

# Section 4: Storage and Handling

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# Storage and handling

Proper storage and handling ensures that vaccine given to patients will protect them from disease.

## Vaccine Refrigerator and Freezer Requirements



Providers must have equipment that can maintain proper temperature conditions for storing vaccine. Providers with storage equipment that fails may be billed for the cost of spoiled vaccine.

**Refrigerators and freezers** used for vaccine storage must comply with the following requirements:

- Able to maintain required vaccine storage temperatures
  - Refrigerator: 2° – 8° Celsius (35° – 46° Fahrenheit)
  - Freezer: -15° – -50° Celsius (5° – -58° Fahrenheit)
- Large enough to hold the largest number of doses expected at one time without overcrowding (typically during school exclusion and influenza season)
- Dedicated to the storage of vaccines (and other pharmaceuticals only as necessary)

The Oregon Immunization Program urges providers to use pharmacy- or biologic- grade storage units. Equipment specifically designed for vaccine storage is more likely to be able to maintain the appropriate temperature range and reduce the risk of vaccine loss.

Clinics should use stand-alone refrigerators and stand-alone freezer units only (meaning a self-contained unit that only refrigerates or only freezes).

Household refrigerator/freezer combination units are discouraged and may not be allowed in the future. Clinics may opt to use the refrigerator compartment of a combined unit and store their frozen vaccine in a separate, stand-alone freezer.



CDC does NOT allow dorm-style refrigerators to be used for vaccine storage under any circumstances. Dorm-style refrigerators are no longer allowed for temporary, day storage.

## Vaccine Thermometer Requirements

**Thermometers** used for vaccine storage must meet the following requirements:

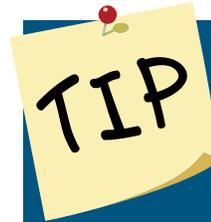
- Be continuous tracking
- Have an NIST traceable certificate of calibration
- Oregon Immunization Program and CDC recommend using digital data loggers with glycol-encased probes or a similar temperature buffered probe. This may be required in the future
- You may opt to have an alarm system in addition to continuous tracking thermometer

If purchasing a digital data logger, look for the following functions:

- Hi/Lo alarm for out-of-range temperatures
- Minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings, and device stops recording when full
- User can select the recording interval



The CDC requires clinics have at least one back-up continuous tracking thermometer with a current, valid certificate of calibration.



For more information about selecting vaccine storage units and thermometers, refer to the Oregon VFC Refrigerator and Freezer Guide, and the Oregon VFC Thermometer Guide at <http://1.usa.gov/ImmunizationProviderResources>

## Setting Up Your Vaccine Refrigerators and Freezers

- Determine where to store vaccines based on storage unit type

<b>Biologic- or pharmacy- grade</b>
Vaccine may be stored throughout the units
Leave 2 to 3 inches between the vaccine and the walls, ceiling, and floor
<b>Household-style</b>
Store vaccine on the middle shelves
Do not store vaccine in the door, on the floor, or in crisper bins
Do not store vaccine near the cold air vent

- Ensure refrigerator and freezer doors close properly and the unit is in good working order
- Store only vaccines and other medications in vaccine storage units
- Store vaccine in trays that allow good air circulation. Trays should be clearly labeled with the name of the vaccine
- Store vaccine in original box to prevent exposure to light
- Ensure separate stocks of privately purchased and state-supplied vaccine are clearly distinguishable
- Do not use outlets that are controlled by a wall switch or with built-in circuit switches
- Place “Do Not Unplug” stickers near the outlet and on storage equipment circuit breakers. Your Immunization Health Educator can provide you with these stickers
- Advise maintenance and cleaning personnel to keep vaccine storage units plugged in at all times
- Do not store food, drinks, or specimens (such as urine) in the vaccine refrigerator or freezer
- In refrigerators, fill up empty space with water bottles
- In freezers, fill up empty space with cold packs
- Do not place vaccine directly on cold packs

**TIP**

Additional tips to protect your vaccine supply:

- Limit access to vaccine refrigerators to key staff
- Install locks on storage units
- Install plug guards or locks on outlets
- Provide a backup power source, like a generator
- Periodically clean the storage unit interior and exterior

## Setting up Your Temperature Monitoring Equipment

- Thermometer must be placed in a central location near the vaccine stock
- Follow manufacturer guidelines for setting up your thermometer
- If using a digital thermometer:
  - » Set high and low alarm
  - » Set recording intervals at 5 minutes or less



The Oregon Immunization Program recommends that clinics monitor temperatures for a full week before moving vaccines into a new storage unit to ensure they are within range. After vaccines are added, continue to monitor temperatures closely.

