

COVID-19 Vaccine Operational guidance

1 FEBRUARY 2022

Operational guidance on establishing an ultra-cold chain system in support of the Pfizer-BioNTech COVID-19 Vaccine rollout

Introduction

COVID-19 vaccination is one of the world's fastest and most massively deployed public health interventions in history. To this effect, country readiness is key for smooth deployment of adequate cold chain equipment (CCE) and successful implementation of COVID-19 vaccination.

As part of a national deployment and vaccination plan [\(4\)](#) clear information about the type of COVID-19 vaccine and its formulation, presentation and cold chain requirements during storage and transport is important for proper planning of a cold chain design that effectively supports vaccine rollout. Currently COVID-19 vaccines have different cold chain requirements depending on the type of vaccine, its thermostability, its current condition and shelf life at different storage temperatures.

The Pfizer-BioNTech COVID-19 Vaccine [\(4\)](#) is currently the only COVID-19 vaccine that should be stored and transported at -90°C to -60°C ultra-low temperature (ULT) conditions. To effectively deploy this vaccine requires good cold chain planning, strong management of the vaccine supply, logistics and distribution, and strategic ULT equipment deployment, including installation and effective monitoring and evaluation of the equipment performance and infrastructure.

Part of the Pfizer-BioNTech COVID-19 vaccine rollout readiness is the availability of ultra-cold chain (UCC) storage capacity at least at central level and in strategic locations. Country UCC system readiness is a requirement for Pfizer-BioNTech COVID-19 Vaccine [\(4\)](#) allocation. Therefore, countries requesting a supply of this vaccine should consider establishing a UCC hub at central level and, if needed, in strategic subnational locations to support effective rollout of the vaccine.

Using the Pfizer-BioNTech COVID-19 Vaccine in many low- and middle-income countries (LMICs) will require countries to overcome logistical challenges in three key areas of UCC system management: equipment, transport and deployment. Prior to the development of the Pfizer-BioNTech COVID-19 Vaccine, only a few LMICs that used Ebola vaccine, which requires -80°C storage conditions, had experience using ULT equipment. With the increasing global supply of the Pfizer-BioNTech COVID-19 Vaccine and COVAX Facility's massive deployment of ULT equipment to Advance Market Commitment (AMC) participating countries, more countries are gaining experience in the management of a UCC system. The implementation considerations presented in this document are based on the combined lessons learned from country experiences of managing Ebola and COVID-19 vaccines and UNICEF's experience from the earlier deployment of ULT equipment.

Key lessons include:

- The International Air Transport Association (IATA) limits the volume of flammable refrigerant that can be shipped with the ULT freezers. Therefore, prior to shipment, refrigerant is unloaded and shipped separately to be loaded again once the units are received in-country.
- Some airplanes have limited headroom for upright ULT freezers, delaying deployment because of the need to change to a model that fits into cargo compartments.
- Countries that followed the recommended power system design did not experience problems with having sustained power supply to the ULT freezers. Countries that did not comply reported power interruption or equipment malfunction because the electrical circuitry was not suitable to handle the power demand of the ULT freezers.

This guidance is focused on establishing and managing a UCC system. It provides practical guidance to support countries in planning and selecting the appropriate UCC system design and equipment based on their local context. It outlines the considerations to ensure the UCC equipment will remain functional and utilized even after the Pfizer-BioNTech COVID-19 Vaccine supply has been fully utilized. The implementation considerations apply to countries that are planning to establish a UCC system and to those that already received/installed the UCC equipment.

Currently, there is no World Health Organization (WHO) prequalified ULT freezer model, however, UNICEF Supply Division (SD) has a long-term agreement (LTA) with several manufacturers and the equipment list, including relevant specifications, under this LTA is found in the Annex.

Target audience

Expanded Programme on Immunization (EPI) managers, supply chain/cold chain officers, decision-makers and partners supporting countries' COVID-19 response activities.

Implementation considerations

1. Managing Pfizer-BioNTech COVID-19 Vaccine shelf life at different storage temperatures

Table 1. Summary of recommended storage duration at different storage temperatures

Vaccine condition	Storage and transport temperature	Recommended storage duration ¹
Unopened frozen vial	-90°C to -60°C	9 months after time of manufacturing or until expiry date as indicated on vial label ²
	-25°C to -15°C	Up to 2 weeks for a single period within the vaccine's 9 months, shelf life ³
Unopened thawed vial	+2°C to +8°C (do not refreeze)	31 days/1 month
Diluted vaccine	+2°C to +8°C	6 hours after first puncture
Diluent	Store at room temperature not exceeding 30°C. During the vaccination session, store at +2°C to +8°C	Until expiration date

¹ Applies to Pfizer-BioNTech COVID-19 Vaccine requiring dilution (e.g. vial with purple cap).

² On 21 September 2021 WHO approved the extension of Pfizer-BioNTech COVID-19 Vaccine shelf life from 6 months to 9 months when stored at -90°C to -60°C. This will affect some of the lots already delivered prior to this approval. Check information communicated by the manufacturer with regard to new expiration date.

³ The total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

1.1 Key points

- Vaccine products stored at -90°C to -60°C for up to 9 months should be used prior to the indicated expiration date. The expiration date is marked on the vaccine label and indicated in the shipping document.
- If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C, vials may be transported at -25°C to -15°C in their original trays. Any hours used for transport at this temperature count against the 2-week limit for storage at -25°C to -15°C. Vaccine can also be thawed and stored at +2°C to +8°C before the end of the 2-week period. In this case, the new expiration date at +2°C to +8°C should be updated on the label.
- Implement dynamic labelling whenever vaccine is transferred from one storage temperature to another. Dynamic labelling as applied to the Pfizer-BioNTech COVID-19 Vaccine is explained in Module 1 of Training on handling, storing and transporting Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran) [\(👉\)](#).
- Always check the updated expiration date against the original expiration date. If the end date of the vaccine shelf life at -25°C to -15°C and +2°C to +8°C exceeds the expiration date originally marked on the vaccine label, the original expiration date must always be respected.
- Limit transportation time at +2°C to +8°C to 12 hours to prevent transportation stress.⁴
- Synchronize vaccine delivery with vaccination session plan and consume the vaccine immediately to avoid wastage.

2. Selecting the ultra-low cold chain system design

When planning for UCC, countries should keep in mind the main objective is to reach and vaccinate the priority groups in line with the Strategic Advisory Group of Experts (SAGE) recommendations with considerations to their needs, resources and capacities.

The recommended UCC equipment deployment strategies presented in this section are designed to observe the following principles:

- Minimize UCC infrastructure requirements while allowing broader access and uptake of the vaccine without significant UCC investment; and
- Reduce wastage risk given the novelty of UCC products and stringent vaccine management requirements.

With respect to these principles, the following UCC system design options are recommended with consideration to the different vaccine deployment strategies. Countries are encouraged to make an assessment to determine which strategy is suitable in the local context.

⁴ mRNA vaccine products are much more fragile and susceptible to damage (e.g. by vigorous shaking, vibrations). This is based on available data on physical studies (e.g. shearing, stress conditions, formulation characteristics, etc.) performed by the manufacturer.

2.1 Cascade vaccine deployment strategy

With this strategy vaccines will be distributed from a centralized UCC hub to the different subnational stores with appropriate CCE that can store the vaccine in a way that maximizes its remaining shelf life.

This strategy is applicable to countries where districts are far from the central storage with several layers of strategically located distribution points (e.g. archipelagos and big countries). With this strategy, it is assumed that immunization is conducted at the central hub and secondary locations.

