

Storage & Handling

California Bridge Access Program (BAP)
for uninsured & underinsured adults

For Existing COVID-19 Providers



Summary of new storage & handling requirements:

- No new requirements

Look for the gold stars in [Requirements at a Glance](#) that identify new requirements.

Providers will be notified when [COVID-19 Vaccine Product Guide](#) has been updated and posted after any FDA authorizations.

Click NEXT to review this lesson content.

Welcome

Proper storage and handling protect vaccine viability, which is necessary to stimulate a healthy immune response after vaccination.

This lesson prepares you to store and handle COVID-19 vaccines in your practice. By the end of this lesson, you'll be able to

- list vaccine storage units that meet program requirements,
- monitor temperatures and report excursions,
- manage expiration and beyond-use dates, and
- identify key factors in proper vaccine preparation.

Review Time: about 15 minutes ([there is no audio – click Next](#))



What You'll Learn

1

**Storage Units
&
Data Loggers**

2

**Temperature
Monitoring**

3

**Expiration &
Beyond-Use
Dates**

4

**Vaccine
Preparation**

Storage Units & Data Loggers

Overview

Providers agree to use proper storage units and temperature monitoring devices, and follow protocols outlined in CDC's [Vaccine Storage & Handling Toolkit](#).

A COVID-19 Addendum addresses storage & handling, preparation & administration, and transport for Moderna, Novavax, and Pfizer-BioNTech vaccine products.

Resources: Bookmark CDC's [Vaccine Storage & Handling Toolkit](#).

COVID-19 AND MPOX VACCINES ADDENDUM






COVID-19 Vaccine (Pfizer-BioNTech)

Products: Pfizer-BioNTech COVID-19 Vaccine (Monovalent/Bivalent Gray cap Age 12 and Older), (Monovalent/Bivalent Orange Cap Ages 5 through 11), (Monovalent/Bivalent Maroon Cap Ages 6 months through 4 years)

Manufacturer Website: www.covidvaccine.com

Manufacturer Phone Number: 1-877-829-2619 (1-877-VAX-CO19)

CDC Clinical Guidance for Pfizer-BioNTech COVID-19 Vaccine: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Ages: 6 months through 4 years <small>(Maroon capped vial and bordered label)</small>	Ages: 5 through 11 years <small>(Orange capped vial and bordered label)</small>	Ages: 12 and older <small>(Gray capped vial and bordered label)</small>
 MONOVALENT Primary Series <small>(Dose 1 & 2)</small>	 BIVALENT Primary Series <small>(Dose 3)</small>	 MONOVALENT Primary Series
	 BIVALENT Booster Dose	 BIVALENT Booster Dose <small>Single-dose and Multidose Vials</small>

Vaccine Temperature Ranges:

- Ultra-cold: -90°C and -60°C (-130°F and -76°F) until the expiration date
- Refrigerated: 2°C and 8°C (36°F and 46°F) for up to 10 weeks

Vaccine Storage Unit(s):

- Ultra-cold freezer
- Refrigerator

Temperature Monitoring Device: For accurate temperature monitoring, use a digital data logger (DDL) able to measure minimum and maximum temperatures.

- Ultra-cold freezer:** Use a DDL with an air-probe or a probe designed specifically for ultra-cold temperatures.
- Refrigerator:** Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, or Teflon®).

Delivery:

- Vaccine arrives in a thermal shipping container at temperatures between -90°C and -60°C (-130°F and -76°F) with dry ice or between -25°C and -15°C (-13°F and 5°F).
- Ancillary supplies kit(s), including diluent if needed, will arrive in a separate shipment from the vaccine. Each kit includes the number of supplies needed to support the number of doses ordered. Vaccine for ages:
 - 6 months through 4 years requires diluent
 - 5 through 11 years requires diluent
 - 12 years and older does NOT require diluent
- Follow the manufacturer's guidance for unpacking the vaccine and returning the temperature monitoring device and container, if indicated. (www.covidvaccine-us.com/5-11-yearsold/storage-and-handling).
- Dispose of the single-use thermal shipping container. Do NOT use the thermal shipping container for storage.
- Ancillary supply kits will be delivered separately from the vaccine and have been reconfigured to support the number of doses ordered.

