

Guidance for Receiving and Handling the Pfizer-BioNTech COVID-19 mRNA Vaccine (including dry ice procedures)

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This guide details all user processes and procedures that must be followed upon receiving the Pfizer-BioNTech COVID-19 vaccines including procedures for handling dry ice.



You must take the [Dry Ice Handling Safety Training course](#) in Learning Hub prior to handling dry ice.

Temperature Requirements for Shipping and Storage upon Receipt of the Vaccine

The Pfizer-BioNTech COVID-19 vaccines are shipped in an insulated thermal shipping container with dry ice to keep the vaccine frozen at ultra-low temperatures (-90°C to -60°C). To maintain the integrity of the Pfizer-BioNTech COVID-19 vaccines, they must be stored and handled at the recommended temperatures detailed below.

There are 3 presentations of the Pfizer-BioNTech COVID-19 vaccines that have different storage and handling requirements. The different presentations of the vaccines can be distinguished by the colours of the vial caps and carton label borders which are gray, blue or maroon.

It's critical that the vaccine is maintained under the temperature conditions outlined below **during shipment and after it arrives.**

Storage, Shipping and Handling Information:

Comirnaty® Omicron XBB.1.5 Gray Vial Cap and Label Border (for those 12 years of age and older):

Freezer Storage:

- The vaccine can be stored in a ULT freezer at -90°C to -60°C until its expiry date. If a ULT freezer is not available, the thermal shipping container may be used as temporary storage for up to 30 days. See [Replenishing thermal shipper with dry ice](#).
- **Do not store vaccine in a standard freezer at -25°C to -15°C.**

Refrigerator Storage:

- The vaccine can be stored in a refrigerator at +2°C to +8°C for 10 weeks.
- **Do not refreeze thawed vaccine.**

Handling Frozen Vials:

- Refer to the [Pfizer Shipping, Storage, Thawing and Use Guidelines](#).

Redistribution:

- Refer to the [Pfizer Redistribution Guidelines](#).

Thawing:

- A carton of 10 vials may take up to 6 hours to thaw in a refrigerator when removed from ULT frozen storage. A fewer number of vials will take less time to thaw.
- Vaccine intended for immediate use can be thawed at room temperature (up to +25°C) for 30 minutes when removed from ULT frozen storage. The vaccine can be stored at room

temperature for up to 12 hours prior to first vial puncture. Once punctured, the vial must be kept between +2°C to +25°C and used within 12 hours of first vial puncture.

Comirnaty® Omicron XBB.1.5 Blue Vial Cap and Label Border (for those 5-11 years of age inclusive):

Freezer Storage:

- The vaccine can be stored in a ULT freezer at -90°C to -60°C until its expiry date. If a ULT freezer is not available, the thermal shipping container may be used as temporary storage for up to 30 days. See [Replenishing thermal shipper with dry ice](#).
- **Do not store vaccine in a standard freezer at -25°C to -15°C.**

Refrigerated Storage:

- The vaccine can be stored in a refrigerator at +2°C to +8°C for 10 weeks.
- **Do not refreeze thawed vaccine.**

Handling Frozen Vials:

- Refer to the [Pfizer Shipping, Storage, Thawing and Use Guidelines](#).

Redistribution:

- Refer to the [Pfizer Redistribution Guidelines](#).

Thawing:

- A carton of 10 vials may take up to 6 hours to thaw in a refrigerator when removed from ULT frozen storage. A fewer number of vials will take less time to thaw.
- Vaccine intended for immediate use can be thawed at room temperature (up to +25°C) for 30 minutes when removed from ULT storage. The vaccine can be stored at room temperature for up to 12 hours prior to first vial puncture. Once punctured, the vaccine must be kept between +2°C to +25°C and used within 12 hours of first vial puncture.

Comirnaty® Omicron XBB.1.5 Maroon Vial Cap and Label Border (for those 6 months – 4 years of age inclusive):

Freezer Storage:

- The vaccine can be stored in a ULT freezer at -90°C to -60°C until its expiry date. If a ULT freezer is not available, the thermal shipping container may be used as temporary storage for up to 30 days. See [Replenishing thermal shipper with dry ice](#).
- **Do not store vaccine in a standard freezer at -25°C to -15°C.**

Refrigerated Storage:

- The vaccine can be stored in a refrigerator at +2°C to +8°C for 10 weeks.
- **Do not refreeze thawed vaccine.**

Handling Frozen Vials:

- Refer to the [Pfizer Shipping, Storage, Thawing and Use Guidelines](#).

