

Management of COVID-19 Pfizer (COMIRNATY™) vaccine from shipper to ultra-low temperature freezer

Last updated on 21 February 2021 with:

- Additional guidance around use of lift to move shipper containing dry ice

Purpose

This Procedure describes the process of unpacking and storing frozen COVID-19 Pfizer (COMIRNATY™) vaccine in an ultra-low temperature freezer. The nature of this vaccine requires it to be kept at extremely low temperatures during shipment and storage after it arrives. To achieve this, the multiple dose vials of the frozen vaccine are shipped in insulated thermal shipping containers containing dry ice. This allows the vaccine to remain frozen at this low temperature.

Scope

Unpacking of COVID-19 Pfizer (COMIRNATY™) vaccine from shippers containing dry ice (carbon dioxide) and storage in ultra-low temperature freezers, and safe disposal of the dry ice.

Responsibility

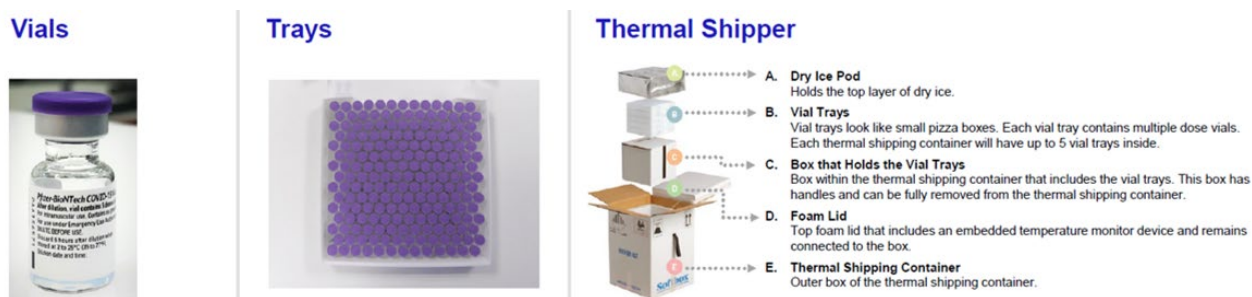
- Only staff suitably trained and competent in handling dry ice (carbon dioxide) may perform this activity. In addition to the PPE provided, staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.
- Handling of the frozen vaccine trays and vials should be performed in pairs. COVID-19 safety measures should also be maintained as far as reasonably practicable.
- It should be noted that the shipper can weigh as much as 36kg so safe manual handling practices need to be observed.
- At all stages the vaccine should be handled carefully, avoiding jarring and shaking as much as possible.

Health and safety rules for handling dry ice and working with ultra-low temperature freezers

- Local safe work practices for using ultra low temperature freezers and dry ice must be observed.
- Dry ice and ultra-low temperature freezers may cause cold burns, and carbon dioxide gas may cause asphyxiation if it is not allowed to escape into the atmosphere.
- Always work in pairs when unpacking deliveries from dry ice in a well-ventilated area.
- PPE for working with the shippers and ultra-low temperature freezer includes goggles, temperature resistant gloves (or gauntlets) and apron.
- In addition to the PPE, staff must wear clothing that covers their legs and arms, and shoes must be completely enclosed.
- Always ensure good ventilation:
 - Ensure that the area is well ventilated and not enclosed

- Never have personnel accompany move shippers containing dry ice if moving via a lift
- Never place shippers containing dry ice in a cold store or fridge, or other unventilated areas
- Never drive in a car or other vehicle with dry ice and no ventilation.
- Always leave the dry ice in the shipper.
- Do not store dry ice in a sealed airtight container as it will expand and become carbon dioxide gas. This can cause an explosion.
- First aid for dry ice burns is the same as for heat burns: treat with tepid running water and seek medical attention.
- Dry ice rapidly sublimates to carbon dioxide gas even at very low temperatures, which may cause difficulty breathing or suffocation. If dry ice has been in a closed area, trailer, or container, open doors and allow adequate ventilation before entering. 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.
- Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces. Operational practices for accessing a closed area where dry ice is present should be reviewed and agreed upon with your Work, Health and Safety officer.

Specifications for COVID-19 Pfizer (COMIRNATY™) vaccine candidate packaging



Vials	Trays	Thermal shipper
2mL type 1 glass preservative free	Single tray holds 195 vials	Holds a minimum of 1 tray, and maximum of 5 trays
A single dose of COMIRNATY™ once diluted and drawn up is 0.3mL		Payload carton submerged in dry ice pellets
5 doses per vial using standard stock needles and syringes	975 doses using standard stock needles and syringes	Thermal shipper keeps ULT -90°C to -60°C for up to 10 days if stored at 15°C to 25°C without opening
6 doses per vial using low dead space needles and syringes (when available)	1,170 doses using low dead space needles and syringes (when available)	Do not open the thermal shipper more than 2 times a day and do not open for more than 3 minutes at a time

Procedure

- A local safe work practice must be developed to manage this procedure. If there is any distance to travel between the shipper and the freezer use a trolley instead of carrying the shipper box.
- Familiarise yourself with the shipper, how you will move within the space you are in, who will do which task and safe handling before commencing.
- Collect ultra-low temperature handling PPE and disposable gloves to wear under the gauntlets.
- Work in the designated well-ventilated area, as close as possible to the freezer.