There are two possible scenarios for establishing UCC hub(s) to support cascade deployment strategy.

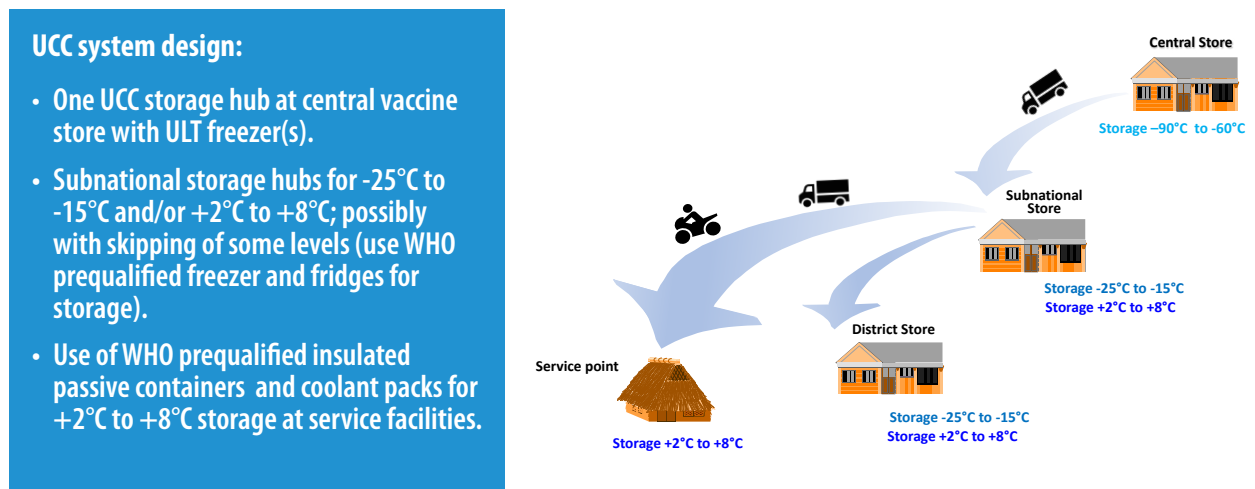
2.1.1 Scenario 1: single, centralized UCC hub

In this scenario, vaccine supply can be transferred directly from the thermal shippers to the ULT freezer(s) at the central vaccine store upon delivery by the supplier. Vaccine supply may be distributed from the central store to the subnational stores either frozen at -90°C to -60°C or at -25°C to -15°C or thawed at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.⁵

Subnational and district stores may need to repack the vaccine supply in smaller quantities and distribute directly to service points either at -25°C to -15°C or at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$, depending on available CCE, capacity to produce coolant packs and travel time.

Following the recommendation to limit the travel time when transporting the vaccine at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$, countries may consider delivering the vaccine frozen at -25°C to -15°C in places where vaccine transport may last more than 12 hours. Keep in mind that vaccine can only be transported and kept at -25°C to -15°C for a single period no longer than 2 weeks, therefore, consider prioritizing deliveries to distant locations.

Fig. 1. Cascade deployment: with single, centralized UCC hub



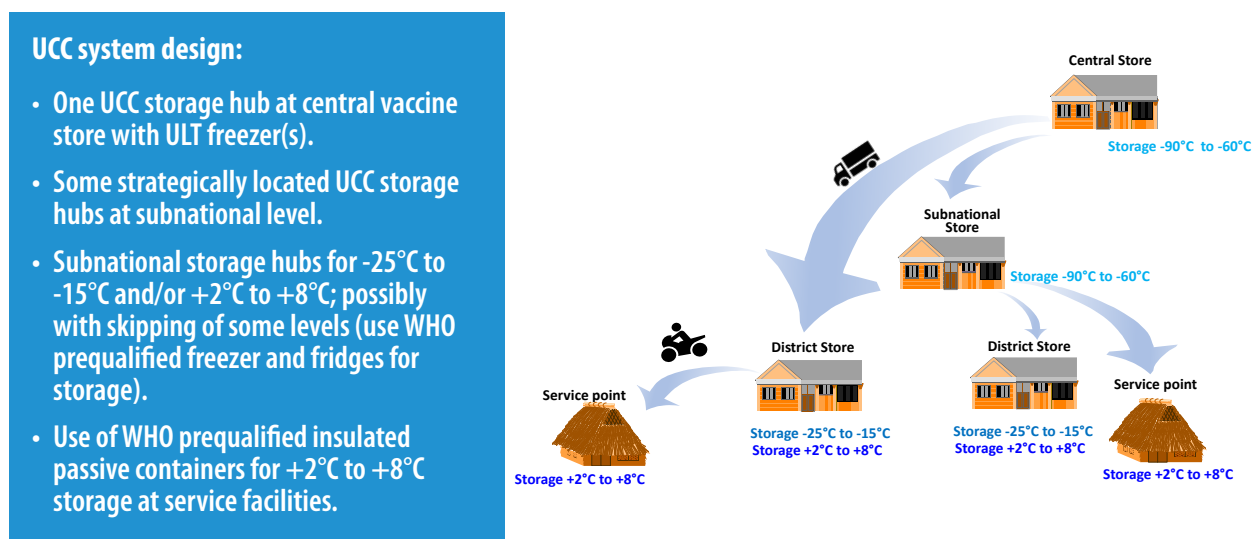
⁵ When redistributing vaccines at -90°C to -60°C , central stores should have adequate number of CCE and appropriate coolant material to ensure ULT is maintained during transport (e.g. secured source of dry ice and adequate thermal shipping containers for dry ice – marked with “UN1845”).

2.1.2 Scenario 2: multiple UCC hubs

In this scenario, the delivery will be allocated so that:

- Some or all vaccines can be transferred directly from thermal shipping containers to the ULT freezer(s) at the central vaccine store to be stored under ULT conditions for a limited period. This vaccine supply can either be used to resupply the subnational UCC hubs with vaccine frozen at -90°C to -60°C and/or supply accessible districts and/or service points with vaccine stored at either -25°C to -15°C or $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.
- Part of the supply may be kept in the thermal shipping containers with re-icing upon receipt at the central vaccine store and every 5 days for a limited period not exceeding 30 days.⁶ This allows redistribution of vaccine maintained at -90°C to -60°C directly to the strategically located subnational UCC hubs to be stored in ULT freezer(s). Then, this vaccine supply can be further distributed at -25°C to -15°C or $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ temperature to the district stores and/or service points.
- Before redistributing the vaccine, the responsible officer at the UCC hub should ensure both the date the vaccine was removed from the ULT freezer or thermal shipper and the end date of the remaining shelf life at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ are clearly stated in the shipping documents and communicated in advance to the recipient vaccine stores. The new expiration date should also be clearly marked on the vaccine label/tray.
- To ensure appropriate cold chain is maintained during the transportation period, it is recommended that vaccine should only be transported using WHO prequalified (PQ) transport boxes:
 - If delivering thawed vaccine at $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$, use standard cold boxes/vaccine carriers with conditioned frozen water packs or freeze-preventive cold boxes/vaccine carriers with non-conditioned frozen water packs.
 - If delivering vaccine frozen at -25°C to -15°C , use standard cold boxes with non-conditioned frozen coolant packs.
- Choice of insulated containers and coolant packs should take into consideration the ambient temperature and equipment holdover time.⁷