Note: There are no ancillary supplies for Pfizer-BioNTech vaccine for persons 12 years of age and older (gray-capped vial)

VACCINE STORAGE AND HANDLING TOOLKIT 58



Storage Units

Overview



Pharmacy-Grade

Purpose-built or pharmaceutical-grade are the gold standard. They are designed for biologics, including vaccines. Storage units can be large or compact, under-the-counter. They

- offer reliable and uniform temperature,
- are designed to reduce cold air loss with door openings, and
- recover quickly after doors are closed.

Commercial or household standalone units are acceptable. If necessary, combination units may be used—but frozen vaccines must be stored in a separate standalone freezer.

Never store vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit.

Resources: See [Requirements at a Glance](#), Storage Equipment.

Bookmark Key Resources

- [Vaccine Storage & Handling Toolkit](#)
- [Requirements at a Glance](#)

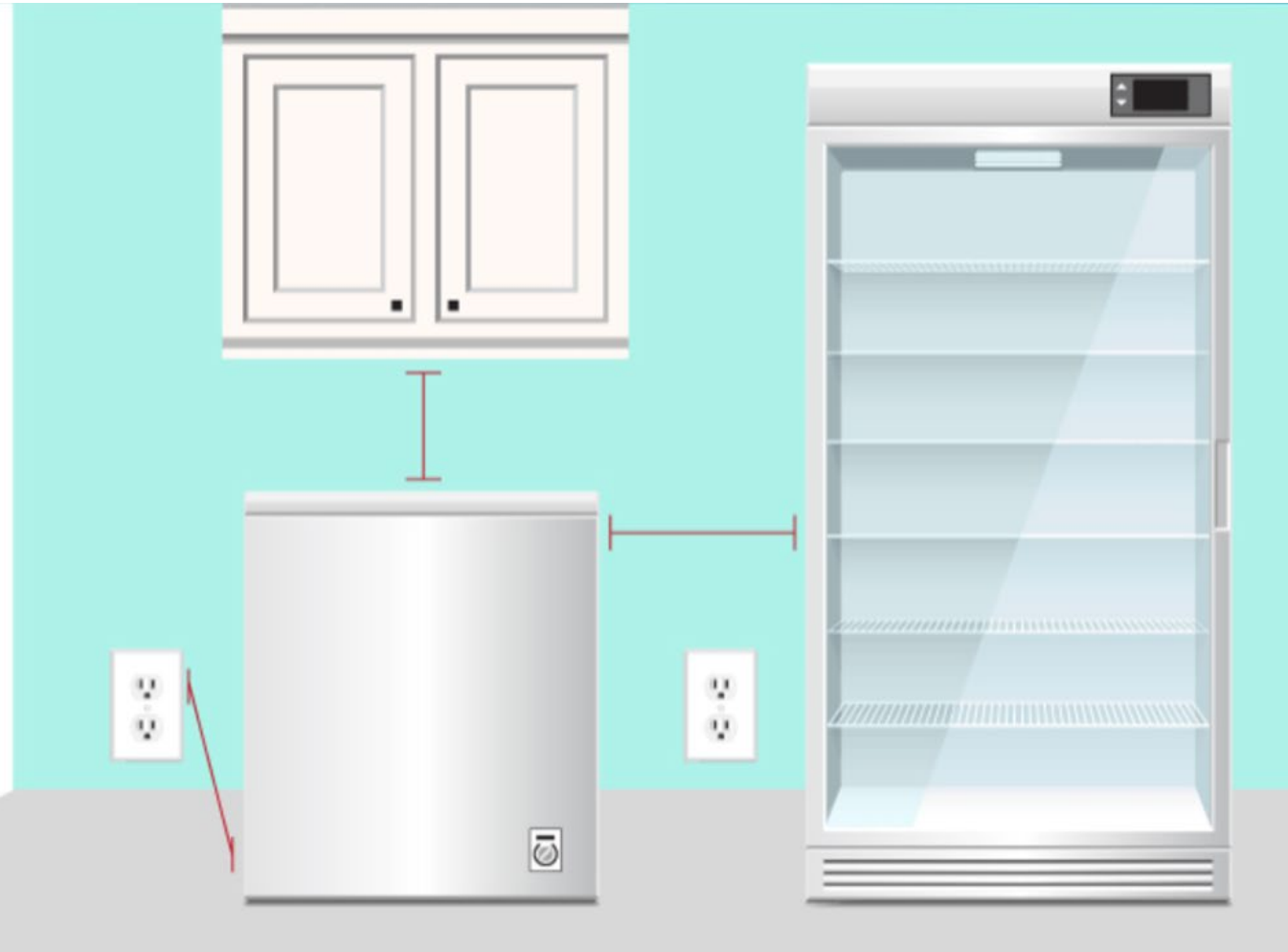
Placement

Storage Units

Leave space along sides and top, and from any wall.

