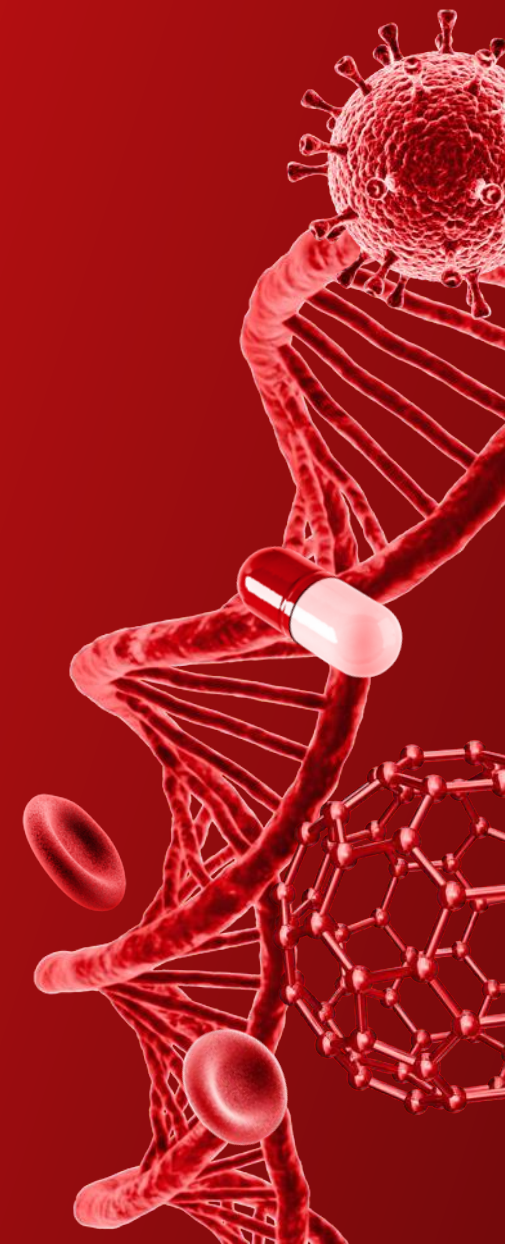


Welcome

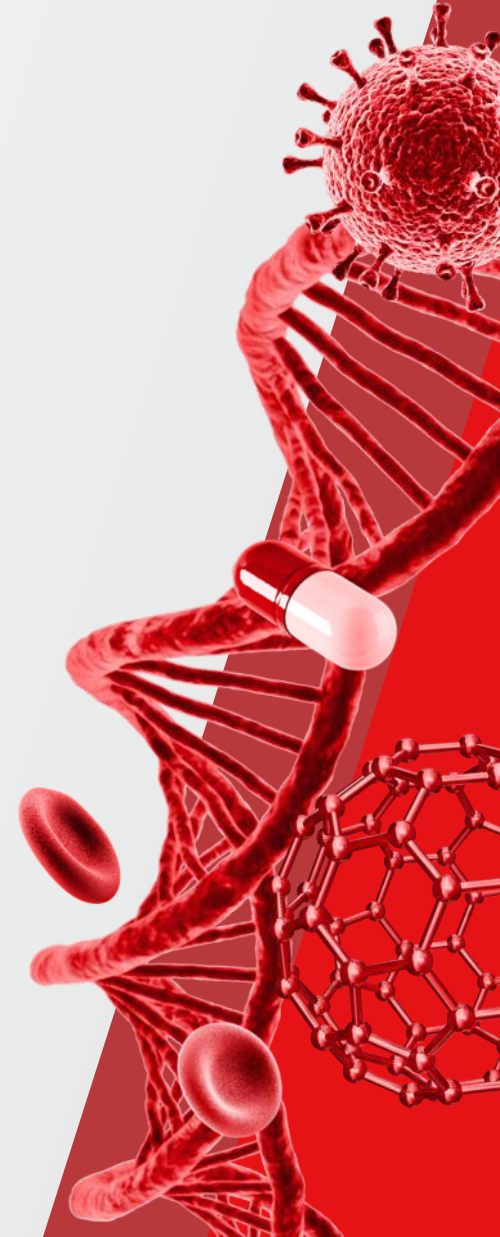


A New Standard for Vaccine Storage

Chase Heibel

Global Product Manager

 The world leader in serving science



Agenda

1 New Era in Vaccines

2 WHO/CDC Vaccine Storage Recommendations

3 New NSF Standards

4 Further Considerations



A New Era of Vaccines

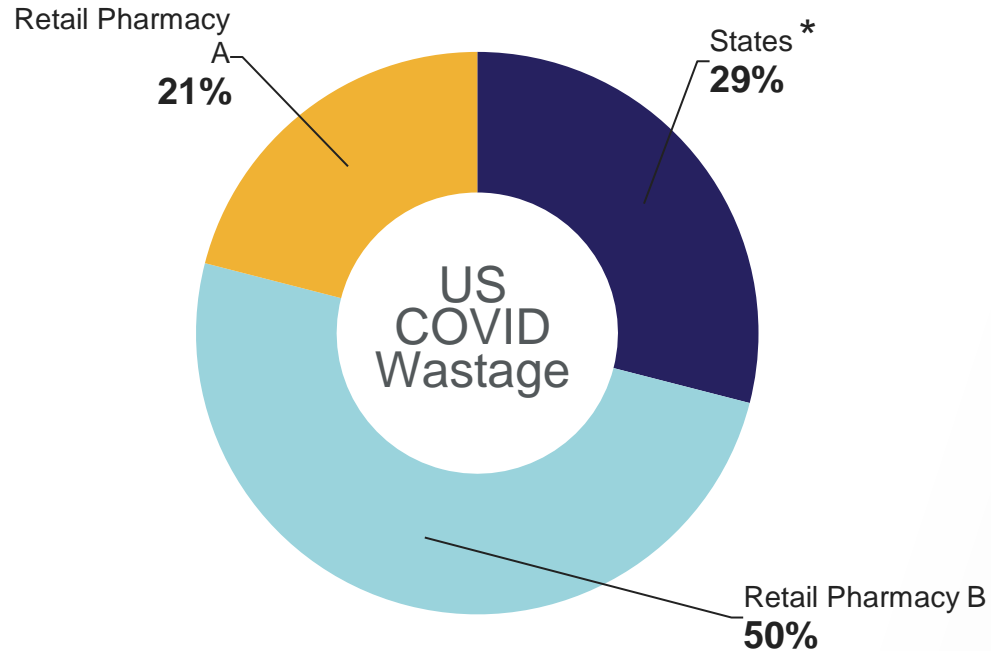
And the Importance of a Robust Cold Chain

A new world for vaccines

- **Vaccines have fundamentally changed**
 - mRNA
 - Viral vector
- **Biological need is driving new temperature profiles**