Fig. 2. Cascade deployment: with multiple UCC hubs



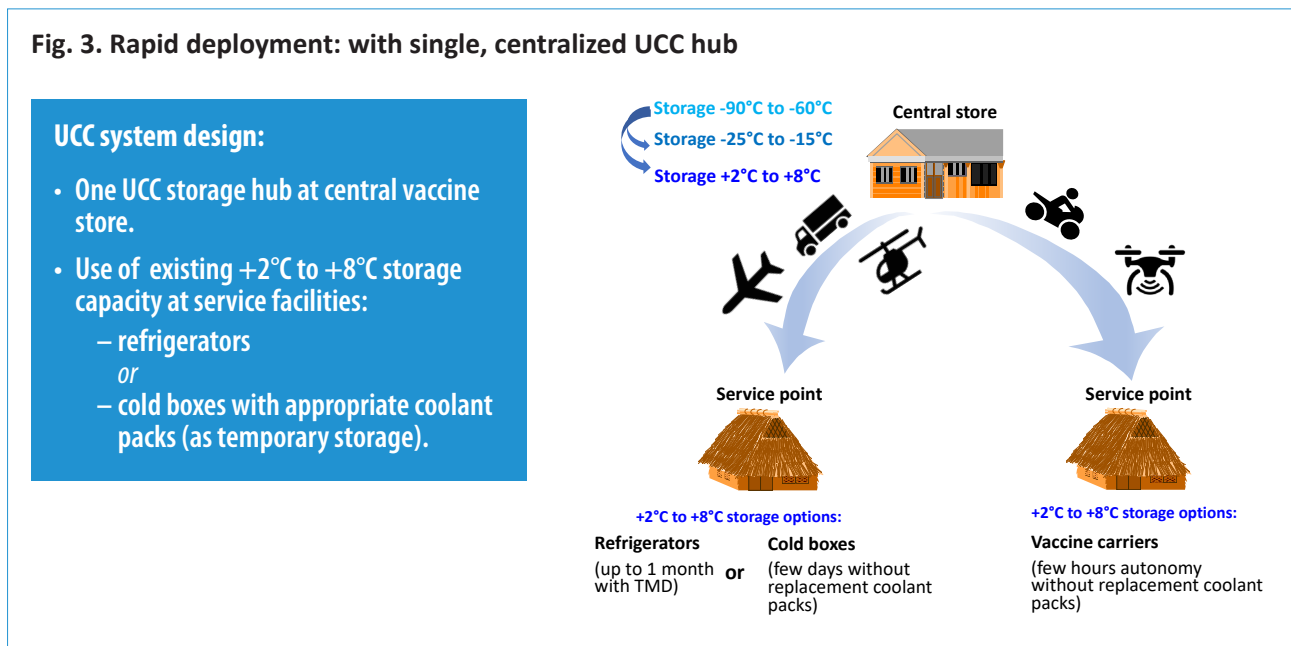
⁶ Keep in mind that Pfizer Softboxes should be returned 30 days from the time international shipment was received at the central store.

⁷ Effective vaccine management handbook: How to use passive containers and coolant packs for vaccine transport and outreach operations (📄).

2.2 Rapid vaccine deployment strategy

With this approach vaccines can be distributed from a central UCC hub directly to the different service points using appropriate transport, with or without the use of a temporary storage facility.

This strategy applies to countries where districts are close to the central storage, therefore travel time is short, and in small countries where districts are easily accessible using various transport means from the central storage.



With this strategy, vaccine supply can be transferred from the thermal shipping container directly to the ULT freezer(s) at the central vaccine store. Vaccines are thawed once the receiving facility is ready to implement vaccination activity. Consider thawing only the required number of doses to be delivered at +2°C to +8°C directly to the service points. Another option is to deliver the vaccine frozen at -25°C to -15°C, especially if the expected travel time is longer than 12 hours, and thawing starts upon receipt of the vaccine at service points.

- If the receiving facility has a vaccine refrigerator, the vaccine can be stored and used before the end of the shelf life at +2°C to +8°C. Make sure the new expiration date is marked on the label (follow instructions for dynamic labelling).
- If the receiving facility does not have a refrigerator, the vaccine can be kept in the cold box with appropriate coolant packs for a few days. Coolant packs should be constantly replaced and only WHO prequalified cold boxes should be used (check equipment specification), including appropriate temperature monitoring device (TMD).
- If the service point is within a short travel distance from the central store, the vaccine can be delivered in a vaccine carrier with appropriate coolant packs for immediate use in a vaccination session.

2.3 Cascade vs rapid deployment strategy

Table 2. Advantages and disadvantages of the cascade vs rapid deployment strategy

Strategy	Advantages	Disadvantages
Cascading vaccine deployment	<ul style="list-style-type: none"> • Cost effective as UCC investment is limited to central store and strategically located areas. • Maximizing the existing dual temperature storage capacity (-25°C to -15°C and +2°C to +8°C) at lower store levels. • Presence of freezer at subnational/district stores would allow vaccine to be delivered frozen at -25°C to -15°C, eliminating the risk of transport stress if delivered at +2°C to +8°C. 	<ul style="list-style-type: none"> • Slow vaccine distribution mechanism. • Risk of further reducing shelf life if vaccine stays longer at subnational stores before reaching service points. • Requires careful tracking of vaccine movement, remaining shelf life and storage temperature at service points. • May yield higher transport cost due to several layers of deliveries. • May yield vaccine wastage due to heat exposure during storage/transport.
Rapid vaccine deployment	<ul style="list-style-type: none"> • Cost saving as UCC investment is limited to central store. • Support rapid vaccine distribution to service facilities and avoiding storage burden on subnational and district levels. • Enabling potentially high vaccine consumption and low wastage as vaccine will be delivered by demand. This means sessions are planned around the expected vaccine delivery period. • Shelf life is maximized as vaccine is stored in ULT freezer and will be thawed only as needed. • May save on transport cost due to skipping of several store levels. • Promotes strong coordination between national and service facility for planning vaccination sessions around the time of delivery. • Enables effective monitoring of vaccine deliveries, uptake and wastage. 	<ul style="list-style-type: none"> • Thawed vaccine is at risk of transportation stress if travel time to service points takes more than 12 hours. • Requires careful tracking of vaccine movement, remaining shelf life and storage temperature at service points. • Requires robust system for monitoring and recording vaccine supply and movement.

3. Key considerations when planning and managing the ultra-cold chain system

3.1 Existing cold chain situation

It is essential to get clear information about the existing cold chain capacity (refrigeration/freezing capacities) and status of the equipment (maintenance and repairing requirements).

Planning for the design of the Pfizer-BioNTech COVID-19 Vaccine supply chain should be done in the most efficient way so that the vaccine can be delivered to the different service points through the shortest pathways under safe conditions. This will have significant impact in minimizing UCC infrastructure requirements, reducing UCC investments and maximizing access to the vaccine.

When designing the supply chain of COVID-19 vaccine, it is essential to answer questions such as:

- How the vaccine will be stored and delivered to the last mile?
- What are the optimal storage points at central, intermediate and service delivery levels, and the delivery route to the storage points and vaccination sites?

During planning, the desired storage temperature, the required storage capacity (storage volume) and the type of CCE appropriate for each site and administrative level shall be determined: ultra-low temperature freezer (-90°C to -60°C); standard freezer (-25°C to -15°C); refrigerator (+2°C to +8°C).

3.2 UCC hub infrastructure and information management

The availability of continuous power supply and air-conditioning to maintain suitable room temperature for ULT freezers in the UCC hub are critical requirements to ensure optimal functionality of the equipment. The facility set up should allow safe operations for handling vaccine and coolant packs during vaccine receipt and preparation for distribution.