Don't block the cover of the motor compartment.

Make sure door opens and closes smoothly.





Getting Ready for Use: Key Points

Storage Units

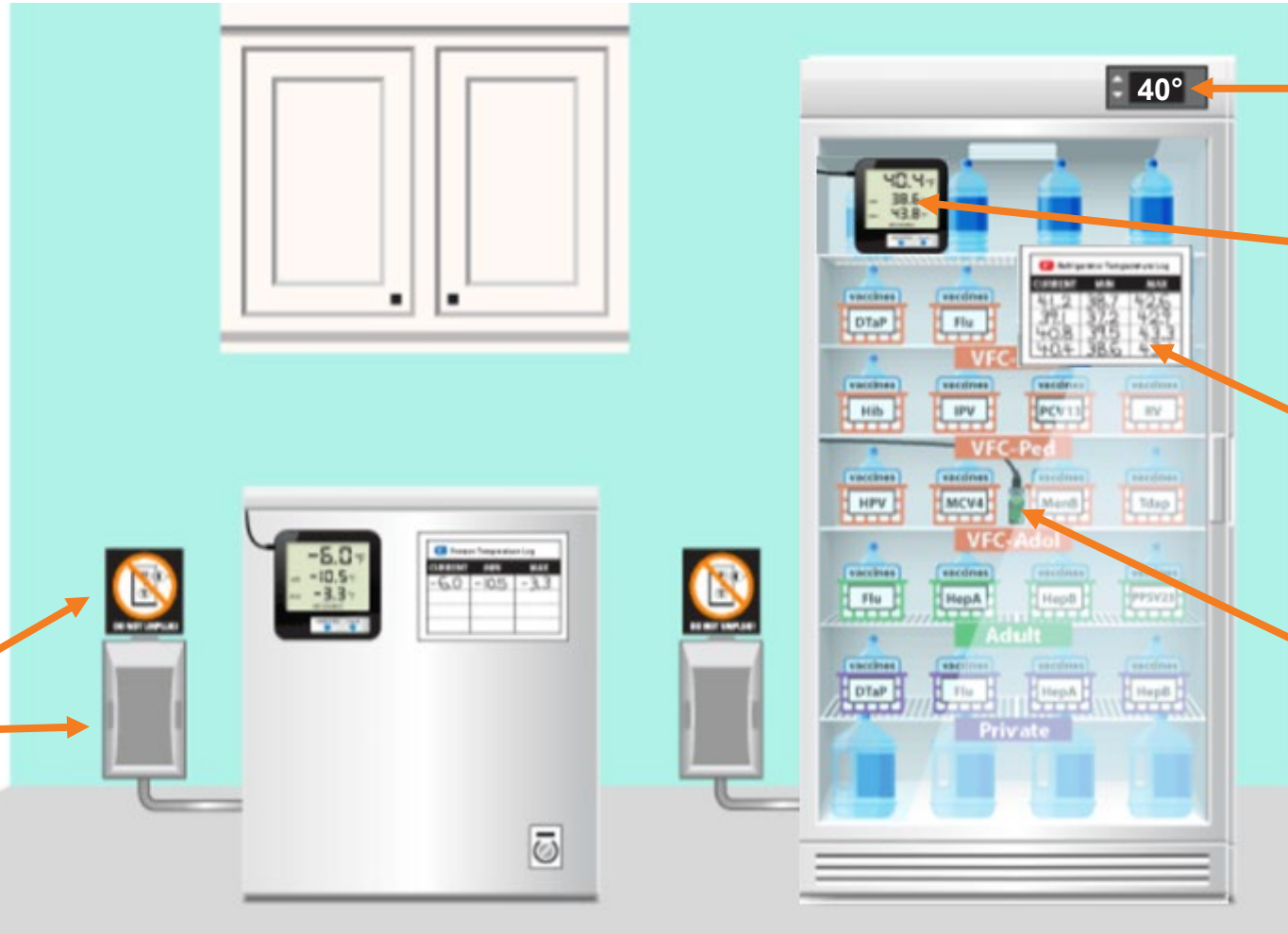
[Preparing Vaccine Storage Units](#)
[Setting Up Vaccine Storage Units](#)

