Washington State Department of Health

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COVID-19 Vaccination Program

Thermometer Requirements and Temperature Monitoring Guide

This guide highlights requirements around temperature monitoring and the different types of thermometers available and identifies those that comply with the Washington State COVID-19 Vaccination Program. Using the correct thermometer or continuous monitoring system to monitor vaccine is critical for protecting your vaccines. It is essential for each vaccine storage unit to have a temperature monitoring device (TMD) to ensure that there is an accurate temperature history that reflects actual vaccine temperatures and that vaccines are stored within the correct temperature range.

Temperature Monitoring Device (TMD)

CDC requires a specific type of TMD called a “digital data logger” (DDL) to monitor COVID-19 vaccines. A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals. Use a DDL) for each vaccine storage unit and each transport unit (emergency or non-emergency). Also, have at least one backup DDL in case a primary device breaks or malfunctions. Providers should use DDLs with the following features:

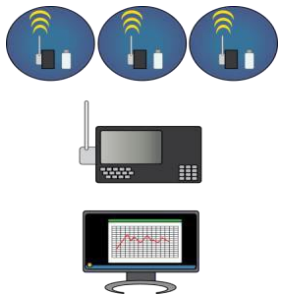
- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

- A current and valid Certificate of Calibration Testing

Digital Data Loggers for Ultra-Cold Temperatures

DDLs using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59° C (-74° F)) or a glycol mixture with a warmer freezing point. Ultra-cold freezers store vaccines at temperatures between -90° to -60°C (-130° to -76°F). For accurate ultra-cold temperature monitoring, it is essential to use an air-probe or a probe designed specifically for ultra-cold temperatures with the DDL.

Approved Thermometers

Temperature Monitoring System	
A temperature monitoring system is the most complex type of thermometer a provider can use. A temperature monitoring system is a series of thermometers connected to a main computer or hub. Large providers or hospitals use these systems because they have multiple storage units over a wide area. Providers can track the temperatures of all units through one computer. **Temperature Monitoring Systems meet best practices for temperature monitoring.**	
Digital Data Logger	
A digital data logger is an electronic thermometer device that records temperatures over time. These recordings are stored into system memory. Data loggers connect to a computer so providers may download temperature information and review it via spreadsheets or charts and graphs. **Digital Data Loggers meet best practices for temperature monitoring.**	

Unapproved Thermometers

Digital Thermometer	
A digital thermometer, also known as a minimum and maximum thermometer, is an electronic thermometer that displays the current temperature of the storage unit. It records the highest and lowest temperatures, referred to as the minimum (or MIN) temperature and the maximum (or MAX) temperature. It does not save temperature data and does not plug into a computer. **Providers cannot use digital thermometers for temperature monitoring.**	
Chart Logger	
A chart logger is the precursor to the digital data logger. It records temperatures over time on a circular paper chart or a scroll using needle with ink. **Providers cannot use chart loggers for temperature monitoring.**	
Fluid-Filled Thermometer	
A fluid filled thermometer consists of a sealed glass tube containing liquid. The glass tube has a numbered scale which is used to measure temperature as the liquid rises and falls. **Providers cannot use fluid filled thermometers for temperature monitoring.**	
Dial or Bimetal Stem Thermometer	
A dial thermometer or bimetal stem thermometer is a most used for cooking. It has a metal probe connected to a circular temperature scale. A needle on the scale moves depending on the temperature reading. **Providers can't use dial thermometers for temperature monitoring.**	

Additional Thermometers not approved for use with vaccine
TMDs used for food Infrared TMDs TMDs that do not have a current and valid Certificate of Calibration Testing **Please note:** Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

Certificate of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

A DDL's Certificate of Calibration Testing should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

Calibration testing should be done every two to three years or according to the manufacturer's suggested timeline. Certificate of Calibration Testing should be issued by an appropriate entity, for each temperature monitoring device used to monitor vaccine storage temperatures. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally accepted standards.

Have at least one back-up temperature monitoring device readily available in case a device fails, calibration testing is needed, or vaccine must be transported. Back-up devices must include the same features as primary devices. It is recommended they have a different calibration expiration date to avoid all devices requiring recalibration at the same time.

Monitoring Temperatures

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and the safety of your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Best Practices:

Temperature alarm ranges should be set within .5 to 1 C/F degree of the acceptable temperature range. This allows providers to address fluctuating temperatures before excursion occurs.

Regular checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines. Check the temperature each time vaccines are accessed in the unit.

Review storage unit temperature readings and review continuous DDL software or website information weekly for changes in temperature trends that might require action.

Storage units must have a digital data logger (DDL) that can continuously monitor temperatures. Staff must check and record temperatures at the beginning of each workday to determine if any excursions have occurred since the last temperature check. Most DDLs measure minimum and maximum temperatures. However, if your

DDL does not display minimum and maximum temperatures, the temperature must be checked and recorded at the beginning and end of each clinic day and you must review the continuous DDL temperature data daily. Monitoring requirements may vary if you are using the manufacturer-provided Pfizer thermal shipper for storage; review the product specific information provided in the toolkit.

You must record temperatures on a temperature log if:

- You do not currently have a DDL with a downloadable temperature log*
- You do not have a DDL with a Min/Max display

When recording include:

- Minimum/maximum temperature
- Date
- Time
- Name of person checking and recording temperature
- Actions taken if a temperature excursion occurred

*DDLs are required to monitor COVID-19 vaccines. If you are unable to obtain a DDL, please check with the COVID-19 Vaccine Team at COVID.Vaccine@doh.wa.gov to discuss options.

Temperature Logs

CDC has provided temperature logs to use with each COVID-19 vaccine. You are not required to send the temperature logs to the Department of Health, but you need to have them available for review if necessary. Temperature records must be kept for a minimum of three years.

Pfizer:

- Refrigerator Storage Temperature Log (Celsius) | (Fahrenheit)
- Freezer Storage Temperature Log (Celsius) | (Fahrenheit)
- Ultra-Cold Vaccine Storage Temperature Log (Celsius) | (Fahrenheit)

Moderna:

- Refrigerator Storage Temperature Log (Celsius) | (Fahrenheit)
- Freezer Storage Temperature Log (Celsius) | (Fahrenheit)

Johnson & Johnson:

- Refrigerator Storage Temperature Log (Celsius) | (Fahrenheit)

Novavax:

- Refrigerator Storage Temperature Log (Celsius) | (Fahrenheit)

Emergency Use Authorization (EUA) Fact Sheet for Health Care Providers:

- Janssen COVID-19 Vaccine (Johnson & Johnson)
- Moderna COVID-19 Vaccine
- Pfizer-BioNTech COVID-19 Vaccine
- Novavax COVID-19 Vaccine

Resources:

- Vaccine Management Plan (PDF)

- How to Report COVID-19 Vaccine Wastage guide (PDF)
- COVID-19 Vaccine Temperature Excursion Guide (PDF)
- Centers for Disease Control and Prevention's (CDC) Storage and Handling Toolkit (PDF)
- Centers for Disease Control and Prevention's (CDC) Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage (PDF)
- Centers for Disease Control and Prevention's (CDC) Vaccine Administration and Storage and Handling Resources Guide (PDF)
- Centers for Disease Control and Prevention's (CDC) Packing Vaccines for Transport during Emergencies (PDF)

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