Redistribution:

- Refer to the [Pfizer Redistribution Guidelines](#).

Thawing:

- A carton of 10 vials may take up to 2 hours to thaw in a refrigerator when removed from ULT frozen storage. A fewer number of vials will take less time to thaw.
- Vaccine intended for immediate use can be thawed at room temperature (up to +25°C) for 30 minutes. The vaccine can be stored at room temperature for up to 24 hours with no more than 12 hours from the time of dilution. Once diluted the vaccine must be kept between +2°C to +25°C and used within 12 hours from the time of dilution, ensuring that the total cumulative time at room temperature (> +8°C to +25°C) does not exceed 24 hours.

Cold Chain Maintenance

It's important to regularly monitor the temperature of the vaccine at the start and end of each work day. If storing in an ultra-low temperature (ULT) freezer, standard freezer or thermal shipper, record the temperature using the [freezer temperature form](#). If storing the vaccine in a refrigerator prior to use, use the [refrigerator temperature form](#).



If a cold chain break occurs fill out the [cold chain incident form](#) (available as [PDF](#) and [Excel](#)) and fax it to your [local public health unit](#).

Equipment

The following equipment is required for receiving and storing the vaccine:

- Ultra-low temperature freezer, standard freezer or refrigerator depending upon the temperature at which the vaccine is intended to be stored
- Temperature monitoring device suitable for the intended storage temperatures
- [Personal protective equipment](#) (PPE) suitable for handling dry ice

Dry Ice

Dry Ice Facts

Dry ice is the frozen form of carbon dioxide. When heated, most frozen solids melt to a liquid form, but dry ice transforms directly into a gas (sublimation). Dry ice sublimates at temperatures at or above -78°C. The main hazards of dry ice include **asphyxiation** and **burns**. Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, resulting in asphyxiation. Exposed skin should be protected from contact with dry ice. **To ensure appropriate controls are in place, please refer to the [Dry Ice Safety Data Sheet](#) BEFORE accessing the contents from the thermal shipping container.**

Dry Ice Handling

When you receive the thermal shipping container, inspect to confirm you received the number of vial trays you ordered. **Do not open the vial trays or remove vials until you are ready for thawing or use.** If there are any issues or concerns with the shipment, contact Pfizer Customer Service immediately at 1-833-VAX-COVI (1-833-829-2684).





Use caution when lifting the shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the shipping container can weigh up to approximately 36.5 kg (81 lbs). Review [the guidelines regarding lifting heavy items](#).

When preparing to handle dry ice, you'll need to take precautions. Before opening the thermal shipping container:

- Make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, causing asphyxiation.
- Make sure you are wearing safety glasses with side shields or safety goggles and cryogenic gloves when handling dry ice. Please refer to [Equipment and PPE](#) for more information on appropriate PPE.

To ensure all appropriate safeguards are in place, please refer to the [Dry Ice Safety Data Sheet](#).

General Safety Guidance for Dry Ice **Caution**

	<p><u>Do not touch & avoid eye contact</u> Use cryogenic gloves when removing or adding dry ice to prevent cold burns and frostbite. Avoid contact with face and eyes. Wear appropriate personal protective equipment (PPE) like safety glasses with side shields or safety goggles when handling dry ice or items stored with dry ice.</p>
	<p><u>Do not eat</u> Dry ice is harmful if eaten or swallowed. If ingested, seek immediate medical care.</p>
	<p><u>Do not store in confined spaces</u> Dry ice changes to a gas very rapidly at room temperature, displacing oxygen. Only use dry ice in open or well-ventilated areas.</p>
	<p><u>Do not place in airtight containers</u> If dry ice is packaged in an airtight container, fridge freezer, or anywhere that does not allow for release of the gas, these containers may explode as dry ice rapidly expands to a gas when exposed to temperatures above -78°C. Only store dry ice in a container with a lid that is not airtight.</p>

Ventilation for Dry Ice

At room temperature (including most cold storage temperatures), dry ice becomes carbon dioxide gas, which may cause difficulty breathing or suffocation. Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces.