Store vaccines in original packaging (trays)

Store biologics on separate shelf; no food or drinks to minimize door openings

Avoid outlets with **RESET** button, outlets controlled by wall switch, and power strips

Use “Do Not Disconnect” labels; use outlet covers



Set thermostat within required range

Ensure digital display is easily visible

Post temperature logs on corresponding unit

Position data logger probe in the center near vaccines

Setup

Storage Units

Never borrow BAP-supplied vaccines to supplement private stock, or vice versa

Organize your storage unit to avoid administration errors

Sample Refrigerator

- Clearly label VFC, VFA, BAP, and private vaccines.
- Group vaccines (pediatric, adolescent, adult).
- Label shelf space or baskets to make vaccines easy to find.
- Position vaccines or baskets 2-3 inches away from walls, floor, and other baskets.
- Store vaccines in original packaging with earliest expiration date in front.
- Diluents may be stored next to refrigerated vaccines unless manufacturer states otherwise. Never store diluents in the freezer.
- If necessary, medications or biologics may be stored below vaccines and on a different shelf.

Usable space for vaccine is inside dashed lines.

- Do not block air vents.
- Do not stack baskets on top of each other.
- No vaccines in doors.
- No food or beverages.

Sample Chest Freezer

Refrigerator temperatures
36.0°F — 46.0°F

Freezer temperatures
-58.0°F — 5.0°F

CDPH Contact:

[Preparing Vaccine Storage Units](#)
[Setting Up Vaccine Storage Units](#)



Recommended Temperatures

Storage Units

Vaccines must be stored under manufacturer-recommended storage temperatures defined in EUA Fact Sheets for HCPs and CDC's [Vaccine Storage & Handling Toolkit & COVID-19 Addendum](#).

Resources: See [COVID-19 Vaccine Product Guide](#) for summary chart.

Bookmark Key Resources

- [Vaccine Storage & Handling Toolkit](#)
- [Requirements at a Glance](#)
- [COVID-19 Vaccine Product Guide](#)



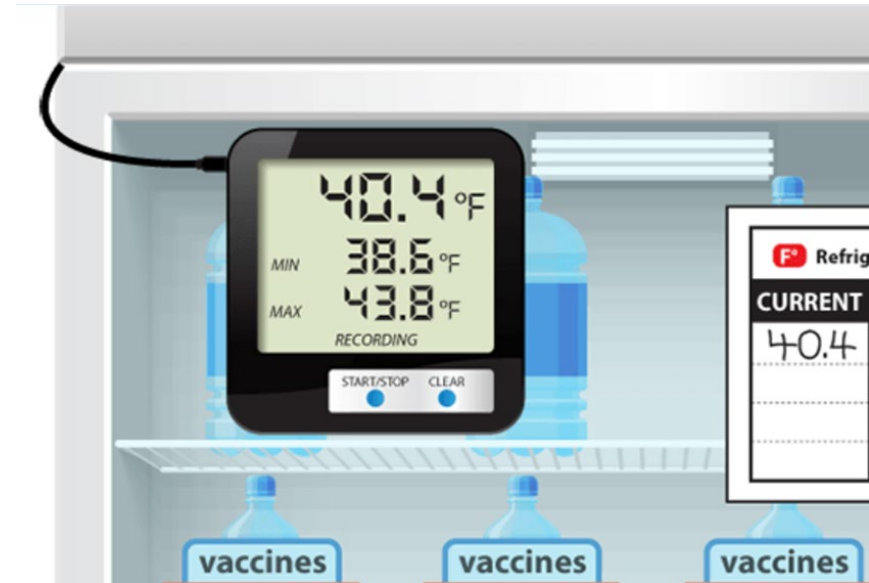
Data Loggers

Overview

Storage units must be equipped with a digital data logger; devices with buffered probes provide more accurate readings. For ultra-cold storage, devices must use an air-probe, or probe designed for vaccine temperatures.