 - (-)70°C never before commonly used in vaccine storage
 - (-)20°C has limited use in vaccine storage
- **Infrastructure changes needed**
 - Standard cold chain management not appropriate for the needs of new vaccines
 - Standard refrigerators and freezers won't support the needs of (-)70°C

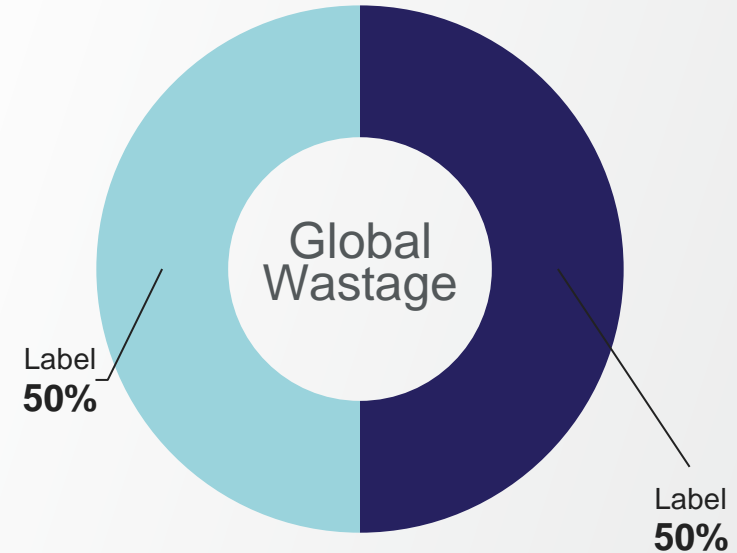


Vaccine Wastage



Wastage for COVID-19 Vaccines

The CDC requires all organizations that administer the vaccine to report the number of vaccine doses “that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.”