The supply and logistics information management system should consider the peculiarities of the COVID-19 vaccine, including functionality for monitoring temperature, tracing vaccine movement, monitoring of expiration date and application of dynamic labelling, and monitoring wastage and utilization.

Note that ULT phase change material (PCM) packs and dry ice cannot be stored in the same freezer with the vaccine. The central UCC hub may need the following additional equipment based on the coolant packs used for transporting vaccine at -90°C to -60°C to supply subnational UCC hubs:

- Smaller ULT freezer for preparing and storing ULT PCM packs if ArktekTM is used for vaccine storage and transport;⁸ or
- Dry ice machine if dry ice will be used as coolant material for transport.

The UCC hub can leverage on existing fridges and freezers for preparing coolant packs for delivering vaccine at -25°C to -15°C and +2°C to +8°C temperatures.

3.3 Continuous power supply

To guarantee continuous electric power supply to the ULT freezer, ensure:

- Power transformer dedicated to the installation site or facility (if possible).
- All power and lighting circuits, including sockets, must be in a safe condition, tested and approved to national standards by a qualified engineer or electrician.

⁸ PCM packs are needed for transporting vaccine using ArktekTM (YBC-5E) – a super-insulated, double-walled large bottle-like passive container that uses multi-layer insulation technology and eight PCM packs (1 L each) to keep vaccines at ULT.

Pfizer-BioNTech COVID-19 Vaccine

- Power circuits serving refrigeration equipment must be rated to suit the required refrigeration loads including ancillary electrical equipment (fans, air conditioners, light fittings, etc.) and should have no significant electrical or mechanical defects.
- Availability of a generator as a backup power source during mains power outage, including adequate standby fuel supply.
- Set up automatic transfer switch (ATS) to ensure equipment will automatically switch back and forth between mains power supply and the backup generator in case of power interruption.
- Compliance with recommended emergency and routine maintenance of the backup power sources.

3.4 Human resource capacity

Each UCC hub should have, at minimum, a cold chain technician and two assistants (one for handling vaccine and one for handling ULT PCM or dry ice).

Ensure staff at national and subnational UCC hubs are properly trained to manage day-to-day operations, including:

- Supply and inventory management;
- Monitoring storage temperature and tracking of shelf life, including dynamic labelling;^{9,10}
- Vaccine allocation and dispatch;
- Preparation and dispatch coolant packs (dry ice, PCM packs or water packs) and transport containers; and
- Using appropriate TMD when transporting vaccine in cold boxes and vaccine carriers.

Ensure that technical competence in maintaining the ULT equipment is available and within easy reach of the ULT equipment in your country.

3.5 Operations safety and personal protective equipment

Ensure all staff in-charge of managing the UCC hubs have access to appropriate and adequate supply of personal protective equipment (PPE).

3.5.1 PPE when handling ULT freezers and dry ice for thermal shipping containers

- Cryogenic/insulated gloves;¹¹
- Safety goggles.

The room should be well-ventilated and set up to safely handle the thermal shipping containers and dry ice, including an appropriate area to safely discard dry ice.

Fig. 4. Insulated gloves are required when handling dry ice and PCM



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⁹ Guidance on managing COVID-19 vaccine without VVM at vaccination service points (🔗).

¹⁰ Training on handling, storing and transporting Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran) (🔗).

¹¹ UNICEF SD is supplying ULT equipment with pairs of cryogenic gloves.

3.5.2 PPE when handling ULT PCM for Arktek™ passive device

- Long-sleeved cryogenic/insulated gloves (to avoid frostbite when handling conditioned Arktek™ and to protect from contact with PCM liquid);
- Respirator mask to avoid inhalation of lithium chloride from PCM liquid.

The procedures for preparing vaccine for transport at ULT condition using Arktek™ with PCM or thermal shipping container with dry ice are described in Module 2 and Module 6 of the Training on handling, storing and transporting Pfizer-BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran) (👉).

Fig. 5. Long insulated gloves



3.6 Shipping requirements and customs clearance

International shipping of ULT equipment is the responsibility of the manufacturer and procurement agencies such as UNICEF. It is important to note that IATA has restrictions on the amount of flammable refrigerant loaded in each equipment and therefore most models of ULT freezers cannot be transported by air and will have to be delivered by sea. Even when allowed by air, there is significant impact on the shipment cost as ULT equipment is voluminous and heavy. The height of the ULT freezer could be a constraint as not all models are allowed by the manufacturer to be transported horizontally. Only a few manufacturers produce chest-type ULT freezers.

Early planning and coordination are critical to facilitate air or sea transport to save cost and minimize impact on planned campaign implementation. Selecting the appropriate mode of transport based on the UCC freezer model is a joint decision of the recipient country, UNICEF SD and the freight forwarder.

Countries are responsible for customs clearance upon arrival of the ULT equipment at the port of entry. The provision of import permits in the shortest time possible is important for efficient deployment of the equipment.

Countries should ensure the following are in place to facilitate shipment and delivery:

- Assign a responsible staff member to manage the receipt, clearance and transport of the ULT equipment.
- Identify a decision-making official who can provide immediate intervention in case of challenges/delays with customs clearance.
- Agreement with customs and regulatory authorities to provide import permits (waiver) for ULT equipment.
- Prepare all documentation requirements for customs clearance before arrival of the shipment to facilitate immediate release of the equipment and transport to central warehouse.

3.7 Warehousing and distribution

In-country logistics and distribution include various activities (warehousing, logistics, transportation, etc.).

Engage the existing logistics working group to support the MOH officer responsible for developing the plan for UCC implementation, including distribution list and schedule, details of the warehouses and storage facilities, site readiness and equipment installation.

Consider organizing meetings or workshops with concerned cold chain/supply chain managers at central, subnational and district levels before the ULT equipment distribution begins to ensure smooth implementation and minimize deviations.

3.8 Vaccine transport equipment and logistics

Follow the WHO and manufacturer’s guidelines on distributing and transporting the Pfizer-BioNTech COVID-19 Vaccine to ensure vaccine potency up to the service points.

The following table summarizes the recommended equipment, coolant packs and TMD when transporting the Pfizer-BioNTech COVID-19 Vaccine supplied at -90°C to -60°C, -25°C to -15°C, or +2°C to +8°C.

Table 3. Passive equipment, coolant packs and TMD options

Vaccine condition	Passive containers	Coolant packs	Temperature monitoring device
Unopened vial frozen at -90°C to -60°C	Thermal shipping container marked with “UN1845”	Dry ice	Use TMD for ultra-low temperature
	Arktek™ YBC-5E model	ULT PCM (e.g. Pulse E-75)	The Arktek™ YBC-5E is equipped with TMD called “HOBO logger”
Unopened vial frozen at -25°C to -15°C	WHO prequalified standard cold box	Frozen water packs	User-programmable data logger
Unopened vial thawed at +2°C to +8°C	WHO prequalified standard cold box (use for limited period up to < 12 hours)	Conditioned frozen water packs	Electronic freeze indicator, multi-use user-programmable data logger
	WHO prequalified freeze-preventive cold box	Frozen water packs	Electronic freeze indicator, multi-use user-programmable data logger
	WHO prequalified standard vaccine carrier	Conditioned frozen water packs	Electronic freeze indicator, multi-use user-programmable data logger
	WHO prequalified freeze-preventive vaccine carrier ¹²	Frozen water packs	Multi-use user-programmable data logger

If the international shipping boxes (e.g. thermal shipping containers for dry ice) will be used to deliver the vaccine to subnational UCC hubs, a dry ice production machine or a local dry ice source must be identified. Consider having a separate storage equipment for dry ice. The dry ice replenishment should be done according to WHO and vaccine manufacturer’s instructions.¹³

UNICEF SD has an LTA with Aucma for the Arktek™ YBC-5E, a passive insulated container which can be used for storage and transportation of the Pfizer-BioNTech COVID-19 Vaccine at ULT conditions, though it has smaller capacity than usual transportation boxes. This Arktek™ model comes with a built-in TMD called the HOBO temperature data logger, which records and displays temperature continuously. To put the vaccine into the Arktek™, vials should be taken out of their original tray.¹⁴ Follow the manufacturer’s instructions for handling the vaccine when taken out of the original tray and WHO guidance on the use of Arktek™ for transporting vaccine under ULT conditions.