Keep a backup device on hand for transports and should primary devices fail. Devices must have a current and valid Certificates of Calibration Testing.

Resources: See [Requirements at a Glance](#), Storage Equipment.



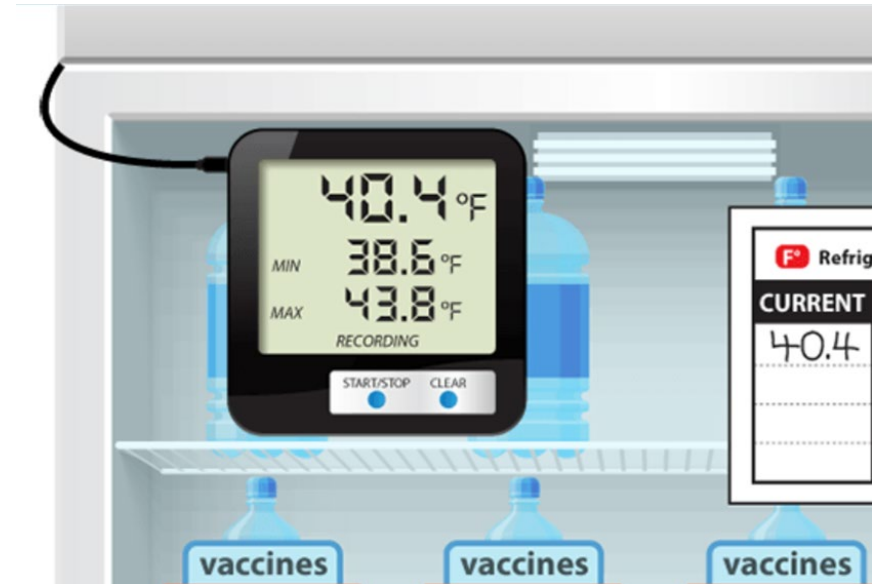
Features

Data Loggers

CDC recommends devices with the following features:

- Current, minimum, and maximum temperatures
- 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
- Reset button
- Accuracy within $\pm 0.5^{\circ}\text{C}$ accuracy ($\pm 1^{\circ}\text{F}$)
- Low-battery indicator

Resources: See CDC's [Vaccine Storage & Handling Toolkit](#).



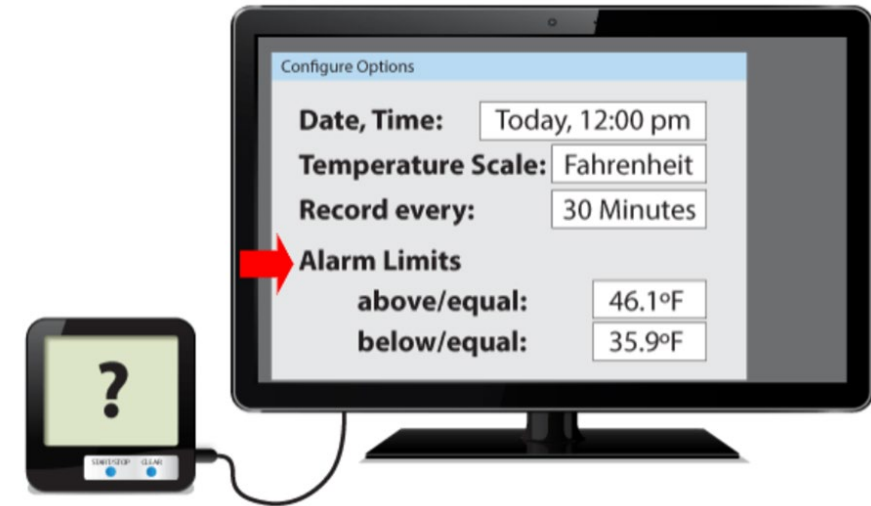
Setup

Data Loggers

To ensure you are notified if temperatures drift outside recommended ranges, [configure device settings](#) carefully.

- Set HI & LO alarm limits to reflect recommended product temperatures.
- Select the temperature scale that matches your temperature range.
- Record every 30 minutes (or less) so you can respond promptly to alerts.

