

Thermal Shipper Unpackaging & Re-Icing

Current as of December 6, 2020



Current as of December 2020, Operation Warp Speed has requested that prior to the potential FDA authorization of the Pfizer-BioNTech Covid-19 Vaccine, Pfizer send select training materials containing information for properly storing, preparing and administering the vaccine to anticipated vaccination sites. Although there is no guarantee that the vaccine will be authorized by FDA, given the urgency of the pandemic, providing these materials in advance will enhance sites' preparation. Materials, specifications and assumptions are subject to change. For the most up-to-date materials upon authorization, please visit www.cvdvaccine.com. Pfizer will not begin shipment of the vaccine unless and until FDA has granted an Emergency Use Authorization. PFIZER CONFIDENTIAL.

Change Log

Version	History of Changes
01	Initial version
02	Updated formatting and pictures for clarity.
03	<p>Softbox</p> <ul style="list-style-type: none"> • Section 5.1 Unpackaging Section: <ul style="list-style-type: none"> ○ Step 5, updated with payload box. ○ Step 6, updated that inspections must be completed within 5 mins. • Appendix 1, Softbox Diagram updated with payload box. <p>Aerosafe</p> <ul style="list-style-type: none"> • Section 5.1 Unpackaging Section: <ul style="list-style-type: none"> ○ Step 7, updated that inspections must be completed within 5 mins.
04	<p>Softbox</p> <ul style="list-style-type: none"> • Section 3.2 Recommendations updated from 1 min to 3 mins for opening thermal shipping container. • Section 5.1 Unpackaging Section: <ul style="list-style-type: none"> ○ Step 6, added information about vial trays not being out longer than 10 mins. <p>Aerosafe</p> <ul style="list-style-type: none"> • Section 3.2 Recommendations updated from 1 min to 3 mins for opening thermal shipping container. • 5.1 Unpackaging Section: <ul style="list-style-type: none"> ○ Step 7, added information about vial trays not being out longer than 10 mins.
05	<ul style="list-style-type: none"> • Removed Aerosafe as thermal shipping container. • Updated High Level Requirements when using the thermal shipping container as temporary storage. • Minimum dry ice quantity updated to 20 kg. • Unpackaging section updated for clarity on certain steps. Verbiage was updated to indicate that the vial trays must be immediately stored in ULT freezer upon receipt. • Re-Icing section streamlined.

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Softbox Medium

1. Overview

The purpose of this controlled document is to provide unpackaging and re-icing requirements on the Softbox Medium ULT Parcel Shipper with Dry Ice.

CAUTION: 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. Eye protection is recommended (for example, safety glasses with side shields).

Appropriate training should be conducted for personnel handling dry ice and documented within their relevant training system as required.

2. General Requirements

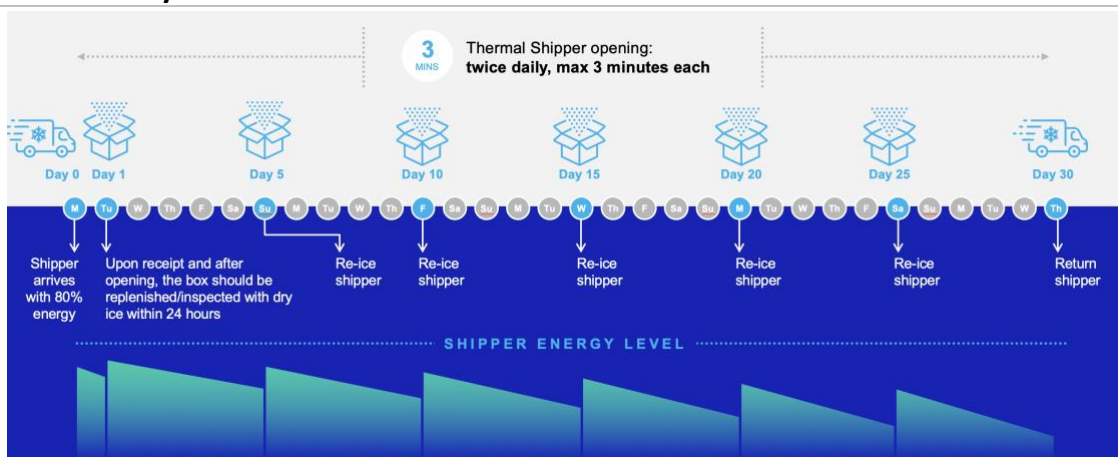
2.1. Materials

Specification Number	Description
N/A	Waterproof Thermal Gloves
N/A	Safety Glasses with Side Shields
N/A	Carton Sealing Tape
N/A	Dry Ice Pellets (10 to 16 mm)

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2.2. High Level Requirements (Using Thermal Shipping Container as Temporary Storage)

- The thermal shipping container is qualified with a minimum of 20 kgs of dry ice pellets (10 mm – 16 mm pellets). Upon receipt and after opening, the box should be replenished/inspected with dry ice within 24 hours by adding dry ice to the maximum within the payload insert areas and dry ice pod.
- The thermal shipping container should be stored at 15° to 25° C (59° to 77° F).
- The thermal shipping container should be re-iced every **5 days**. This can help maintain the level of dry ice and the temperature of the vaccine product. It is recommended that the thermal shipping container not be opened more than **2 times a day**, and shouldn't be opened for more than **3 minutes** at a time. If that is followed, the thermal shipping container should then be re-iced every **5 days**.