Yearly Global Vaccine Wastage

The WHO estimates that approximately 50% of vaccines are wasted yearly.

A leading cause wastage is improper storage during the vaccine cold chain

Storage Recommendations

And how they could leave vaccines vulnerable

US CDC - Vaccine Storage and Handling Toolkit

A comprehensive [guide](#) for health care providers on recommendations and best practices for:

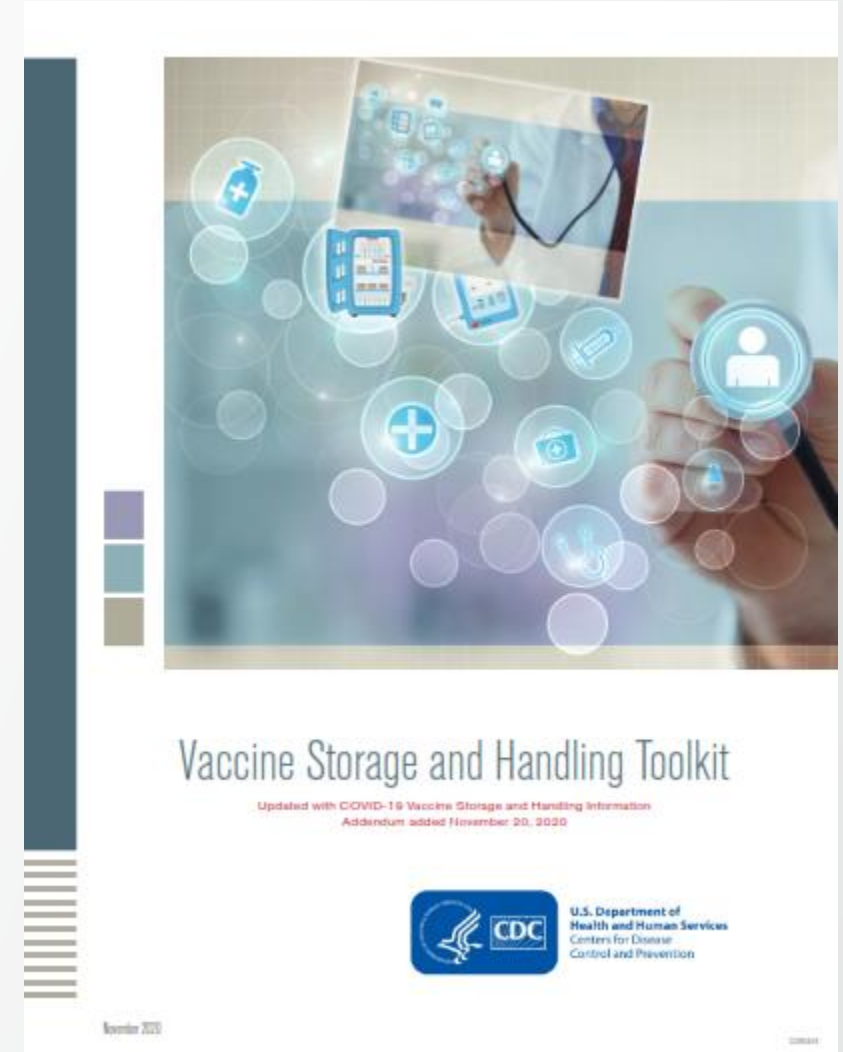
- Storing and preparing vaccine
- Monitoring vaccine temperature
- Using and maintaining storage unit and temperature monitoring equipment

The following recommendations for vaccine storage units are included:

- No dormitory-style or bar-style combos
- **Enough space to store the largest inventory**
- **Water Bottles to help maintain stable temperatures**
- Door safeguards
- **Refrigerated: 2° C and 8° C, @ 5° C**
- **Frozen: -50° C and -15° C**

Recommends Digital Data Loggers and Monitoring Devices with the following features:

- Independent
- Detachable probe that best reflects vaccine temperatures (e.g. a probe buffered with glycol)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended **uncertainty** of +/-0.5° C (+/-1° F)
- Programmable reading interval within minimum 30 minutes interval
- Valid Certificate of Calibration Testing that meets a national standard (ISO 17025, NIST, ASTM Standard E2877, etcetera)



Special [Requirement](#) for Vaccines for Children Program

WHO Recommendation

Storage conditions and monitoring

Manufacturer	Vaccine	Storage Temp
Pfizer/BioNTech	BNT162b2/COMIRNATY Tozinameran (INN)	-70
AstraZeneca Oxford	AZD1222	2 to 8c
Serum Institute of India	Covishield (ChAdOx1_nCoV19)	2 to 8c
Janssen	Ad26.COVS.2.S	2 to 8c
Moderna	mRNA-1273	-15 to -25c
Sinopharm/BIBP	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	2 to 8c
Sinovac	COVID-19 Vaccine (Vero Cell), Inactivated/ CoronavacTM	2 to 8c

Status of COVID-19 Vaccines within WHO EUL/PQ Evaluation Process

2: The vaccine cold chain

About this module...

The purpose of the vaccine "cold chain" is to maintain product quality from the time of manufacture until the point of administration by ensuring that vaccines are stored and transported within WHO-recommended temperature ranges.

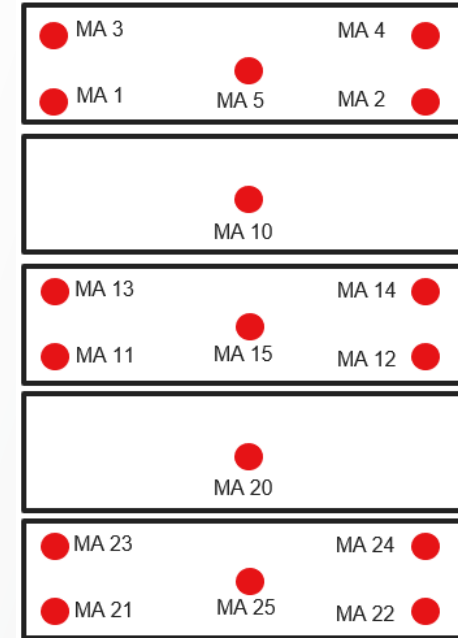
This module provides guidance for workers at health facility level. It covers the use of cold chain and temperature monitoring equipment and the basic maintenance of cold chain equipment. The module describes the existing range of WHO prequalified equipment at the time of publication. Up-to-date information on prequalified equipment is available on the WHO Performance Quality Safety (PQS) website (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/).

Some of the figures in this module show equipment from specific manufacturers. This is for illustrative purposes only and does not indicate WHO official endorsement of these products.

Why the Current Standards may not be Adequate

What you aren't seeing is affecting your vaccines

A temperature reading every 30 minutes using a weighted probe may leave you blind to what is really happening in that "conventional unit."



	MA1	MA2	MA3	MA4	MA5	MA10	MA11	MA12	MA13	MA14	MA15
AVG	4.34	4.33	4.31	4.33	4.17	3.99	3.89	3.90	3.83	3.90	3.77
MAX	7.78	7.73	7.73	7.74	7.72	7.13	6.57	6.58	6.58	6.59	6.62
MIN	-2.67	-2.24	-2.58	-2.26	-3.28	-1.76	-0.65	-0.77	-0.59	-0.59	-1.20
	MA20	MA21	MA22	MA23	MA24	MA25					
AVG	3.74	3.88	3.87	3.80	3.91	3.81					
MAX	6.41	6.36	6.35	6.31	6.41	6.36					
MIN	-0.24	0.50	0.81	0.32	0.79	0.47					

New NSF Standard

And how they improve protection

The Council

Tasked with creating a national standard for construction and performance for vaccine storage

**NSF, CDC,
NIST**

**Standards Organizations and
Regulatory Bodies**



Healthcare Providers

ThermoFisher
SCIENTIFIC

The world leader in serving science

**Vaccine and Equipment
Manufacturers**

NSF 456- Vaccine Storage

Highlights from the standard and their importance

Design

- **Display and Controls** – Digital display, Display shows temp inside unit. Accuracy within +/- .5C with 0.1 C resolution for ref, +/-1C for frz, can be adjusted for calibration but discourage accidental adjustment
- **Alarms** – Immediate audible/visual alarms if outside 2/8C range for ref, above -15C for frz, Alarm silence no longer than 15 min for ref, 30 min for frz
- **Useable space** – Prevent storage in areas that don't meet temp requirements
- **Doors** – Self closing and a good seal