Resources: See [Requirements at a Glance](#), Storage Equipment.



What You'll Learn

1

Storage Units
&
Data Loggers

2

Temperature
Monitoring

3

Expiration &
Beyond-Use
Dates

4

Vaccine
Preparation



Temperature Monitoring

Overview

Temperature monitoring is a critical step to protect vaccines.

Monitor and record your data logger's current, MIN, and MAX readings **twice daily** on your temperature logs for refrigerated, frozen, or ultra-cold vaccines, or use this [COVID-19 Temperature Log](#).

Post refrigerated and frozen temperature logs on corresponding storage units to prevent recording errors.

Resources: See [Requirements at a Glance](#), Temperature Monitoring.

COVID-19 Temperature Log

MONTH & YEAR: _____ VACCINE STORAGE UNIT LOCATION/ID: _____ COVID PIN: _____

Day	Time	Initials	Alarm	CURRENT	MIN	MAX	Excursion Resolved
Example	8:00 am	NN		-75.1 C	-76.5 C	-73.8 C	
	4:00 pm	NN	✓	-58.6 C	-76.2 C	-58.6 C	✓
1	am						
	pm						
2	am						
	pm						
3	am						
	pm						
4	am						
	pm						
5	am						
	pm						
6	am						
	pm						
7	am						
	pm						
8	am						
	pm						
9	am						
	pm						
10	am						
	pm						
11	am						
	pm						
12	am						
	pm						
13	am						
	pm						
14	am						
	pm						
15	am						
	pm						

Identify product and storage unit:

All Pfizer-BioNTech:

ULT Freezer: until expiration

Refrigerator: 10 weeks

All Moderna:

Freezer: until expiration

Refrigerator: 30 days

Novavax:

Refrigerator: until expiration

Fill in temperature range:

Check temperatures twice a day:

- Fill out clinic details in header.
- Record the time and your initials.
- Record a check if alarm went off.
- Record Current, MIN, and MAX.

If no alarm:

- Clear MIN/MAX.
- Ensure data logger is recording.

IF ALARM WENT OFF:

- Clear MIN/MAX and alarm symbol.
- Post "Do Not Use Vaccines" sign.
- Alert your supervisor.
- Complete "Report Temperature Excursion" worksheet.
- Contact vaccine manufacturer.
- Report excursion to myCAVax.
- Record a check after the incident has been resolved.
- Ensure data logger is recording.

Keep all temperature logs and data files for three years.

Questions? Call (833) 502-1245.

Staff Names and Initials: _____

On-Site Supervisor's Review – When log is complete, check all that apply:

Temperatures were recorded twice daily.

I reviewed data files to find any missed excursions. Download date: _____

Any excursions were reported.

Name: _____ Signature: _____ Date: _____

California COVID-19 Vaccination Program
IMM-1311 Page 1 (5/9/23)



Temperature Monitoring (Cont.)

Overview

Take these steps to prepare for your initial vaccine shipment:

- Ensure staff are trained to operate your data loggers and download any temperature data file in the event of an excursion; refer to device's product guide.
- Some devices must be cleared (MIN/MAX temperatures and alarm symbol) after each recording to ensure staff don't record previous readings again (see image); check your device's product guide.
- Train staff not to ignore alarm alerts; if temperature alarms go off repeatedly, do not disconnect the alarm until it has been confirmed as a false alarm.
- Supervisors should plan to review logs to ensure staff understand how to record temperatures, record twice daily, and respond to all out-of-range temperatures.





Temperature Monitoring (Cont.)

Overview

Record storage unit temperatures following the instructions on the COVID-19 Temperature Log.

- 1 Record the time and your initials next to the day of the month:

a.m. temperatures **before** opening the refrigerator or freezer.

p.m. temperatures about an hour before the office closes to allow time for corrective actions.

- 2 Record a check mark if you see or hear an alarm.

If the alarm did not go off, leave blank.

- 3 Record **CURRENT**, **MIN**, and **MAX** temperatures neatly, accurately, and in the correct columns.

Day	Time	Initials	Alarm	CURRENT	MIN	MAX
16	8:00 am	CS	✓	2.4 C	0.6 C	4.1 C
	pm					





Temperature Monitoring (Cont.)

