only information about warmest and coldest temperatures that were reached, the continuous temperature monitoring device provides detailed information on all temperatures recorded at preset intervals. This information may make a difference in determining if vaccine is still viable or not.

Required features of continuous temperature monitoring devices:

▪ Continuous monitoring and recording capabilities to track and record temperatures over time.
▪ The capacity to routinely download temperature data to a computer (recommended at least weekly).
▪ Probe in buffered material (e.g., biosafe glycol) placed in the center of the storage unit with the vaccine.
  ▪ In a pharmaceutical unit, placement in other locations may be acceptable because pharmaceutical units maintain more consistent temperatures throughout the unit.
▪ Active temperature display that can be easily read from the outside of the unit.
Recommended features of continuous temperature monitoring devices:

- Alarm for out-of-range temperatures.
- Accuracy within +/-1°F (+/- 0.5°C).
- Low battery indicator.
- Display of current, minimum, and maximum temperatures.
- Memory storage of at least 4,000 readings.
- User programmable logging intervals (e.g., the user can set how often the device records the temperature).

**Temperature monitoring devices**

**Thermometers**

As of 2018, thermometers are no longer allowed for monitoring vaccine. MDH does not supply or calibrate thermometers. Sites should discard any expired thermometers.

**Data loggers**

A portable measurement instrument that can be programmed to record temperatures at preset intervals. They are capable of recording and storing thousands of temperature readings that can then be retrieved, viewed, and evaluated.

Data logger manufacturers and distributors:

- **Control Solutions**
  35851 Industrial Way, Suite D
  St. Helens, OR 97051
  1-888-311-0636
  [www.vfcdataloggers.com](http://www.vfcdataloggers.com)

- **DeltaTrak, Inc.**
  P.O. Box 398
  Pleasanton, CA 94566
  1-800-962-6776
  [www.deltatrak.com](http://www.deltatrak.com)

- **InTemp by Onset**
  470 MacArthur Blvd.
  Bourne, MA 02532
  1-800-564-4377

**Continuous temperature monitoring systems**

A system that provides information on temperatures for multiple vaccine storage units throughout a clinic or system, recorded at preset intervals. It transmits real-time data to a computer and has the ability to alert multiple people via text and/or email.
Continuous temperature monitoring system manufacturers and distributors:

Cooper-Atkins (TempTrak)
33 Reeds Gap Road
Middlefield, CT 06455
860-349-3473
www.cooper-atkins.com/Products/TempTrak

Veracity Group (VersaTrak)
7575 E. Kemper Road
Cincinnati, Ohio 45249
888-369-3601
www.veracitygroupinc.com

Isensix
42244 Remington Avenue
Temecula, CA 92590
866-634-2767
www.isensix.com/index.php/products

STANLEY Healthcare
130 Turner Street, Suite 700
Waltham, MA 02453
888-622-6992
www.stanleyhealthcare.com

Lab-Call
1880 Livingston Avenue, Suite 102
West St. Paul, MN 55118
651-552-0478
www.lab-call.com

SMART Temps
435 Park Place Circle
Mishawaka, IN 46545
877-272-3111
www.smart-temps.com

Temperature monitoring devices not recommended by CDC:

- Fluid-filled bio-safe liquid temperature monitoring devices.
- Bi-metal stem temperature monitoring devices.
- Food temperature monitoring devices.
- Household mercury temperature monitoring devices.
- Chart recorders.
- Infrared temperature monitoring devices.
- Temperature monitoring devices that are not calibrated.

These devices can have significant limitations. They can be difficult to read and only provide information on the temperatures at the precise time they are read. Most do not have a Certificate of Calibration. Testing demonstrated that infrared thermometers are not reliable or accurate for assessing vaccine storage temperatures.

Calibration

Calibration of temperature monitoring devices must be performed at a minimum of every two years from the last calibration testing date (date certificate issued). Temperature monitoring devices will "drift" over time and normal use can affect their accuracy, so all of these devices need recalibration.

Certificates of calibration must include the following items to be considered valid:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Instrument passed testing (instrument in tolerance)
- Documented uncertainty (recommended uncertainty = ± 0.5° C / ± 1.0° F)
To determine if a certificate of calibration testing was issued by an appropriate entity, check to see if the certificate indicates one or more of these items:

- Conforms to ISO 17025.
- Performed by an ILAC/MRA Signatory body accredited laboratory. You can review this list of the ILAC MRA and Signatories [here](http://ilac.org/ilac-mra-and-signatories/).
- Traceable to the standards maintained by NIST.
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better.
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.

**Minnesota laboratories that provide calibration services**

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<tr>
<th>JW Electronics, LLC</th>
<th>Palen Kimball, LLC</th>
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<tbody>
<tr>
<td>16625 Imperial Way</td>
<td>1717 University Avenue West</td>
</tr>
<tr>
<td>Lakeville, MN 55044</td>
<td>St. Paul, MN 55104</td>
</tr>
<tr>
<td>612-408-7670</td>
<td>651-646-2800</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.palenkimball.com/calibration-services">www.palenkimball.com/calibration-services</a></td>
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<tr>
<th>NBS Calibrations</th>
<th>SiteCal, Inc.</th>
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<tr>
<td>9556 W. Bloomington Fwy</td>
<td>2120 108th Lane NE, Suite 200</td>
</tr>
<tr>
<td>Minneapolis, MN 55431</td>
<td>Blaine, Minnesota 55449</td>
</tr>
<tr>
<td>800-722-5398</td>
<td>763-213-1284</td>
</tr>
<tr>
<td><a href="http://www.nbscalibrations.net">www.nbscalibrations.net</a></td>
<td><a href="http://www.sitecal.com">www.sitecal.com</a></td>
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Bio-medical services that calibrate other equipment at your site may also be able to provide calibration services. Other local companies may be able to perform this service as well. They must provide you with proper documentation of the Certificate of Calibration (including model/device name or number, serial number, date of calibration (report or issue date), instrument passed testing or in tolerance) to keep with your MnVFC records.

If you are a vendor of devices and/or services related to temperature monitoring and would like to be listed in this guide, please contact us at 651-201-5522.

**Disclaimer**

As a state agency, we cannot endorse any specific brand or product. The terms and conditions of your purchase are between you and your vendor.

*Adapted with permission from the Oregon Immunization Program.*