In addition, UNICEF SD has an LTA for one active portable ULT freezer (ULT25NEU), which can be used for storage and transportation of the Pfizer-BioNTech COVID-19 Vaccine stored in a tray. This device can store up to 7 boxes (7 × 195 vials) of the Pfizer-BioNTech COVID-19 Vaccine. When mains power is not available, this

¹²Guidance on selecting, commissioning and using freeze-preventive vaccine carriers (25 October 2021) (🔗).

¹³Procedures for re-icing of Pfizer Softbox thermal shipper and other commercial thermal shippers is described in Module 2 and Module 6.1 of the Training on handling, storing and transporting Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran) (🔗).

¹⁴The Arktek YBC-5E is supplied with two sets of PCM packs and 20 L PCM. To maintain ULT in an Arktek equipment, the frozen PCM packs should be replaced every 5 days (Ultra-low temperature (ULT) storage and transport for vaccines: an overview of options and challenges (🔗) (WHO, 15 February 2021).

portable equipment operates on 12 volts (V) direct current (DC) power supply or from a vehicle's power port during transportation.

At lower distribution levels, vaccine can be transported either at -25°C to -15°C or at +2°C to +8°C, depending on the capacity to produce coolant packs and the available CCE of the receiving facility. To ensure cold chain is maintained up to the last mile, it is recommended to use only WHO prequalified cold boxes, vaccine carriers, coolant packs and TMDs during vaccine transport. Follow good practices in using passive containers and coolant packs for vaccine transport and outreach operations.¹⁵

4. Guide to selection of appropriate UCC equipment

4.1 Overview of ULT equipment and compatible temperature monitoring device (TMD) options

ULT freezers are different compared with the standard freezers (-25°C to -15°C) traditionally used by EPI. The most significant characteristics of ULT freezers are:¹⁶

- ULT freezers operate at extremely low temperatures and therefore working in such a freezer requires PPE, especially insulated gloves (cryogenic gloves) and safety goggles.
- ULT freezers are very sensitive to the ambient temperature, which can affect their ability to maintain ultra-low temperatures. Therefore, they should be housed in an air-conditioned area to keep the ambient temperature under 30°C.
- Because their operating temperature is far below normal ambient temperatures, they have very short “holdover time” until they reach -60°C, which is the limit for the Pfizer vaccine.^{17,18}
- They have powerful refrigeration systems; therefore, when running at -86°C their power consumption is much higher than regular vaccine freezers. In some models, the power consumption of a single 700-L ULT freezer is equivalent to a 20-m³ walk-in cold room (WICR).
- These freezers generate a large amount of heat which adds to the ambient temperature and therefore increases the workload and decreases thermal unit efficiency of the air conditioner.
- One manufacturer uses a new piston Stirling motor technology, which requires less maintenance and uses less power compared with cascading compressor systems.¹⁹ This piston Stirling motor does not have the cycle start/stop operation of a compressor system and therefore does not have fluctuating power consumption (spikes) during steady state running.
- Some ULT freezer models can be adjusted to operate at -25°C to -15°C, which would be an advantage, permitting their continued use in routine health service delivery after the COVID-19 pandemic. This increases the value for money of the ULT investment.
- Most ULT freezers are supplied with a built-in temperature monitor and an external control panel with temperature reading and alarms. Most have the capability to provide temperature logs via a USB port.
- 30-day temperature recorders for ULT freezers are also now available (although they are not yet WHO PQS certified) such as the Fridge-tag Ultra Low from Berlinger and the UTREL30-16 from LogTag; both models have USB port for PDF data download.²⁰

¹⁵ How to use passive containers and coolant packs for vaccine transport and outreach operations (🔗) (WHO, July 2015).

¹⁶ Ultra-low temperature (ULT) storage and transport for vaccines: an overview of options and challenges (🔗) (WHO, 15 February 2021).

¹⁷ WHO product information: Pfizer BioNTech COVID-19 Vaccine (🔗).

¹⁸ In ULT freezers the “holdover time” is the time it takes for the temperature inside the freezer to move from -80°C (or -86°C) to -60°C (limit for Pfizer) when it has no power supply. The holdover time will be longer when the ULT freezer is fully loaded than when empty due to the presence of more frozen mass that retains temperature. The holdover time will also be longer at lower ambient temperatures.

¹⁹ Ultra-low temperature freezer performance and energy use tests (🔗) (Delphine Faugeroux, Office of Sustainability, University of California, Riverside, June 2016).

²⁰ This new model has a USB connector and does not need the separate download cradle. The download cradle often presents programmatic management challenges and needs to be procured separately.

4.2 ULT freezer selection criteria and key considerations

Based on the above description and the information in the list of UCC equipment included in the UNICEF SD LTA, the following are the key considerations when selecting ULT freezers.

4.2.1 Required equipment storage capacity

There are 17 different models of ULT freezers with different storage capacities in the UNICEF SD LTA. They are categorized as small (80–300 L); medium (300–600 L); or large size (600–900 L).

When choosing the ULT freezer with the appropriate storage capacity, consider the following packaging information of the Pfizer-BioNTech COVID-19 Vaccine:

- The Pfizer vaccine is supplied with an insulated box containing five secondary cartons/trays;
- Each secondary packaging/tray holds 195 vials;
- Each vial contains 6 doses;
- The external dimensions of the secondary packaging/tray are 232 mm × 232 mm × 40 mm;
- The vaccine's packed volume is 10.75 cm³/vial or 1.8 cm³/dose.

The Pfizer-BioNTech COVID-19 Vaccine should be kept in its secondary packaging/tray when stored in the ULT freezer, therefore limiting the storage space available for vaccine. In addition, the doses allocated may not represent the peak volume required for storage. Allocation may also increase according to country needs and availability of doses. These points should also be considered when calculating the storage capacity need.

It is therefore recommended to:

- Determine which volume category of ULT freezer is required by calculating the required storage capacity for the supply of the Pfizer-BioNTech COVID-19 Vaccine; and
- Include a surge storage capacity (e.g. extra storage space) that can accommodate possible future increase in storage volume requirement.

While Pfizer reports the vaccine volume per dose in secondary packaging as 1.8 cm³ there is a large amount of unusable storage space in the ULT freezers once the vaccine is stored due to the size of the trays. Each ULT freezer can store a different amount of Pfizer doses. The average doses per litre storage among the ULT freezers included in the UNICEF SD LTA, is 2.7 cm³. To ensure adequate space is available in any ULT freezer model, a volume of 3 cm³ per dose is used in the calculation.