## Monitoring Temperatures

- Maintain proper temperatures for vaccine storage at all times:
  - Refrigerator: 2° – 8° Celsius (35° – 46° Fahrenheit)
  - Freezer: -15° – -50° Celsius (5° – -58° Fahrenheit)
- Check and document temperatures twice daily using your continuous-tracking thermometer
- Twice daily temperature logs must include the time the temperature was checked and the initials of the recorder



If your clinic uses an alarm system, test your system on a routine basis to make sure it functions as expected. One way to test your alarm system is to wrap your hand around the probe, or place the probe in ice water, to intentionally trigger the alarm.

- If your clinic has more than one thermometer in your storage unit, make sure to always record twice daily temperature from the same continuous tracking thermometer
- Clinics using digital data loggers, or similar devices, should download data every week, preferably Monday mornings, or when returning to the clinic after a weekend or day of closure
- Keep temperature monitoring documentation for three years. This includes continuous tracking data, twice-daily logs, data from alarm systems, and incident log
- Have the calibration of your thermometers tested annually, or according to manufacturer recommendations
- If temperatures are outside the recommended range, restrict access and take immediate action to correct the problem. See **Out-of-Range Temperatures section**



CDC recommends that, in addition to documenting temperatures twice daily, clinics also document the high and low temperatures once per day. This is likely to become a requirement in the future.

# Out-Of-Range Temperatures

Quick action can prevent vaccine loss.

## If temperatures are currently out-of-range:

1. **Restrict use of the refrigerator and/or freezer.** Place a “DO NOT USE” sign on the unit and notify your clinic’s primary responsible staff
2. **Determine the cause and take action.** The following table provides examples of how you might handle different types of excursions

<p><b>If there is a slight temperature fluctuation due to inventory or the door being left ajar:</b></p>
<ul style="list-style-type: none"> <li>• Close the door. Recheck temperatures in 30 minutes to make sure they have returned to the recommended temperature range.</li> </ul>
<p><b>If there is a slight temperature excursion due to an unknown cause:</b></p>
<ul style="list-style-type: none"> <li>• Make a slight adjustment to the thermostat. Recheck temperatures in 30 minutes.</li> <li>• If temperatures have returned to normal range, continue to monitor temperatures closely until you are confident you have not over-adjusted and your storage unit can maintain the appropriate temperature.</li> <li>• If temperatures have not returned to the recommended temperature range, consider moving vaccine to a functioning unit, or implementing your vaccine emergency plan. See <b>Vaccine Emergency Plan section</b></li> </ul>
<p><b>If your refrigerator or freezer appear to be malfunctioning:</b></p>
<ul style="list-style-type: none"> <li>• Move vaccine to a functioning storage unit, or implement your vaccine emergency plan. See Vaccine Emergency Plan section</li> <li>• At your clinic, it might be appropriate to contact your maintenance, risk management, or quality control team to investigate. You may also want to contact the manufacturer of your vaccine storage equipment for guidance.</li> </ul>

**If there is a power outage:**

- Contact your power company. They may be able to tell you how long the power outage is expected to last.
- If the power outage is not expected to last longer than a couple of hours, do not move your vaccine. Most storage units will maintain their temperatures for a couple of hours as long as the door remains closed.
- If the power outage is expected to last longer than a couple of hours, implement your vaccine emergency plan. See **Vaccine Emergency Plan section**



Use the space below to document any additional information about how your clinic will manage out-of-range temperatures.

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3. **Notify your Health Educator.** (You do not need to notify your Health Educator for brief fluctuations due to conducting inventory)
4. **Document the Incident.** Include length of excursion and minimum and maximum temperatures, steps you took to address the excursion, and the outcome on your incident log



The decision about how long to wait before moving vaccine depends on many factors and may vary clinic-to-clinic. Consider the following:

- How warm or cold temperatures are
- Whether your thermometer measures ambient or buffered air
- How long it will take you to transport vaccine

Your Health Educator can help you think through these issues for your clinic.

### **If you discover an excursion while reviewing your continuous tracking data:**

1. **Restrict use of the refrigerator and/or freezer.** Place a “DO NOT USE” sign on the unit and notify your clinic’s primary responsible staff
2. **Determine the extent of the excursion,** and, if possible, the cause
3. **Contact your Health Educator** for anything more than a brief fluctuation due to conducting inventory
4. **Document the incident.** Include length of excursion, minimum and maximum temperatures reached, steps you took to address the excursion, and outcome on your incident log

### **If you suspect the excursion is due to a malfunctioning thermometer (rather than a true excursion):**

1. **Restrict use of the refrigerator and/or freezer.** Place a “DO NOT USE” sign on the unit and notify your clinic’s primary responsible staff
2. **Place backup thermometer in the storage unit** to confirm the temperature reading
3. **Note the reason** you suspect the issue is due to a malfunctioning thermometer.
4. **Contact your Health Educator**
5. **Document the incident** on your incident log

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