Required Thermometer Specifications

December 2024

Overview

NCIP participants are required to use a digital data logger thermometer with the minimum requirements listed below. A thermometer that does meet these requirements should not be used to read and record temperatures.

Digital Data Logger Requirements:

- 1. Probe Requirements:
 - **Detachable Buffered Probe:** Must be used, and the probe must be capable of being centrally located near the vaccines for accurate temperature monitoring.
- 2. Accuracy:
 - The thermometer must maintain an accuracy of ±0.5°C (1°F) or better.
- 3. Calibration:
 - Valid Certificate of Calibration or a Report of Calibration testing, is required.
 - The certificate must indicate one or more of the following:
 - a) Compliance with **ISO 17025** or testing by an ILAC MRA (International Laboratory Accreditation Cooperation) signatory laboratory.
 - A list of ILAC/MRA signatories may be found at ILAC.org/ILAC-MRA-and-signatories/
 - b) Traceability to NIST (National Institute of Standards and Technology) standards.
 - c) Compliance with **ASTM Standard E2877 Tolerance Class F** ($\leq 0.5^{\circ}$ C).
 - Calibration Certificate Must Include:
 - a) Clearly identifiable accreditation (e.g., ILAC/MRA signatory).
 - b) Model number of the probe.
 - c) Serial number of the probe.
 - d) Date of calibration (report or issue date).
 - e) Measurement results demonstrating that the unit passed the test, with documented uncertainty within the ± 0.5 °C (± 1 °F) range.
 - f) Current, minimum, and maximum temperatures clearly visible.
 - g) Alarm notification for out-of-range temperatures.
 - h) Low battery indicator.
 - i) Downloadable capabilities.
 - j) User-programmable logging interval, with a maximum of 30 minutes.

Temperature Monitoring Requirements

To remain compliant with program requirements, NCIP participants are required to maintain the following on their digital data logger thermometers:

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1. Location & Recording:

- The digital data logger thermometer must be centrally located near the vaccines.
- **Manual Temperature Recording:** Temperatures must be manually recorded **once per day**, including on half-days.
- **Clear Min/Max Readings:** The thermometer's minimum/maximum temperature readings should be manually recorded and cleared **once a day** when the clinic opens.

2. Log Maintenance:

- Temperature logs should be posted on the vaccine storage unit and copies must be retained for **3 years**.
- Ensure all records include:
 - o Time of reading.
 - o Name or initials of the person conducting the temperature check.

3. Data Review:

Download and review data logger readings weekly to ensure continuous monitoring.

4. Calibration Requirements:

- Calibration of the digital data logger thermometer should occur **every 2 years** (or as per the manufacturer's recommended schedule).
- Maintain a valid and **up-to-date certificate of calibration**.

5. Backup Digital Data Logger:

 Maintain a backup digital data logger with a different calibration date than the primary digital data loggers

Digital Data Logger Thermometer Models

All thermometers must be digital data loggers. The models listed below meet the minimum requirements. *NCIP does not recommend any specific brand or supplier of digital data logger thermometers.*

Table: 1.1 Approved Digital Data Logger Thermometers

Product Name	Brand	Website
Aegis Remote Temperature Monitoring for Vaccine and Product Storage (Model: SNT X1	O O	aegisfridge.com
Web enabled with glycol bottle and A2LA Calibration Certificate)		
Berlinger Fridge-tag® 2L Vaccine	Berlinger USA	berlinger.com
Thermometer Data Logger (Refrigerator model and freezer model)		fishersci.com; us.vwr.com
DeltaTrak® FlashLink® Certified Vaccine USB PDF Data Logger (Models 20932, 20938, or 40527)		deltatrakvfc.com; deltatrak.com

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InTemp® VFC Bluetooth Low Energy Temperature (with Glycol) Data Logger (Model: CX402-VFCxxx)	Onset	onsetcomp.com
McKesson Datalogging Refrigerator / Freezer Thermometer (Fahrenheit / Celsius -58° to +158°F (-50° to +70°C, Models: MCK80021P, MCK80022P)	McKesson	mms.mckesson.com
SensoScientific (with bi-annual A2LA Calibration, Models: B11- 200-XV10C, B10- 202-XV10C, B10-202-K202C, B80-202-OTA)	SensoScientific	sensoscientific.com
Temperature Guard VM605 E (with A2LA Calibration Certificate)	Temperature Guard	temperatureguard.com
Thermco® Vaccine Temperature Data Logger (Model: ACCRT8002, Software- Less Reporting)	Thermco	thermcoproducts.com; amazon.com; mms.mckesson.com
Traceable® Excursion-Trac™ Datalogging Refrigerator or Freezer Thermometer (Models: 6430, 6431, 6437, or 6438, with glycol or vaccine bottle)	Traceable	traceable.com; fishersci.com
Traceable® Memory-Loc™ Datalogging Refrigerator or Freezer Thermometer (Models: 6440, 6441, 6447, or 6448, with bottle or vaccine bottle)	Traceable	traceable.com; fishersci.com
TraceableLIVE®™ Refrigerator/ Freezer Datalogging Traceable Thermometer (Model: 6500 with glycol bottles)	Traceable	traceable.com; fishersci.com

Note: Digital temperature displays must be maintained in the same room as the refrigerator/freezer unit(s) so temperatures can be easily read from the outside of the unit. Web-based products must have a display or computer in the same room as the refrigerator/freezer unit(s) with a battery back-up connected to the computer to ensure no interruption in power to the digital data logger.

For assistance, contact the NCIR Help Desk Phone: 1.877.USE.NCIR (873-6247)

Email: ncirhelp@dhhs.nc.gov

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