Thermal Performance

- **Short Door Test** – 3 hrs of (2s to open, 4s open, 2s to close) every 10 min. 1 hr of (2s to open, 4s open, 2 s to close) every 5 min Must stay between 2-8C
- **Long Door Test** – at least 15 min after short door openings, open for 3 min.
- Must recover to between 2-8C within 15 min. Must never go below 1C
- **Closed Door Test** – Stays between 2-8C

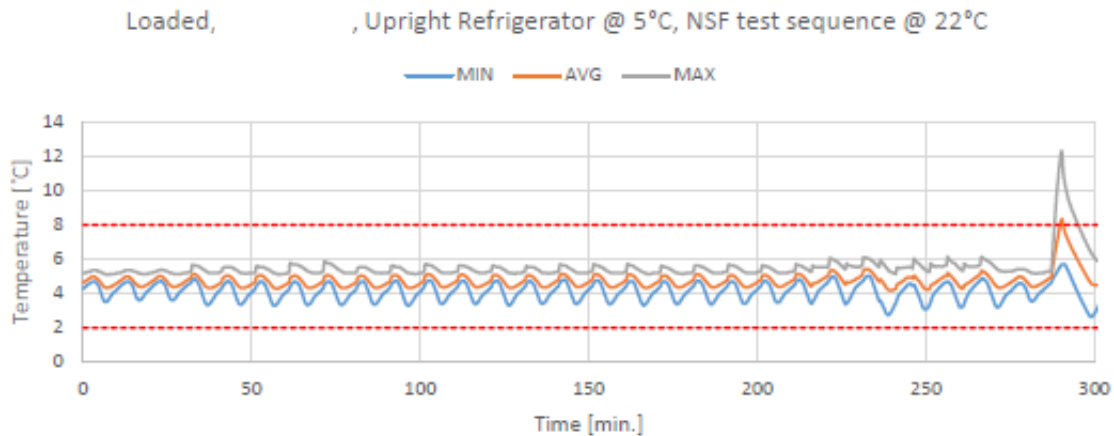
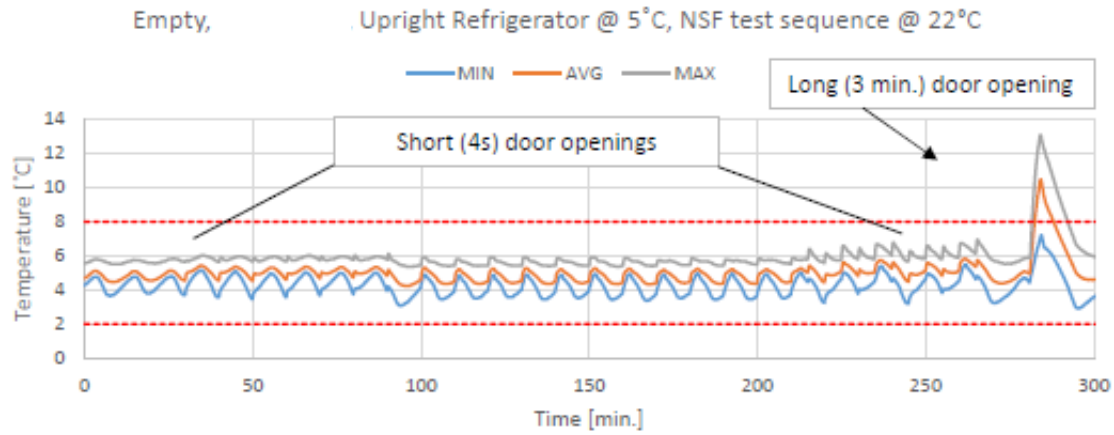
Documentation

- **Manual** – shall indicate that the external probe of any 3rd party temp monitoring system is to be placed within the usable space
- **Labeling**- the unit with usable interior space (cubic m) where product can be stored. This can be part of the digital display.
- **Calibration** – Manual must suggest recalibration schedule