- Be sure to choose a well-ventilated room when working with dry ice or storing dry ice.
- Ensure room doors and windows (where possible) are open to allow air exchange.

- If dry ice has been in a closed area, trailer, or container, open doors and allow adequate ventilation before entering the storage area.
- If you feel short of breath or develop a headache, these may be signs that you have inhaled too much carbon dioxide. Leave the area immediately.

First Aid Measures When Handling Dry Ice

- After inhalation: Relocate to an area with fresh air. Seek medical attention if you develop symptoms, such as difficulty breathing.
- After skin contact: flush affected area with lukewarm water (not hot water). Do not rub the affected area. Seek medical attention if the skin blisters or comes off.
- After eye contact: Flush eyes with lukewarm water (not hot water) for at least 15 minutes, lifting lower and upper eyelids. Remove contacts if worn. Contact ophthalmologist.
- For information on first aid measures, please refer to the [Dry Ice Safety Data Sheet](#).

Dry Ice Disposal

Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily sublime from a solid to a gas.

- DO NOT leave dry ice in an unsecured area.
- DO NOT drain or flush in toilet.
- DO NOT dispose in the trash.
- DO NOT place in a closed area such as an airtight container or walk-in cooler.

Thermal shipping containers

There are two types of thermal shipping containers: a Softbox thermal shipping container and an AeroSafe thermal shipping container. Their outer appearance is different, but their components are very similar. **Do not discard the original thermal shipping container or any of its components including the box it arrived in as the box will be used to return the thermal shipping container and components to Pfizer.**

The thermal shipping container you received can weigh up to approximately 36.5 kg (81 lbs) and should be opened on the floor, as it may be heavy.

Softbox



Item	Description
A DRY ICE POD	Holds the top layer of dry ice.
B VIAL TRAYS	Vial trays contain multiple-dose vials. Each thermal shipping container will have up to 5 vial trays inside.
C BOX THAT HOLDS THE VIAL TRAYS	Box within the thermal shipping container that includes the vial trays. This box has handles and can be fully removed from the thermal shipping container.
D FOAM LID	Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box.
E THERMAL SHIPPING CONTAINER	Outer box of the thermal shipping container.

AeroSafe



Item	Description
A DRY ICE POD	Holds the top layer of dry ice.
B VIAL TRAYS	Vial trays contain multiple-dose vials. Each thermal shipping container will have up to 5 vial trays inside.
C BOX THAT HOLDS THE VIAL TRAYS	Box within the thermal shipping container that includes the vial trays. This box can be fully removed from the thermal shipping container.
D FOAM LID	Top foam lid that can be removed from the AeroSafe thermal shipping container. The temperature-monitoring device can be found embedded in the foam lid.
E THERMAL SHIPPING CONTAINER	Outer box of the thermal shipping container.

Unpacking Thermal Shipping Containers

Equipment and PPE

Ensure you have the proper equipment before dealing with dry ice containers, dry ice bags and thermal shippers. Always read [usage instructions specified by the manufacturer](#).

PPE required

- Apron (only if available)
- Lab coat or coveralls
- Cryogenic gloves
- Dry ice scoop
- Safety glasses with side-shields or full-face shield
- Vial tongs

Vaccine delivery to health units

Vaccine shipments require immediate attention.

Receiving dry ice shipments and accessing vaccines inside thermal shipper

1. For both types of thermal shipping containers, you must first break the seal to open.

Softbox



AeroSafe



2. When you open the thermal shipping container, **you will see a temperature-monitoring device embedded in the foam lid**. In the Softbox thermal shipping container, this lid will be attached to the thermal shipping container.



Take caution when opening the Softbox lid, as you'll notice one flap of the thermal shipping container is permanently affixed to the lid. Do not pull this flap. When opening the lid, use the three-finger holes in the foam lid, which will then allow the lid to swing open.

The Softbox thermal shipping container has an attached foam lid, which is permanently affixed to the lid.

The AeroSafe thermal shipping container has a foam lid that comes completely off.

When opening the AeroSafe foam lid, gently remove the entire lid (with the temperature-monitoring device still attached) and place to the side. Do not remove the temperature-monitoring device from the inner lid or container, because it must be returned with the thermal shipping container after use.