Formula for calculating ULT freezer storage capacity for the Pfizer-BioNTech COVID-19 Vaccine:

Number of doses to be stored × 3 cm³ ÷ 1000 = required ULT freezer storage space in litres

The freezer capacity is calculated in litres. In the formula, 3 cm³ is the vaccine packed volume per dose and 1000 is the conversion ratio from cm³ to litre.

4.2.2 Required space for installation of ULT freezer

Large capacity ULT freezers are big equipment.

- Consider selecting units with the smallest footprint per litre storage space required. Chest-type freezers generally have a larger footprint than upright freezers.
- Calculate the space requirement when planning to install multiple ULT freezers in the same location so that there is at least 0.5 metre free space around each ULT freezer. This is necessary to enable hot air emission to escape. Some models may allow placement against a wall and some models may have the hot air escaping at the top of the ULT freezer.
- The room that will house the ULT freezers should have entrance doors big enough to bring in the ULT freezers for installation.
- Identify a location for the installation of ULT freezers that is not directly exposed to sunlight/heat source.
- Install an appropriate number and type of air-conditioning units that can consistently keep the ambient temperature below 30°C.

4.2.3 Power supply

Most of the models require a specification of power voltage and frequency when placing the order.

- Select a ULT freezer model with power voltage (V) and frequency that match the specifications of local power supply.
- The local power system should provide an uninterrupted electricity supply with stable required parameters. This can be achieved with the main grid plus backup through standby generators and/or other uninterrupted power systems (e.g. solar generators, battery banks, etc.).
- Select a model with built-in multi-voltage power supply capability if your country needs both 110/115 V and 220/230 V. It is also possible to order a ULT freezer with a standalone voltage stabilizer appropriate for 110 V/50/60 Hz.
- Make sure the backup generator has an automatic start-up functionality and is connected to a standby uninterrupted power supply (UPS) for the generator lag time before it starts.

4.2.4 Power consumption

- Select a model with the lowest power consumption (kWh/day) to reduce the size of the required backup generator and operation cost.
- Consider a model that reduces the demand placed on the power supply.²¹ Note that the increased power demand during start-up occurs only once at the initial start-up for the Stirling piston pump models whereas for the cascading compression models each cycle uses increased power.

4.2.5 ULT freezer “holdover time”

- The “holdover time” is an important factor to consider in equipment selection.
- Different ULT freezers available for the emergency use of the Pfizer-BioNTech COVID-19 Vaccine have varying holdover times at different ambient temperatures. Also note that these times will differ if tested empty or filled.²²
- Review manufacturers’ information on holdover time when selecting an appropriate ULT equipment to be installed in each UCC hub. This will provide an indication of the time available for restoring power in the unlikely event that the auto switch-over between the generator and mains malfunctions.

²¹ Ultra-low temperature freezer performance and energy use tests (🌐) (Delphine Faugoux, Office of Sustainability, University of California, Riverside; June 2016).

²² Check the holdover time for each ULT freezer from the UNICEF SD LTA list.

- When procuring a portable ULT freezer, check if the unit is supplied with a 12 V DC adaptor, which can provide for a 12 V battery backup. However, 12 V is not enough to supply the amount of power required to support a ULT freezer pull down to -86°C , but it can easily support steady state operation at -86°C set point. To support a pull down from a warmer temperature to -86°C , maximum power is required and should be supplied from mains power/generator before it is connected to the 12 V DC.

4.2.6 Climate zone

- Select ULT freezers that have been tested for the ambient temperatures that fall within your country's climate zone. This can help increase the resilience of the ULT freezer in case of a power failure or air conditioner failure.
- Sustained air-conditioning at the installation site is crucial for proper functioning of any ULT freezer.



It is important to consider the correct operating ambient temperature of equipment suitable for local conditions during equipment selection. Ultra-low freezers could be designed for:

- **Moderate zone** (appliance operates at a steady $+27^{\circ}\text{C}$ ambient temperature);
- **Temperate zone** (appliance operates at a steady $+32^{\circ}\text{C}$ ambient temperature); or
- **Hot zone** (designed for hot zone up to $+43^{\circ}\text{C}$ of ambient temperature).

4.2.7 Required maintenance

- Consider models that come with a supplier's guarantee for maintenance.
- Select ULT freezer models that are similar to the existing ULT freezers for ease of use and maintenance.
- Select models that require less maintenance (such as changing filters, replacement of parts, etc.)

4.2.8 Dual temperature functionality

- ULT freezers models are available in different temperature ranges (either -20°C to -86°C , -40°C to -86°C , or -60°C to -86°C).
- Consider selecting a ULT freezer model that can operate at a wide range of freezing temperature (i.e. a unit that can freeze at -86°C and -20°C) to allow flexibility in use in the health care setting especially if ULT storage is no longer necessary.

4.2.9 Temperature monitoring

While almost all ULT freezer models rated for hot or temperate zones are delivered with USB ports to allow downloading of data, this remains an optional requirement for inclusion in the LTA. Currently, USB ports are optional additions in three models in the UNICEF SD LTA list.

It is recommended that a remote temperature monitoring device (RTMD) with alarm is installed in each ULT freezer. However, RTMD are not supplied with the models under the UNICEF SD LTA but they can be provided upon request.

4.3 Installation site readiness

Site readiness for installation of ULT equipment is a key factor for smooth deployment and implementation of the Pfizer-BioNTech COVID-19 Vaccine. All requirements should be addressed prior to arrival of the equipment and the store facility should be operational and accessible when ULT equipment is planned for delivery and installation.

The ULT equipment should be housed in a permanent building, designed and constructed to a good standard that is appropriate for local climatic conditions. Refer to the WHO guideline for establishing or improving primary and intermediate vaccine stores [\(6\)](#) for more information.



Countries receiving ULT freezers as emergency supply to store the Pfizer-BioNTech COVID-19 Vaccine are encouraged to immediately prepare the storage area as described above with at least one autostart (less than 15 minutes) backup generator (with or without standby uninterrupted power supply) and to ensure full installation, including the uninterrupted power supply if not initially installed, is implemented per PQS_E003_POW_01.0 specification as soon as possible.

5. Pfizer readiness criteria for logistics and ULT equipment

Pfizer-BioNTech developed a checklist for assessing country readiness to receive the Pfizer-BioNTech COVID-19 Vaccine. The following are the key aspects related to Pfizer readiness criteria for the category “Logistics & ULT equipment”:

1. The country has certified a functional and commissioned ultra-cold chain storage point for receiving the shipment (e.g. central store), with enough capacity to receive at least 50% of the allocated volume.
2. The country has a plan for storage, transport and distribution of the vaccine which:
 - accounts for the current temperature parameters; and
 - has mechanisms for managing the expiry tracking at each temperature range.
3. The country has sufficient subnational ULT storage capacity and/or traditional cold chain capacity to implement the distribution plan.
4. The country has trained all staff handling the product under ULT conditions on the proper management of ULT equipment and vaccine.
5. Import and customs waivers have been prepared for any ordered ULT equipment.
6. The country has a plan for storage, transport and distribution of the diluent which accounts for the current temperature parameters.
7. The country has acknowledged that the thermal shippers and temperature device used for vaccine shipment will be returned to Pfizer post delivery within 30 days of receipt.

6. Sustainability and contingency planning

Due to the urgent need to procure ULT freezers to support the Pfizer-BioNTech COVID-19 Vaccine rollout, the COVAX Facility provided opportunities to support countries in obtaining the required ULT equipment to store the vaccine effectively under ULT conditions. However, to ensure value for money of this investment, countries are urged to include the sustainability and maintenance plan for the UCC system in their respective health emergency preparedness plan and/or national immunization strategy plan.