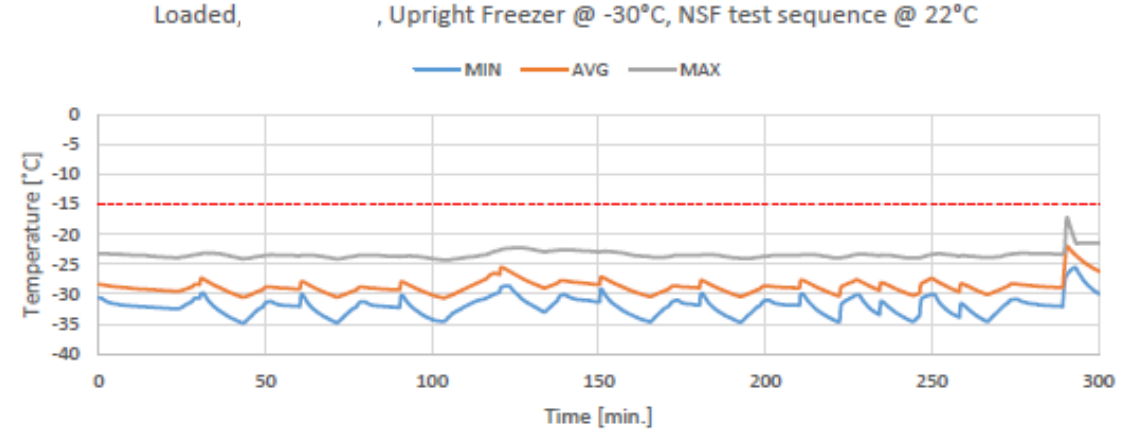
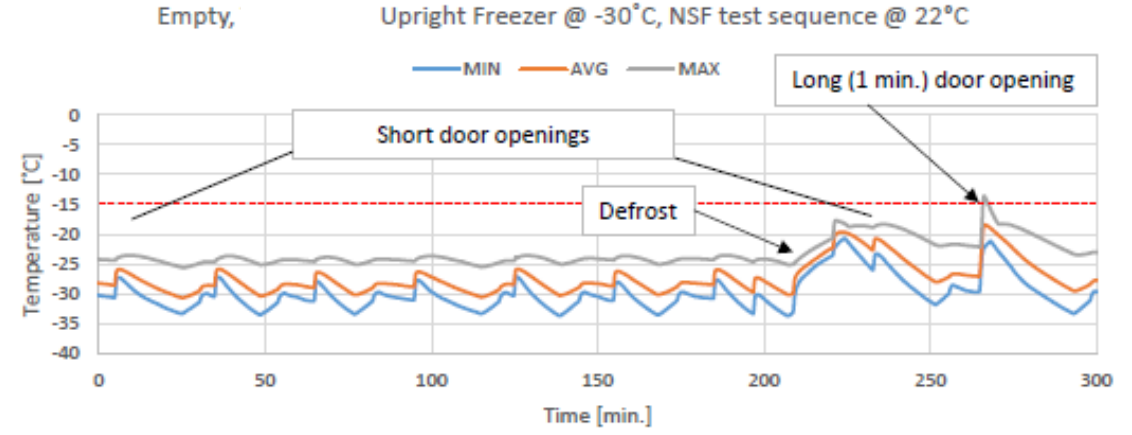