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3. The temperature–monitoring device continuously monitors the temperature during shipment, to ensure the frozen vaccine product has been maintained at the required temperature during transport to vaccination centers. The temperature-monitoring device you receive will be either a Controlant Real-Time Monitor or a Sensitech Temperature Monitor.



The temperature-monitoring device you receive will be either a Controlant Real-Time Monitor (pictured above to the left) or a Sensitech® Temperature Monitor (pictured above to the right).

Upon receipt, press and hold the stop button for 5 seconds. Sites are responsible for continuing to monitor the product storage temperature using their own monitoring device.

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4. Make sure that you are now wearing cryogenic gloves and safety glasses with side shields or safety goggles as you prepare to handle layers of the container that have dry ice.

Beneath the foam lid is the dry ice pod, which holds a layer of dry ice to help maintain the temperature of the multiple-dose vials.

There will also be dry ice in compartments in the container that surround the box that holds the vial trays.

If using the thermal shipping container as temporary storage, both of those areas will need to be filled when re-icing.

Using your cryogenic gloves, remove the dry ice pod. If shipper contains dry ice pellets then use scoop to remove dry ice pellets and store in another container (dry ice chest). Place dry ice container in a well-ventilated area for disposal. Clearly label container as containing dry ice.



The Softbox thermal shipping container has compartments that allow dry ice to be distributed on all sides of the box. They are only accessible after removing the dry ice pod.



The AeroSafe thermal shipping container has dry ice compartments on the sides that can be accessed with the dry ice pod still in the container.

5. You will now see the box that holds the vial trays. Open the box and you will see the vial trays. There will be up to 5 vial trays inside. Carefully remove the vial trays. Leave the box that holds the vial trays inside the thermal shipping container.

Remember, do not open the vial trays or remove vials until you are ready for thawing or use.



6. **After removing the vial trays from the thermal shipping container, you must immediately store the vaccine product in the ultra-low-temperature freezer*.**

* Please refer to page two ([Temperature Requirements for Shipping and Storage Upon Receipt of the Vaccine](#)) for more information on storing the vaccine at standard freezer or refrigerator temperatures.



Masks were worn due to pandemic.

Receiving dry ice shipments

1. Prepare your workspace in advance, so dry ice can be placed in an appropriate location to facilitate thermal shipper replenishment.
2. Dry ice may be received in Styrofoam containers or bags. Both may be heavy. Please lift safely.
3. Arrive at the receiving site prepared with PPE: Safety glasses with side-shields or full-face shield, lab coat or coveralls, apron (if available) and cryogenic gloves.

Replenishing thermal shipper with dry ice

If an ultra-low-temperature freezer is not available, the thermal shipping container may be used as temporary storage. **The thermal shipping container maintains a temperature of -90°C to -60°C. If using the thermal shipping container as temporary storage, it must be opened, inspected, and replenished with dry-ice pellets (20-23 kg, recommended sizes: 9-16 mm) within 24 hours of receipt.**

1. Wear safety glasses with side-shields or full-face shield, lab coat or overalls, apron (if available) and cryogenic gloves.
2. Set up thermal shipper and dry ice container or bag in close proximity to facilitate handling. Open dry ice container or bag; do not place your head inside the opening of the container or bag.
3. Use scoop to transfer dry ice from the container or bag to the thermal shipper. Close the thermal shipper lid.

4. Clearly [label dry ice](#) container or bag and thermal shipper to identify them as containing dry ice.
 - a. Dry ice is classified as a Class 9 material under Transport of Dangerous Goods (TDG) Regulations
 - b. TDG Regulations do not apply to dry ice being used as refrigerant for vaccines in thermal shippers
 - c. It is good practice to [clearly label](#) the container, bag and thermal shipper as containing dry ice. Place label on vertical side of shipper (not top or bottom).
5. After replenishing the thermal shipping container, inspected vial trays should be returned inside and the box taped closed. You should ensure to monitor the temperature inside the thermal shipper using your own monitoring device. Record temperatures twice daily at the beginning and end of each work day on the [Freezer Temperature Form](#).
 - a. To help maintain the level of dry ice and the temperature of the vaccine product
 - i. **2x/Day:** It is recommended that the thermal shipping container not be opened more than two times a day
 - ii. **3 Minutes:** The thermal shipping container should not be opened for more than three minutes at a time
 - iii. **5 Days:** The thermal shipping container should be re-iced every five days
6. It is recommended that the thermal shipping container itself be stored at 15°C to 30°C in order for the thermal shipper to maintain the ultra-low temperatures required.