Considering that most developing countries have limited UCC infrastructure, countries are encouraged to draft a transition plan which provides the insight into how this UCC capacity will be utilized – even outside of EPI – to mitigate the risk of the equipment being earmarked only for immunization and end up being underutilized.

Given the level of effort and resources being invested as part of the COVID-19 response, specifically with regard to establishing UCC system, countries and development partners are encouraged to document both successes and lessons learned to guide further improvement of in-country logistics practices and global/regional level support and guidance.

Methods

A UCC strategy working group was formed through the COVAX Facility Country Readiness and Delivery on Supply Chain Workstream that led the development of this guidance. Information for the WHO prequalification document, UNICEF information on ULT equipment that are under the LTA and the vaccine and equipment manufacturers' study reports and resources were reviewed and these formed the basis for the implementation considerations described in this document. Cold chain and supply chain experts from both UNICEF and WHO were consulted. Feedback from regional supply chain focal points, especially where the Pfizer-BioNTech COVID-19 Vaccine and Ebola vaccine have already been used in ULT conditions, was considered, particularly the strategies to ensure safety when handling the ULT equipment and coolant packs. UNICEF experience with the deployment of the earlier batches of ULT equipment to AMC participating countries formed the basis of the implementation considerations on the selection of context-appropriate UCC equipment.

Remarks

The implementation considerations are aimed to guide countries in making decisions for designing and establishing UCC hub(s) to support the rollout of the Pfizer-BioNTech COVID-19 Vaccine. The COVAX Facility is providing support to countries that have no or limited capacity to store the vaccine under ULT conditions. A UCC capacity survey was conducted by WHO and UNICEF in the middle of 2021. The survey result shows that the available capacity for ULT equipment is 272 000 litres and about 72 000 litres ULT storage capacity is in the pipeline, while the total capacity gap is about 403 000 litres.

The implementation considerations contained in this document were developed leveraging on the experience and lessons learned from managing Ebola vaccine, which also requires ULT, in the context of a health emergency and UNICEF's experience in deploying ULT equipment as part of COVAX support. A review of the product specifications and relevant literatures was conducted to ensure this guidance is based on currently available information and technology development. Following the considerations, countries are expected to be adequately prepared to receive and rollout the Pfizer-BioNTech COVID-19 Vaccine.

Plans for updating

WHO continues to monitor the situation closely for any changes that may affect this operational guidance. Should any factors change, WHO will issue a further update.

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Declaration of interests

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Annex: UNICEF Supply Division long-term agreement on ULT freezers for COVID-19 vaccines

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine										
Manufacturer/supplier	Material number	Equipment type	Model	Gross internal volume	Cabinet type	Cooling performance	Internal temperature range	Operating ambient temperature	Holdover time	Refrigerant
Small volume category ≥ 80 < 300 L										
Qingdao Haier Biomedical Co., Ltd	S0003106	Ultra low freezer	DW-86L100J	100 L	Upright	-86°C	-40°C to -86°C	+32°C	120 mins from -80°C to -50°C at 25°C ambient; 105 mins at +32°C ambient	R600A (75g), R1150 (15g) and R50 (3g)
Qingdao Haier Biomedical Co., Ltd	S0003109	Ultra low freezer	DW-86W100J	100 L	Chest	-86°C	-40°C to -86°C	+32°C	130 mins from -80°C to -50°C at 25°C ambient; 115 mins at +32°C ambient	R290 (120g), and R170 (35g)
Global Cooling Inc./ Stirling Ultracold	S0003118	Ultra low freezer	SU105UE	105 L	Upright	-86°C	-20°C to -86°C	+32°C	2 hrs from -80°C to -60°C; 5.2 hrs to -40°C; 10 hrs to -20°C at 25°C ambient	R170 (30-33g)
B Medical Systems Sarl	S0003103	Ultra low freezer	U201	214 L	Upright	-86°C	-40°C to -86°C	+43°C	78 mins from -80°C to -60°C at +20°C ambient	R290 (150g), R170 (85g)
Vestfrost Solutions	S0003114	Ultra low freezer	VT5258	256 L	Upright	-86°C	-40°C to -86°C	+27°C	7 hrs from -80°C to -60°C at 25°C ambient	R50 + R600 + R1150 (total of 86g)
Vestfrost Solutions	S0003112	Ultra low freezer	VT308	296 L	Chest	-86°C	-40°C to -86°C	+27°C	21 hrs from -80°C to -60°C at 20°C ambient	R50 + R600 + R1150 (total of 143g)
Medium volume category ≥ 300 < 600 L										
Vestfrost Solutions	S0003113	ltra low freezer	VT408	383 L	Chest	-86°C	-40°C to -86°C	+27°C	14 hrs from -80°C to -60°C at 20°C ambient	R50 + R600 + R1150 (total of 161g)
PHC Corporation	S0003110	ltra low freezer	MDF-DU502VH-PE	528 L	Upright	-86°C	-50°C to -86°C	+40°C	41 hrs from -80°C to -20°C at 30°C ambient	R290 (135g +/- 5g), R170 (70g +/- 3g)
Qingdao Aucma Global Medical Co., LTD	S0003101	ltra low freezer	DW-86L567T	567 L	Upright	-86°C	-40°C to -86°C	+32°C	2.5 hrs from -86°C to -60°C at +25°C ambient	R290:150g, R170:130g
Qingdao Haier Biomedical Co., Ltd	S0003107	ltra low freezer	DW-86L578J	578 L	Upright	-86°C	-40°C to -86°C	+32°C	280 mins from -80°C to -50°C at 25°C ambient; 220 mins at +32°C ambient	R290 (120g) and R170 (85g)
B Medical Systems Sarl	S0003104	ltra low freezer	U501	598 L	Upright	-86°C	-40°C to -86°C	+43°C	78 mins from -80°C to -60°C at +20°C ambient	R290 (150g), R170 (85g)
Large volume category ≥ 600 < 900 L										
Qingdao Aucma Global Medical Co., LTD	S0003102	ltra low freezer	DW-86L707T	707 L	Upright	-86°C	-40°C to -86°C	+32°C	2.5 hrs from -86°C to -60°C at +25°C ambient	R290 (150g), R170:130g
PHC Corporation	S0003111	ltra low freezer	MDF-DU702VH-PE	729 L	Upright	-86°C	-50°C to -86°C	+40°C	48 hrs from -80°C to -20°C; 41 hrs at 30°C ambient	R290 (135g +/- 5g), R170 (85g +/- 3g)
B Medical Systems Sarl	S0003115	ltra low freezer	U701	747 L	Upright	-86°C	-40°C to -86°C	+43°C	78 mins from -80°C to -60°C at +20°C ambient	R290 (150g), R170 (90g)
Global Cooling Inc./ Stirling Ultracold	S0003119	ltra low freezer	SU780XLE	780 L	Upright	-86°C	-20°C to -86°C	+32°C	2.5 hrs from -80°C to -60°C; 6.5 hrs to -40°C; 12 hrs to -20°C at 25°C ambient	R170 (90g)
Qingdao Haier Biomedical Co., Ltd	S0003108	ltra low freezer	DW-86L828J	828 L	Upright	-86°C	-40°C to -86°C	+32°C	300 mins from -80°C to -50°C at 25°C ambient; 250 mins at +32°C ambient	R290 (145g), R170 (110g)

