

# Selecting the right cold storage for the COVID-19 vaccines

## Background

Properly storing and handling vaccines is critical for maintaining their optimal potency. Failure to do so can compromise the efficacy of the vaccines, cost thousands of dollars in wasted vaccine and revaccination, and potentially leave a population vulnerable to infection. The World Health Organization (WHO) estimates that more than 50 percent of vaccines may be wasted globally every year due to issues related to temperature control, logistics, and shipment conditions [1]. As vaccines are being rolled out globally with the aim of ending the SARS-CoV-2 crisis, understanding the standards for vaccine management systems and selecting the right freezer for vaccine storage become important.

## COVID-19 vaccine storage

In December 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the Moderna™ COVID-19 vaccine for active immunization against SARS-CoV-2 infection, and recommended strict guidelines for the proper storage of the vaccine. According to the “Fact sheet for healthcare providers administering vaccine (vaccination providers)” [2], the storage guidelines are as follows:

- Multiple-dose vials of the Moderna COVID-19 vaccine are to be stored frozen between  $-25^{\circ}$  and  $-15^{\circ}\text{C}$  ( $-13^{\circ}$  to  $5^{\circ}\text{F}$ ); the  $-25^{\circ}$  to  $-15^{\circ}\text{C}$  range is based on the cabinet temperature of the freezer.
- The vaccine vials need to be stored in the original carton to protect them from light. It is recommended not to store the vials on dry ice or below  $-40^{\circ}\text{C}$  ( $-40^{\circ}\text{F}$ ).
- The vaccine vials can be stored refrigerated between  $2^{\circ}$  and  $8^{\circ}\text{C}$  ( $36^{\circ}$  to  $46^{\circ}\text{F}$ ) for up to 30 days prior to first use.

Similar guidance can be found in the EUAs for vaccines developed by Pfizer, AstraZeneca, and Janssen Pharmaceuticals, as well as other globally approved COVID-19 vaccines. Each EUA stipulates the proper storage conditions for their products in terms of time and temperature. You should always refer to the vaccine manufacturer and local regulatory agencies for guidance on the proper handling and storage of these vaccines.

## Temperature monitoring device

The U.S. Centers for Disease Control and Prevention (CDC) provides a yearly updated guide, the “Vaccine Storage and Handling Toolkit”, which provides guidelines on how to measure the cabinet temperature of a refrigerator or freezer [3]. In the 2020 edition, the CDC recommends the use of a temperature monitoring device (TMD). To protect your vaccines, an accurate temperature history that shows actual vaccine temperatures is critical; this in turn can prevent vaccine wastage due to loss of potency arising from out-of-range temperature storage. A specific type of TMD called a digital data logger (DDL) is recommended by the CDC.

## Digital data logger

A DDL provides superior accuracy of temperature information of a storage unit, which includes data on the operational performance of the unit outside the recommended temperature range. It is important to review the DDL data regularly to determine vaccine viability. Data from the DDL can be accessed from a website or by downloading to a computer using specific software.

## Features of DDL

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon™ material)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Allowed deviation in temperature:  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ )
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least once every 30 minutes

## Evaluating freezers to store the Moderna COVID-19 vaccine

To determine suitability of your current freezers or models for future purchase to store the Moderna COVID-19 vaccine, the following concerns need to be evaluated first.

- Is the model I am evaluating purpose-built for the storage of clinical and laboratory products?
  - Commercial and residential units may not have the required temperature performance.
- Do I or the manufacturer have supporting data to show that the usable space within the cabinet stays within the  $-25^{\circ}$  to  $-15^{\circ}\text{C}$  range, using the methods outlined by the CDC?
- Am I following the manufacturer's recommendations for installation, maintenance, and use?
- Has the manufacturer provided guidelines for the allowable usable space within the freezer to ensure my vaccines stay within the approved temperature range? Am I following those guidelines?
  - All empty space within a cabinet may not be deemed "usable space" by the manufacturer and could have performance outside of the required range.