Overview

[Record storage unit temperatures](#) following the instructions on the [COVID-19 Temperature Log](#).

IF NO ALARM:

- 4 Clear MIN and MAX.**
(Skip this step if your data logger resets automatically.)

Confirm MIN and MAX now match the CURRENT temperature.

- 5 Ensure data logger is in place and recording.**

(Some devices need to be reconnected and restarted.)



Refer to the device's product guide.

Reporting Temperature Excursions

Temperature Monitoring

Any temperature outside recommended ranges is considered a temperature excursion and may spoil vaccines.



A temperature excursion triggers a **visual or audible alarm** or alert depending on the data logger. Staff will need to confirm when the excursion occurred and its duration. There may be multiple temperature excursions overnight or weekend.

Your device may have a **temperature data file** that must be downloaded to get the data manufacturers will need to determine whether vaccines can be administered. The manufacturer's determination is only as accurate as the data you provide.

	Limit	First Event	Events	Time	Pass/Fail
High	8.1°C	1/16/2018 2:34 PM	5	25 Mins	FAIL
Low	1.9°C	None	0		PASS

Bookmark Key Resources

- [Requirements at a Glance](#)



Reporting Temperature Excursions

Temperature Monitoring

If an alarm goes off, take action immediately and report the temperature excursion (instructions provided on the [COVID-19 Temperature Log](#)):

- Clear the alarm symbol to ensure staff don't respond to previous alerts.
- Label exposed vaccines DO NOT USE so vaccines are not administered.
- Alert the Vaccine Coordinator on duty or your supervisor.
- Download the temperature data file (if any) and locate the excursion details.
- Complete the [Temperature Excursion Worksheet](#) to gather data manufacturers will need to determine viability, then contact the manufacturer.
- Report temperature excursions daily in myCAvax under **Vaccine Inventory**. For technical questions, look for the Knowledge Center link in myCAvax.
- Do not administer vaccines until the manufacturer resolution is determined.

Resources: See [Requirements at a Glance](#), Reporting Temperature Excursions.



What You'll Learn

1

Storage Units
&
Data Loggers

2

Temperature
Monitoring

3

Expiration &
Beyond-Use
Dates

4

Vaccine
Preparation



Expiration Dates

Overview

Determining vaccine and diluent expiration dates is critical for proper storage and handling. Do not administer expired vaccine. Expiration dates may be extended as more data come in. To determine expiration dates:

- *Moderna*: **Waiting to hear from the manufacturer.**
- *Novavax*: **Waiting to hear from the manufacturer.**
- *Pfizer-BioNTech*: **Waiting to hear from the manufacturer.**

Resources: See [Requirements at a Glance](#), Managing Expiration & Beyond-Use Dates.

Bookmark Key Resources

- [Requirements at a Glance](#)



Beyond-Use Dates

Overview

Vaccines may have a shortened beyond-use date (BUD) as specified in the EUA Fact Sheet for HCPs and documented in CDC's [Toolkit & COVID-19 Addendum](#).

The BUD replaces the manufacturer's expiration date. If the vaccine has no beyond-use date, use the expiration date.

Discard vaccine after the earlier of the expiration or beyond-use date.

Label vaccines (date, time and staff initials) and track carefully to ensure vaccines aren't used past the beyond-use date.

Resources: Complete [CDC's product training](#) for vaccines your location will order to ensure staff are trained on storage and handling including beyond-use dates and labels.

Bookmark Key Resources

- [Requirements at a Glance](#)



Before Puncture

Beyond-Use Dates

Manufacturer-shortened expiration dates may apply if storing unpunctured vials under conditions other than coldest recommended temperatures.

Apply [CDC’s vaccine-specific BUD tracking labels](#) so vaccines aren’t used past these reduced limits. (Select the vaccine product, click Storage & Handling, and look for the “Labels and Guidance.”)

Resources: See [Requirements at a Glance](#), Managing Expiration & Beyond-Use Dates.

Sample BUD Label

FORMULATION: 5 Through 11 Years of Age
Pfizer-BioNTech COVID-19 Vaccine

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): 123456A


Today's date: 06 / 01 / 2021 Time: 2:30 PM

USE BY*

Date: 08 / 10 / 2021 Time: 2:30 PM

*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Name: Amy Nurse RN





After Puncture

Beyond-Use Dates

Multidose vials have a shortened use-by date/time after the first puncture. Once vial is punctured, label vial with puncture date/time. Do not administer after the use-by date/time.