- Check that the shipper is within its expiry date.
 - Check the control panel on the freezer to check that the temperature is within range (check 'temp- alarm' light is not illuminated) and record this on the appropriate documentation
 - Put on the PPE.
 - Unlock the freezer.
 - Break the seal on the shipper.
 - 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 will 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 temperature-monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperature during transport to vaccination centres. Upon receipt, press and hold the stop button for 5 seconds. Sites are responsible for continuing to monitor the product storage temperature. NB These devices need to be returned to Pfizer.
 - If any shippers, trays or vials need to be quarantined following the checks, ensure they are clearly identified in the freezer e.g. in a separate bag. Such quarantine may be for deliveries where the temperature logger shows a temperature excursion.
 - Make sure that you are now wearing waterproof insulated 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 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. Using your waterproof insulated gloves, remove the dry ice pod.
 - You will now see a lid for 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. Check you have the number of trays you expected.
 - Remove the box that holds the vial trays from the thermal shipping container in order to access the vial trays.
- Caution:** If you feel resistance when trying to remove the box that holds the vial trays, do not pull it out by force. Keep the box inside the thermal shipping container and remove the vial trays separately using the clear plastic straps.
- Replace the inner lid on the shipper to contain the dry ice.
 - Open the outer and inner freezer door and immediately transfer the vial trays into the freezer, close the inner and outer door and lock it (remove gauntlets if necessary).

Receiving ULT shipper

Receipt of ULT Thermal Shipper at Point of Vaccination



- Upon receipt, disable the GPS enabled logger by pressing the stop button on the device
- Immediately transfer trays to ULT freezer or keep stored in thermal shipper.

- Temperature monitoring is recommended if shipper is used as temporary storage using own monitoring device.

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

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If ULT Freezer Available; Transfer Trays to ULT Freezer



- Remove the dry ice pod from the thermal shipping container
- Remove payload box, remove vial trays(s), inspect outer cartons for damage and transfer to freezer
- **Closed vial trays containing 195 vials** may be at room temperature (<25°C) for up to **5 minutes** for transfer between ULT environments
- After vial trays are placed in the freezer following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again for transfer to another ultra-low temperature environment
- Close the shipper box and use the trolley to remove it to a pre-identified secure, well-ventilated location.
- Keep on all PPE, except gauntlets if it is essential to remove them e.g. to open a locked door.
- Put gauntlets back on again (if removed) and position the shipper box with lid ajar.
- Ensure the location is secured (e.g. a well-ventilated space with a warning sign) and leave to allow the carbon dioxide to turn to gas (sublime) for at least 24 hours.
- Check the control panel on the freezer again to ensure 'temp-alarm' light is not illuminated according to freezer Temperature Monitoring and Recording).
- Remove PPE and store in a designated clean, dry location. If the goggles or visor may be worn by someone else, wash in soapy water or wipe them down with a bactericidal wipe and leave to dry.
- Remove and discard the disposable gloves according to local waste disposal practices and wash your hands.
- Once the carbon dioxide has completely sublimed, return the shippers with logs to Pfizer as directed. This will include covering the labels regarding the shipper containing dry ice. Use peel-off stickers to cover UN1845 markings.

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

COVID-19 Pfizer (COMIRNATY™) vaccine images

Ultra-low temperature thermal shipper

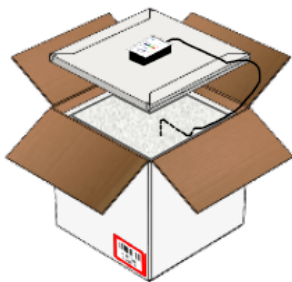
Item	Description
1	Dry Ice Pod
2	Vial Trays
3	Payload Box (Holds Vial Trays)
4	Inner Lid
5	Outer Carton

Shipper Dimensions L x W x H 15.75" x 15.75" X 22.04"
Single Tray Dimensions 9" x 9" x 1.6"

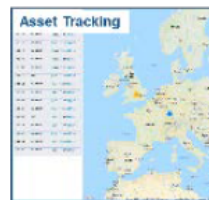


Softbox Medium ULT Weights and Dimensions	
Empty Shipper Weight	8.5 kgs
Available Payload Space	9.65" x 9.65" x 9.49"
External Dimension	15.75" x 15.75" x 22.04"
Amount of Dry Ice	20 kgs
Take Weight w/ Dry Ice	31.5 kgs
Total Weight w/ 1 Vial Tray	32.6 kgs
Total Weight w/ 5 Vial Trays	36.7 kgs

Temperature & Location Tracking During Transportation



Controllant Reusable RTM Logger



- Each thermal shipper has a reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPC monitoring device to ensure end to end distribution within required temperatures
- Temperature records of shipment will be provided within 1 hour of pushing the stop button.