

COVID-19 Vaccination Program

Monthly Temperature Monitoring and Thermometer Requirement Guide

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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 an accurate temperature history that reflects actual vaccine temperatures and vaccine storage is 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:

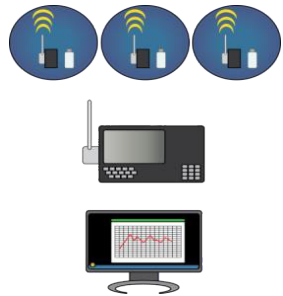

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (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	
<p>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.</p> <p>Temperature Monitoring Systems meet best practices for temperature monitoring.</p>	
Digital Data Logger	
<p>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.</p> <p>Digital Data Loggers meet best practices for temperature monitoring.</p>	

Unapproved Thermometers

Digital Thermometer	
<p>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.</p> <p>Providers cannot use digital thermometers for temperature monitoring.</p>	
Chart Logger	
<p>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.</p> <p>Providers cannot use chart loggers for temperature monitoring.</p>	
Fluid-Filled Thermometer	
<p>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.</p> <p>Providers cannot use fluid filled thermometers for temperature monitoring.</p>	
Dial or Bimetal Stem Thermometer	
<p>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.</p> <p>Providers can't use dial thermometers for temperature monitoring.</p>	
Additional Thermometers not approved for use with vaccine	
<p>TMDs used for food</p> <p>Infrared TMDs</p> <p>TMDs that do not have a current and valid Certificate of Calibration Testing</p> <p>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.</p>	

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.

Submitting Temperature Logs

Starting April 1, 2022, providers enrolled in the COVID Vaccine Program will be required to submit temperature logs monthly for all units listed on their provider agreement.

Providers enrolled in the Childhood Vaccine Program (CVP) still need to follow all the requirements of that program including the temperature log requirements and how those temperature logs are submitted.

Disenrolled providers and providers who have requested to become inactive in the program are not required to upload temperature logs and will not receive the notification emails that temperature logs are due. However, if an inactive provider requests to become active in the program, they will need to send us their most recent temperature logs for their storage units, which we will review before we turn ordering and transfers back on.

Automated emails will be sent out to the Primary Vaccine Coordinator and Backup Vaccine Coordinator listed on their provider agreement for each facility. The initial email will be sent out the 1st of each month letting providers know that temperature logs are due.

Acceptable Temperature Logs	
<p>CDC COVID Vaccine Temperature logs</p>	<p>CDC has provided temperature logs to use with COVID-19 vaccines.</p> <p>CDC has created a log for each storage unit type:</p> <ul style="list-style-type: none"> • Refrigerator Temperature Log (Celsius) (Fahrenheit) • Freezer Temperature Log (Celsius) (Fahrenheit)

	<ul style="list-style-type: none"> Ultra-Cold Freezer Temperature Log (Celsius) (Fahrenheit)
Childhood Vaccine Program (CVP) Temperature logs	<p>Providers enrolled in the Childhood Vaccine Program (CVP) may submit the temperature logs approved for use in the CVP program.</p> <p>CVP Vaccine Temperature Monitoring Log (wa.gov)</p> <p>All providers enrolled in the CVP still need to follow all the requirements of that program including the temperature log requirements and how those logs are submitted.</p>
Digital Data Loggers (DDL)/Temperature Monitoring System (TSM) Summary Reports	<p>We are also accepting Digital Data Loggers (DDL)/Temperature Monitoring System Summary Reports with prior review/approval by the program.</p> <p>The summary report will need to be brief (1-2 page) and display the following:</p> <ul style="list-style-type: none"> One month of temperature data with dates displayed. Data points listed on the CDC paper temperature logs. For example, daily min/max record or a graph displaying monthly data trend that clearly illustrates whether your unit experienced an excursion. If possible, please list the alarms set for each unit.

Monthly Temperature Log Submission Survey Process

Temperature Log Submission Screens

At the top of the temperature log submission screen, it will list the name of the facility and the month that you are submitting for. There will be a spot for each of the storage units listed in the provider agreement and will include the storage type, storage manufacturer and the thermometer brand/model.

Cold Storage 1

Type: Ultra-Cold Freezer (-60C to -80C)

Manufacturer: McKesson

Thermometer Brand/Model: TSX40086AQ4

<p>Active Unit</p>	<p>Each storage unit will have a question about whether the unit was used to store vaccine during the past month. This field is required.</p> <div data-bbox="407 310 1442 426" style="border: 1px solid gray; padding: 5px;"> <p>Have you used this unit during the past month to store any COVID-19 vaccine? <input type="radio"/> Yes <input type="radio"/> No</p> <p><small>* must provide value</small></p> </div> <ul style="list-style-type: none"> • If this unit was used to store COVID vaccine in the last month, select “Yes”. Selecting yes will open additional questions and a file upload field. • If this unit was not used to store COVID vaccine in the last month, select “No”. No additional questions will appear for this unit.
<p>Temperature Excursion</p>	<p>For active storage units, please identify if the storage unit experienced a temperature excursion during the past month. This field is required. This question will repeat for each storage unit listed on your provider agreement.</p> <div data-bbox="415 835 1450 961" style="border: 1px solid gray; padding: 5px;"> <p style="text-align: right;">Yes <input type="radio"/> No <input type="radio"/></p> <p>Was there a temperature excursion during this month for this unit?</p> </div> <ul style="list-style-type: none"> • If this unit experienced an excursion during the past month, select “Yes”. This will open additional questions about the excursion. Please document the details in the provided comment field. • If this unit did not experience an excursion during the past month, select “No”. No additional questions around temperature excursions will appear for this unit.
<p>Temperature Excursion – Additional Details</p>	<p>If the storage unit experienced a temperature excursion during the past month, you will need to complete the following questions. For steps on addressing temperature excursions, see the COVID-19 Vaccine Temperature Excursion Guide.</p> <p>Indicate if the manufacturer was contacted. This field is required.</p> <div data-bbox="415 1514 1450 1629" style="border: 1px solid gray; padding: 5px;"> <p style="text-align: right;">Yes <input type="radio"/> No <input type="radio"/></p> <p>Was the manufacturer contacted?</p> </div> <ul style="list-style-type: none"> • If the storage unit experienced an excursion and the manufacturer was contacted, select “Yes”. Please document the details in the provided comment field. • If the storage unit experienced an excursion and the manufacturer was not contacted, select “No”. Please note, you are required to reach out to the