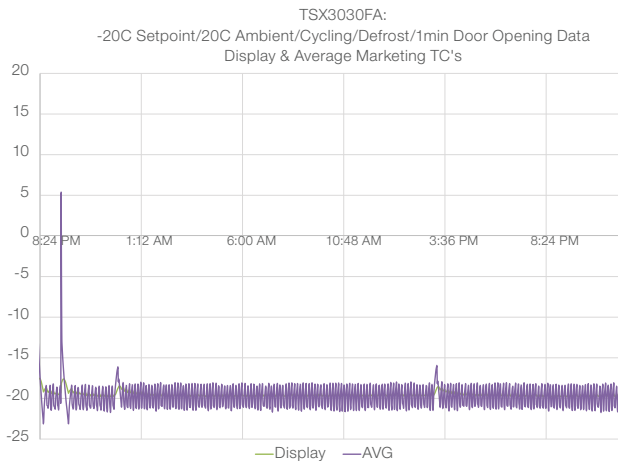
- After a door opening to retrieve a vaccine or to load more vaccines, am I allowing the cabinet temperature to recover back to the set point before opening the door again?
  - Door opening can have significant impacts on cabinet temperature. If the freezer is not allowed to recover before the door is opened again, vaccines could be exposed to temperatures outside of the specified range. Some types of freezers are equipped to recover from these events better than others.
- Purpose-built manual defrost freezers will have more consistent temperatures when there are infrequent door openings.
- If door openings are more frequent, purpose-built auto-defrost (frost-free) freezers will have more consistent temperatures, as they can recover more quickly from temperature changes during door openings.
- Am I using a temperature monitoring device, like a DDL, that conforms to the CDC recommendations? Am I maintaining and calibrating the device routinely?

Forthcoming guidelines from the National Sanitation Foundation (NSF International), in conjunction with the CDC, will further define what constitutes a vaccine cold storage device. The NSF Joint Committee on Vaccine Storage was formed in 2015 to develop these standards, and they take into account the questions above. Many products marketed today as "vaccine" refrigerators and freezers may not meet these new standards.\*

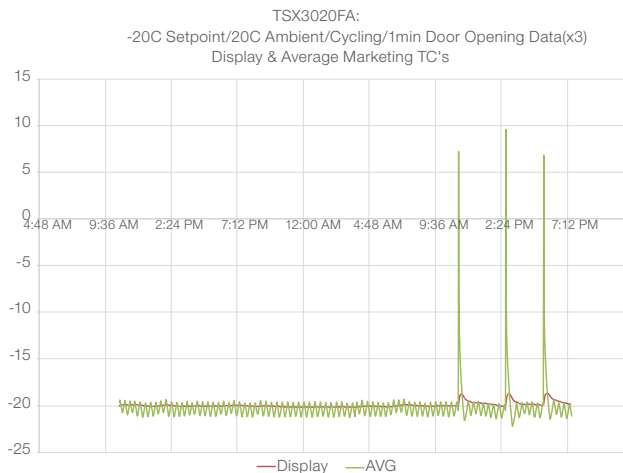
## Thermo Scientific freezers

Several freezers are available on the market today, but not all of them have an intended use for clinical applications, regardless of how they are designed for defrosting. The questions noted above can help you determine if you have or are getting the right choice. Thermo Scientific™ freezers offer a complete range for sample storage between  $-10^{\circ}\text{C}$  and  $-86^{\circ}\text{C}$ , and are designed to deliver superior temperature uniformity and the lowest variation possible.

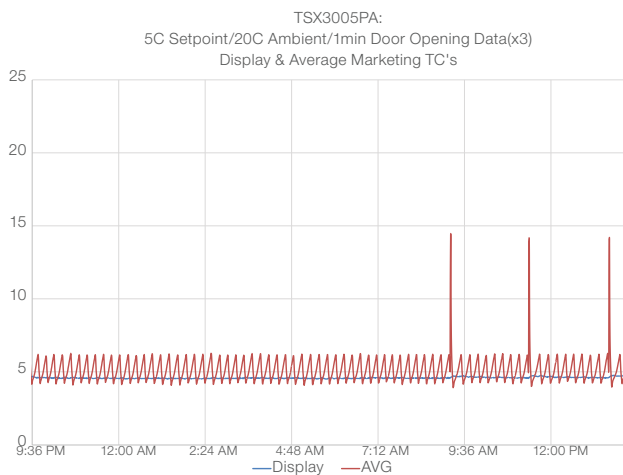
\*<https://https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>



**Figure 1. Average cabinet temperature and display of Thermo Scientific™ Auto-Defrost Freezer at a -20°C set point tested within a 20°C ambient environment.** “AVG” is the average temperature of unweighted open-air temperature measurement devices. “Display” is a weighted temperature measurement device used to represent product temperature. Peaks from left to right: 1-minute door opening (AVG recovery to below -15°C in 5 minutes), auto-defrost, auto-defrost.