Notes on more frequent openings and vaccination site closures: If more frequent openings are necessary, more frequent dry ice replenishment will be required. Ensure that the thermal shipping container is re-iced at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays.



For detailed instructions on re-icing/replenishing the thermal shipper, refer to [Pfizer/BioNTech's instructions on dry ice replenishment](#).

Dry ice storage

Dry ice should be ordered to match replenishment timing to avoid dry ice storage. Store excess dry ice supply in dry ice containers or chests with lid on (ensure it is not airtight), kept away from other workers and occupied workspaces. Inappropriate containers include cardboard boxes and rubber-insulated, airtight bags. Only store dry ice in a space that is well ventilated.

Discarding Dry Ice

After the thermal shipping container is no longer needed, you can discard the dry ice.

Take necessary precautions by reviewing the [Dry Ice Safety Data Sheet](#).

1. Wear safety glasses with side-shields or full-face shield, lab coat or coveralls, apron (if available) and cryogenic gloves.
2. Use a scoop to transfer excess dry ice into a container.
3. Clearly label container.

4. Let container sit in a well-ventilated area away from workers, to let dry ice change to gas. This may take a few days depending on the quantity of dry ice.
 - **DO NOT leave dry ice in an unsecured area.**
 - **DO NOT drain or flush in toilet.**
 - **DO NOT dispose in the trash.**
 - **DO NOT place in a closed area such as an airtight container or walk-in cooler.**

Returning Thermal Shipping Containers and Real-time Temperature Monitors

The thermal shipping container may be used as temporary storage for up to 30 days from delivery. After use, the thermal shipping container, including the temperature-monitoring device, must be returned to the supplier to help Pfizer fulfill its commitment to using reusable resources.

When the thermal shipping container is ready to be returned and all the components are inside, seal it with tape. A preprinted return shipping label will be included inside the thermal shipping container or already affixed to the inner flap of the thermal shipping container.

Note: Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice.

Blank sticker labels to place over the UN1845 markings can be found on the back page of the Shipping and Handling Guidelines.

- When coordinating the return of the Softbox thermal shipping container, apply the preprinted return shipping label over the existing shipping label.
 - Elements required for return:
 - Temperature-monitoring device
 - Foam lid (remains attached to box)
 - Dry ice pod
 - Box that holds the vial trays
- When coordinating the return of the AeroSafe thermal shipping container, follow instructions on the inner flap of the thermal shipping container to ensure the return label is facing outside.
 - Elements required for return:
 - Temperature-monitoring device
 - Foam lid (can be fully removed from box)
 - Dry ice pod
 - Box that holds the vial trays

You can contact the carrier identified on the return label to arrange the return. Place the thermal shipping container at the front desk, or a designated pickup location.

For returns assistance, please contact Pfizer Customer Service at 1-833-VAX-COVI (1-833-829-2684).

Resources

Cold Chain

- [Appendix E – Management of Biologicals](#) for more information on routine practices for the management of biologicals at refrigeration temperatures (+2°C to +8°C)
- [Freezer temperature log form](#)
- Refrigerator temperature [log form](#) | [instructions](#)
- Cold chain incident form [PDF](#) | [Excel](#)

Pfizer-BioNTech Vaccine

- [Pfizer-BioNTech COVID-19 vaccine website](#)
- [Pfizer-BioNTech Comirnaty® Omicron XBB.1.5 vaccine product monograph](#)
- [Pfizer-BioNTech COVID-19 vaccine shipping and handling guidelines](#)

Standard Operating Procedures

- [COVID-19 Immunize BC Operations Centre: Standard Operating Procedures](#)

Dry Ice

- [Dry ice safety training on LearningHub](#)
- [Dry ice labels](#)
- [Pfizer-BioNTech dry ice safety data sheet](#)
- [Pfizer-BioNTech instructions on dry ice replenishment](#)
- [Linde safety data sheet](#)
- [University of Notre Dame's standard operating procedure for safe handling of dry ice](#)
- [University of Washington's guide to working safely with dry ice](#)