Performance- Loaded and Unloaded

Refrigerator

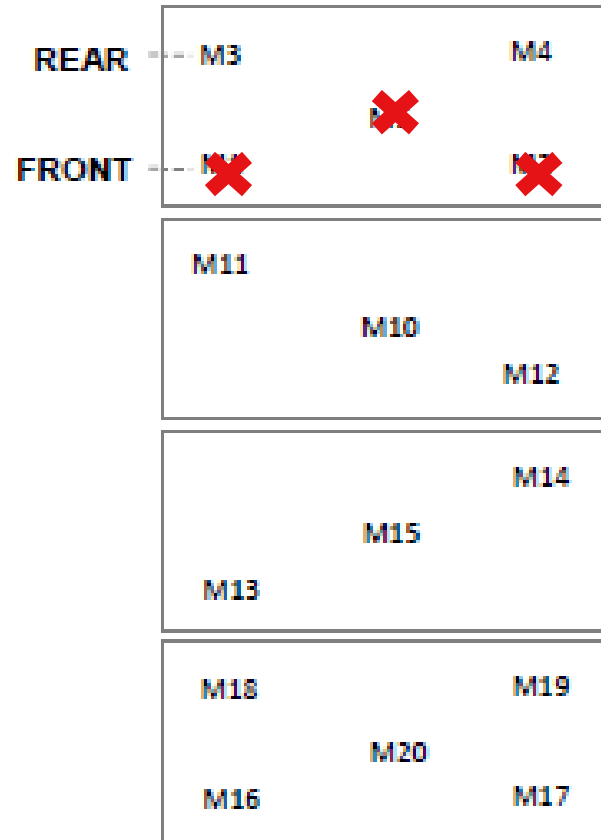


Freezer



Why Barriers

Top View of Shelves



Some areas may comply
Some areas may not

	M1	M2	M3	M4	M5	M10	M11	M12
Avg	-23	-22.8	-22.6	-22.6	-22.5	-22.9	-23	-23
Min	-28.7	-28.9	-28.1	-28.4	-28.2	-28.9	-29.6	-29.6
Max	-14.9	-14.9	-15.1	-15.1	-14.5	-15.4	-15.2	-15.15

	M13	M14	M15	M16	M17	M18	M19	M20
Avg	-23.4	-23.3	-23.2	-23	-22.2	-23.2	-23.2	-23.2
Min	-29.9	-29.9	-29.9	-29.7	-29.5	-30	-30	-29.9
Max	-15.1	-15.1	-15.4	-15.7	-15.4	-15	-15	-15.2

Further Considerations

And Best Practices

How you use your equipment can greatly impact their performance

- **Follow some best practices**
 - Minimize the duration of door openings
 - Minimize the frequency of door openings
 - Have a system of inventory management
 - Pay attention to what the unit is telling you
 - Make use of the onboard capabilities
 - Consolidate cargo—each vial is its neighbor's best friend from a thermodynamics perspective

A little TLC will go a long way

Standard care and maintenance are recommended

- **Follow the recommendations in the user manual for care and maintenance**
 - Keep filters clean
 - Remove excess frost or ice from shelves and gaskets
- **Consider warranty upgrade or service plan to ensure maximum uptime with committed on-site response**
- **Always have contact information handy for your service provider**

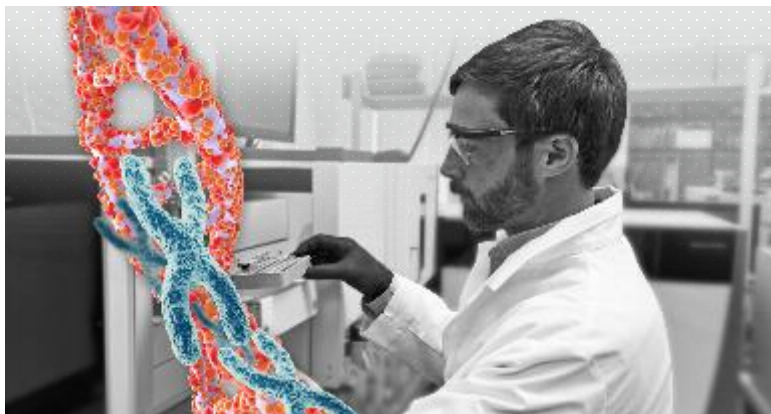
A size to fit your need



Site	Endpoint storage			Production and distribution hubs	
Size (cubic feet)	5.5	11.5	23.0	29.2	51.1
Boxes (Pfizer)	275	400	945	1,323	1,890
Vials (Pfizer)	6,875	7,920	23,625	33,075	47,250
Doses (Pfizer)	41,250	60,000	141,750	198,450	283,500

Make sure to select the product that most closely aligns to your volume needs!

Why should organizations invest in a remote monitoring system as part of their risk mitigation strategy?



Sample safety and security



Workflow efficiency



**Asset management &
cost savings**

Reduce risk and gain operational efficiency

Thank you

For all you do and all you will do!