**Figure 2. Average cabinet temperature and display of Thermo Scientific™ Manual Defrost Freezer at a -20°C set point tested within a 20°C ambient environment.** “AVG” is the average temperature of unweighted open-air temperature measurement devices. “Display” is a weighted temperature measurement device used to represent product temperature. Peaks from left to right: 1-minute door openings (AVG recovery to below -15°C in 8 minutes).



**Figure 3. Average cabinet temperature and display of Thermo Scientific™ Pharmacy Refrigerator at a 5°C set point tested within a 20°C ambient environment.** “AVG” is the average temperature of unweighted open-air temperature measurement devices. “Display” is a weighted temperature measurement device used to represent product temperature. Peaks from left to right: 1-minute door openings (AVG recovery to below 8°C in 10 seconds).

Figures 1–3 show the typical performance of Thermo Scientific™ TSX Series high-performance, purpose-built freezers at a -20°C set point, and high-performance refrigerators at a +5°C set point tested in a 20°C ambient environment. The data show the effects of an auto-defrost function (if applicable) and prolonged door openings on air temperature within the cabinet as well as product temperature. These purpose-built units quickly recover from prolonged door openings and keep sample temperatures well within the limits of the COVID-19 vaccines.

Depending on the type of DDL you are using, the ambient environment in which the unit is installed, variation between units, and the frequency of access to the unit, you may need to adjust the set point or other settings of your unit in order to stay within the acceptable range as outlined in the EUA guidance. Whether you are procuring or using a Thermo Scientific product or another manufacturer’s freezer, please be sure to contact the supplier so that they can help you determine if their product meets the needs as laid out in the EUA of the COVID-19 vaccine you are storing.

**Applicable to all performance data:**

1. Performance is nominal and individual units may vary.
2. Product performance will differ due to product amount, product size, and operating conditions.
3. Continuous product enhancements may, without notice, result in amendments or omissions to this specification.

## Summary

To achieve success in efforts against vaccine-preventable infections, understanding the importance of proper storage and handling of vaccines is crucial. Determining the compatibility of your freezer of choice to store and handle the Moderna COVID-19 vaccine according to the CDC guidelines is an important step towards that goal. Thermo Scientific TSX Series high-performance, purpose-built freezers are intended to support temperature conditions for pharmaceuticals, vaccines, chemotherapy drugs, and other medical-grade products.

## Ordering information and specifications

Cat. No.	Temp. range (set point)	Capacity	Electrical plug	Doors	Shelves (bins)	Defrost	Certification	Interior dimensions	Exterior dimensions	Shipping weight
TSX3020FA	-25°C to -15°C (-20°C)	29 cu. ft. (827 L)	115 V, 60 Hz (NEMA 5-15)	1 solid	4 (0)	Manual	UL, cUL	28.5 x 30 x 58 in. (72 x 76 x 147 cm)	39 x 34 x 78.5 in. (99 x 86.5 x 199.5 cm)	483 lb (219 kg)
TSX3030FA	-35°C to -15°C (-30°C)	29 cu. ft. (827 L)	115V, 60Hz (NEMA 5-15)	1 solid	4	Auto	UL, cUL	28.5 x 30 x 58 in. (72 x 76 x 147 cm)	38 x 34 x 78.5 in. (96 x 86.5 x 199.5 cm)	439 lb (199 kg)

The Thermo Scientific™ Smart-Vue™ Pro system is a remote monitoring solution for sample processing and storage applications from research through production to patient care.

Find out more at [thermofisher.com/smartvuepro](https://thermofisher.com/smartvuepro)



## References

- <https://www.weforum.org/agenda/2018/07/the-biggest-hurdle-to-universal-vaccination-might-just-be-a-fridge>
- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). [fda.gov/media/144637/download](https://www.fda.gov/media/144637/download)
- Vaccine Storage and Handling Toolkit. U.S. Centers for Disease Control and Prevention.

Find out more at [thermofisher.com/vaccinestorage](https://thermofisher.com/vaccinestorage)