Pfizer-BioNTech
<p>Up to 12 hours (including thaw time) at 8°C to 25°C (46°F to 77°F)</p> <p>Discard unused vaccine after this timeframe.</p>

9 AM



Label Vial Use-By & Initials

11/12/23
9 PM TP

Bookmark Key Resources

- [Requirements at a Glance](#)

Resources: See [COVID-19 Vaccine Product Guide](#) for summary chart.

What You'll Learn

1

Storage Units
&
Data Loggers

2

Temperature
Monitoring

3

Expiration &
Beyond-Use
Dates

4

Vaccine
Preparation



Vaccine Preparation

Overview

Use [this administration checklist](#) (to be updated after FDA authorization) to ensure your patients receive sufficient protection after vaccination and to minimize revaccination efforts due to administration errors.

- Always check expiration & beyond-use dates before preparation and administration.
- Prepare vaccine according to the manufacturer fact sheet.
- Don't exceed the number of doses in the fact sheet.
- Never use partial doses (pool) from two or more vials to obtain a dose of vaccine.
- Administer COVID-19 vaccines in the correct site and route.

Resources: See [Requirements at a Glance](#), Vaccine Preparation.

Bookmark Key Resources

- [Requirements at a Glance](#)

Summary

You have now completed the lesson. You should now be able to:

- **list vaccine storage units that meet program requirements,**
Ranked in order: purpose-built or pharmaceutical; commercial or household standalone; combination units (frozen vaccines stored in standalone freezer)
- **monitor temperatures and report excursions**
Record temperatures twice daily; for excursions, quarantine vaccines, contact manufacturer for guidance, and report excursions in myCAvax.
- **manage expiration and beyond use dates**
[Requirements at a Glance](#), Managing Expiration & Beyond-Use Dates
- **identify key factors in proper vaccine preparation**
[Requirements at a Glance](#), Vaccine Preparation




Go to eziz.org/vfa-317/bap/ for provider alerts, job aids, Provider Call Center contact details, and more!

Looking for myCAvax Training Resources?

The Knowledge Center houses key job aids and videos that are updated every release to include enhancements across vaccine programs.

You can access the Knowledge Center from the myCAvax homepage (or at various places throughout the system) using the links as shown below.

 Need help? View our jobs aids in the [Knowledge Center](#), or [contact us](#).



myCAvax Coordinator Resources
 Job aids, quicksheets, and other resources specifically designed for Location and Organization Coordinators using myCAvax.

[Back to Knowledge Center](#)

Vaccine Order Requests

- Placing Standard Vaccine Order Requests**
 This document summarizes the steps to place standard vaccine order requests in the myCAvax system. Placing a vaccine order request is the first step to procure vaccine... [View](#)
- Placing Small Vaccine Order Requests**
 This document summarizes the small vaccine ordering process and steps to place small vaccine order requests in the myCAvax system. Placing a small vaccine order request... [View](#)
- Reviewing Shipments**
 This document explains how to navigate the Shipment tab, where users can find the shipping information for their vaccine orders. [View](#)

Vaccine Inventory Management

- Recording Waste Events**
 This document provides an overview of the Vaccine Waste Incident process and the steps to report wasted vaccines in the myCAvax system. Vaccine waste management is an... [View](#)
- Transferring Vaccine Inventory**
 This document provides an overview of how to log transfer and redistribution events. All instances of transfer and redistribution must be recorded using the... [View](#)
- Navigating and Posting on Vaccine Marketplace**
 The purpose of this document is to provide an overview of The Vaccine Marketplace. The marketplace allows you to post excess inventory that cannot be used and to request... [View](#)
- Recording Shipment Incidents**
 This document provides an overview of logging and editing shipment incidents in myCAvax. All issues, such as receiving vaccine shipments that have damaged vaccine or ancillary... [View](#)
- Recording Temperature Excursions**
 The purpose of this document is to provide an overview of reporting an Excursion Event. A Provider must report an excursion when vaccine doses are exposed to temperature... [View](#)

Done!

You have completed the **Storage & Handling** lesson.
Click “EXIT” at the top of page.