manufacturer for all temperature excursion to verify that the vaccine is still viable.

Indicate if the Department of Health (DOH) was notified. This field is required.

	Yes	No
Was DOH notified?	<input type="radio"/>	<input type="radio"/>

- If the storage unit experienced an excursion and DOH was notified, select “**Yes**”. Please document the details in the provided comment field.
- If the storage unit experienced an excursion and DOH was **not** notified, select “**No**”. Please note, you are required to notify DOH about all temperature excursions.

Indicate if the manufacturer deemed the vaccine viable. This field is required.

	Yes	No
Was the vaccine deemed viable?	<input type="radio"/>	<input type="radio"/>

- If the storage unit experienced an excursion and the manufacturer deemed the vaccine viable, select “**Yes**”. Please document the details in the provided comment field.
- If the storage unit experienced an excursion and the manufacturer deemed the vaccine **not** viable, select “**No**”. This will open an additional question.

If the vaccine was **not deemed viable** by the manufacturer, the following question will appear. This field is required.

	Yes	No
Was any vaccine administered?	<input type="radio"/>	<input type="radio"/>

- If the vaccine was not deemed viable and there were doses administered, select “**Yes**”. This will open an additional question.
- If the vaccine was not deemed viable and there were no doses administered, select “**No**”.

If the vaccine was **not deemed viable** by the manufacturer and there was vaccine administered, the following question will appear. This field is required.

Estimated number of doses administered

Enter the total number of doses that were administered.

Enter any additional details on the temperature log for this unit or all excursion details in the following comment field.

Comments


Expand

File Upload

To upload an [acceptable temperature log](#) for your unit, select the green **“Upload file”** link. This field is required.

Upload File for Storage 1

* must provide value

 [Upload file](#)

An “upload file” window will appear. Click **“Choose File”** to select and upload the temperature log for that unit.

✕

Upload File for Storage 1

Select a file then click the 'Upload File' button

Choose File

 No file chosen

✕

Upload File for Storage 1

Select a file then click the 'Upload File' button

Choose File

 Pharmacy R...2020 (1).pdf

✕

Upload File for Storage 1

Select a file then click the 'Upload File' button

Choose File

 No file chosen

✕

Upload File for Storage 1

Select a file then click the 'Upload File' button

Choose File

 Pharmacy R...2020 (1).pdf

The file name should appear next to the **“Choose File”** button. Select **“Upload File”** to finish.

These fields will repeat for the number of storage units listed in the provider agreement.

Updates to Storage

You can indicate if you need to update storage units listed on your provider agreement. If you indicate that changes need to be made, someone from the Provider Support Team will reach out to you.

Do you need to update your storage units on your provider agreement? If Yes, someone from the Provider Support Team will reach out to you.

Yes
 No

<p>Additional Comments</p>	<p>If there are any additional details that you would like to share with us, you can add those here.</p> <div data-bbox="407 312 1442 678" style="border: 1px solid #ccc; padding: 10px;"> <p>Is there anything else you would like to share?</p> <div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div> <p style="text-align: right;">Expand</p> </div>
<p>Saving Progress</p>	<p>If you need to save your progress and return to it later, select “Save & Return Later” at the end of the form. You can enter an email address to receive an emailed link to return to the Temperature Log Submission Form.</p> <div data-bbox="704 898 1156 1016" style="border: 1px solid #ccc; padding: 10px; text-align: center;"> <p>Save & Return Later</p> </div>
<p>Submit</p>	<p>At the end of the Temperature Log Submission Form, you will need to click “Submit” when finished. Once you click “Submit”, your answers for this survey will be complete and you will not be able to return and edit answer. Please review your responses before submitting.</p> <div data-bbox="685 1283 1192 1419" style="border: 1px solid #ccc; padding: 10px; text-align: center;"> <p>Submit</p> </div> <p>Once submitted, you should see the following message:</p> <p>Thank you for submitting your temperature logs. The COVID-19 Vaccine Response Team will be in touch with you. If you have any questions, please send an email to Covid.Vaccine@doh.wa.gov and include your facility pin.</p>

Approval Process

Once a provider has submitted temperature logs, through the Monthly Temperature Log Survey, the Provider

Support Team reviews each temperature log and note whether the submission has been approved, approved but requires follow up/education or not approved. Reasons for not approving a temperature log include:

- Temperature excursion that was not reported on the submission screen
- Temp log not in approved format
- Missing days/data

Provider Support Specialists will work with the provider to resolve issues or provide education.

Pausing Orders/Transfers

If a decision is made to temporarily pause orders/transfers, the provider will be notified beforehand. As soon as the issue(s) has been resolved, we will resume orders/transfers. If a provider is actively working with us to address the issue(s), no pause to ordering/transfers will be placed.

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, Adjuvanted](#)

Additional 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 \(PDF\)](#)

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.