- **Remember:** The thermal shipping container is a passive (non-compressor) device that contains dry ice as the energy source to maintain the required temperatures when maintained properly as defined by Pfizer instructions. The dry ice in the thermal shipper will deplete over a number of days (duration will vary depending on use and care), which will impact how long the shipper holds the temperatures. This differs from an ultra-low-temperature freezer, an active (electronically powered, compressor-driven) device, which when plugged in, is designed to maintain ultra-low temperatures indefinitely. The longer the thermal shipping container remains closed, the longer it will take for the dry ice to deplete.
- The thermal shipping container and Controlant monitor must be returned within the allowable time allotted for use.

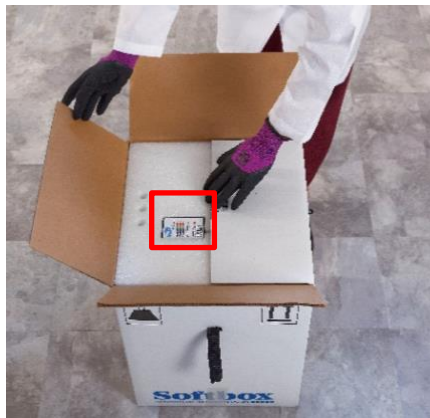
3. Unpackaging and Re-icing Overview

3.1. Unpackaging

1. 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, resulting in asphyxiation.
2. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.



3. When you open the thermal shipping container, you will see a temperature monitoring device embedded in the foam lid. The temperature monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperatures during transport.



Press and hold the stop button for 5 seconds on the Controlant Monitor. Do not remove the Controlant monitor from the foam lid or container because it must be returned with the thermal shipping container after use.

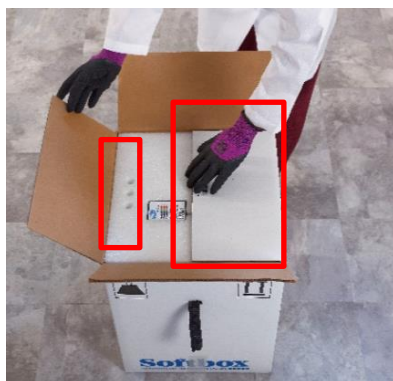
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Note: In cases where the thermal shipping container contains a Sensitech TempTale Ultra Temperature Monitor press and hold the Stop button for 1-3 seconds.

Sites are responsible for continuing to monitor the product storage conditions.

4. Open the lid.

Note: One side of the thermal shipping container is permanently affixed so it is recommended to use the three finger hole die-cut on the foam.



Once the lid is opened the dry ice pod will be seen as illustrated below.



5. While wearing insulated (thermal) gloves, take out the Dry Ice Pod.



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6. Remove the Payload Box from the thermal shipper by carefully pulling directly upwards with the handles.



7. Immediately store vial trays in an ultra-low temperature (ULT) freezer. Remember, do not open the vial trays until you are ready to remove vials for thawing or use.



*If an ULT Freezer is not available, the thermal shipping container may be used as temporary storage. Refer to 2.2 High Level Requirements Section (Using Thermal Shipping Container as Temporary Storage) and then immediately process to Re-Icing Section of this procedure for further details on using the thermal shipping container as temporary storage.

8. If not using the thermal shipping container as temporary storage, insert all components back into the thermal shipping container for return.

Dry ice must be discarded in a well ventilated area before considering returning the thermal shipping container.

Thermal Shipper Unpackaging & Re-Icing

3.2. Re-Icing

1. 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, resulting in asphyxiation.

2. Below is an overview of the components within the thermal shipping container for re-icing activities.



3. In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside and open the lid using the three holes.



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4. The dry ice pod is visible. While wearing waterproof thermal gloves, take out the Dry Ice Pod.



5. Fill the sides of the payload sleeve with dry ice until it's equal with the corrugated structure.



6. Reinsert the Dry Ice Pod and fill with dry ice leaving room between dry ice level and sides of shipper.



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7. Close the Lid, the Outer Corrugated Shipper and reseal with tape and store back in a well ventilated location.



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