Annex continued

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine										
Manufacturer/supplier	Material number	Equipment type	Model	Gross internal volume	Cabinet type	Cooling performance	Internal temperature range	Operating rated ambient temperature	Holdover time	Refrigerant
Portable										
Global Cooling Inc./ Stirling Ultracold	S1185086	Ultra low freezer (portable for storage and transportation)	ULT25NEU	25 L	Top opening	-86°C	-20°C to -86°C	+32°C	30 mins to -60°C; 70 mins from -80°C to -40°C at 25°C ambient	R170 (10-12g)

Notes

- a) The coolant packs need a dedicated freezer (they cannot be stored in the same freezer with the vaccines).
- b) Due to the flammable nature of the refrigerant, ultra-low freezers with > 100 g refrigerant gas CANNOT BE SENT BY AIR.
- c) Ambient temperature: it is very important to identify the correct rated temperature appliance when choosing the ultra-low freezer.
- d) Each model has been designed for a specific climate zone (the ambient temperature) as indicated in the table above. The climate zone is the ambient temperature range in which the appliance can operate effectively without air-conditioning the room. If the room temperature exceeds the rated ambient temperature of the equipment, then the room should be air conditioned to maintain the room temperature at least no warmer than the rated temperature of the appliance. For example, if the equipment is designed for ambient temperature of +32°C, the room temperature should not exceed +32°C.
- e) Power supply: ultra-low freezers require continuous electricity supply (no power interruption is allowed). Essentially, the electricity supply will have to be continuous even if the mains supply drops out, therefore it is critically important to make sure that the ultra-low freezers are getting power continuously without interruption using diesel generators or other options as backup.
- f) When placing order provide single phase voltage and frequency available at installation sites.
- g) Manufacturers' instructions should be strictly followed during installation, temperature setting, usage and maintenance.
- h) If spare parts are needed please contact the cold chain unit/HTC for technical support.
- i) RTMS can be ordered upon request.

Annex continued

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine												
Manufacturer/ supplier	Controller				Pfizer vaccine storage capacity (estimation of freezer manufacturer)				Electric supply requirement			
	Microprocessor controlled	With temperature data logging	With digital display	With alarms	With data downloading/ USB port	Number of boxes (secondary packaging) with 232 × 232 × 40 mm external dimensions to be stored	Total number vials (195 vials/secondary packaging) to be stored	Total number of vaccine doses to be stored (6 doses per vial)	Freezer available for 220-240V/50Hz single phase	Freezer available for 110V/60Hz single phase	Freezer available for 220V/60Hz single phase	
Small volume category ≥ 80 < 300 L												
Qingdao Haier Biomedical Co., Ltd	Yes	Yes	Yes	Yes	Yes	28	5460	32 760	Yes	No	No	
Qingdao Haier Biomedical Co., Ltd	Yes	Yes	Yes	Yes	Yes	40	7800	46 800	Yes	No	No	
Global Cooling Inc./ Stirling Ultracold	Yes	Yes	Yes	Yes	No	30	5850	35 100	Yes	Yes	Yes	
B Medical Systems Sarl	Yes	Yes	Yes	Yes	Yes	48	9360	56 160	Yes	No	Yes	
Vestfrost Solutions	Yes	Yes	Yes	Yes	Yes	83	16 185	97 110	Yes	Yes	No	
Vestfrost Solutions	Digital	No	Yes	Yes	No	100	19 500	117 000	Yes	Yes	No	
Medium volume category ≥ 300 < 600 L												
Vestfrost Solutions	Digital	No	Yes	Yes	No	144	28 080	168 480	Yes	Yes	No	
PHC Corporation	Yes	Yes	Yes	Yes	Yes	120	23 400	140 400	Yes	No	No	
Qingdao Aucma Global Medical Co., LTD	Yes	Yes	Yes	Yes	Yes	96	18 720	112 320	Yes	Yes	No	
Qingdao Haier Biomedical Co., Ltd	Yes	Yes	Yes	Yes	Yes	204	39 780	238 680	Yes	No	No	
B Medical Systems Sarl	Yes	Yes	Yes	Yes	Yes	192	37 440	224 640	Yes	No	Yes	

Annex continued

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine											
Manufacturer/ supplier	Controller				Pfizer vaccine storage capacity (estimation of freezer manufacturer)				Electric supply requirement		
	Microprocessor controlled	With temperature data logging	With digital display	With alarms	With data downloading/ USB port	Number of boxes (secondary packaging) with 232 × 232 × 40 mm external dimensions to be stored	Total number vials (195 vials/secondary packaging) to be stored	Total number of vaccine doses to be stored (6 doses per vial)	Freezer available for 220-240V/50Hz single phase	Freezer available for 110V/60Hz single phase	Freezer available for 220V/60Hz single phase
Large volume category ≥ 600 <900 L											
Qingdao Aucma Global Medical Co., LTD	Yes	Yes	Yes	Yes	Yes	144	28 080	168 480	Yes	Yes	No
PHC Corporation	Yes	Yes	Yes	Yes	Yes	180	35 100	210 600	Yes	No	No
B Medical Systems Sarl	Yes	Yes	Yes	Yes	Yes	288	56 160	336 960	Yes	No	Yes
Global Cooling Inc./ Stirling Ultracold	Yes	Yes	Yes	Yes	No	307	59 865	359 190	Yes	Yes	Yes
Qingdao Haier Biomedical Co., Ltd	Yes	Yes	Yes	Yes	Yes	288	56 160	336 960	Yes	No	No
Portable											
Global Cooling Inc./ Stirling Ultracold	Yes	Yes	Yes	Yes	No	7	1365	8190	Yes	Yes	Yes

Pfizer-BioNTech COVID-19 Vaccine

Annex continued

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine													
Manufacturer/ supplier	Consumption		Energy consumption	Running current	Voltage regulation		With wheels/ casters	Supplied with sets of cryo gloves	Prices		Lead time and FCA point		Warranty period
	Power consumption				Supplied with voltage stabilizer	Supplied with UPS			Unit price (equipment)	Currency	FCA delivery point	Manufacturer lead time (to FCA delivery point)	
Small volume category ≥ 80 <300 L													
Qingdao Haier Biomedical Co., Ltd	680 W	5.5 KWh/24h		3A	Yes	No	Yes	Yes	3008.32	USD	FCA Qingdao Seaport, China	45 days	24
Qingdao Haier Biomedical Co., Ltd	550 W	5 KWh/24h		4A	Yes	No	Yes	Yes	2896.32	USD	FCA Qingdao Seaport, China	45 days	24
Global Cooling Inc./ Stirling Ultracold	300 W	4 KWh/24h		1.5A	No	Yes	Yes	Yes	10765	USD	FCA New York, USA	30 days	24
B Medical Systems Sarl	2 KW	12.0 KWh/24h (230V 50Hz) / 12.0 KWh/24h (220V 60Hz)		10A	Yes	No	Yes	Yes	5729	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24
Vestfrost Solutions	1150 W	10.3 KWh/24h		6A	Yes	No	Yes	Yes	3920	EUR	FCA Aarhus, Denmark	30 days	24
Vestfrost Solutions	800 W	8.0 KWh/24h		5A	Yes	No	Yes	Yes	2120	EUR	FCA Aarhus, Denmark	30 days	24
Medium volume category ≥ 300 <600 L													
Vestfrost Solutions	800 W	9.0 KWh/24h		5A	Yes	No	Yes	Yes	2340	EUR	FCA Aarhus, Denmark	30 days	24
PHC Corporation	0.42 KW	6.7 KWh/24h		3.9A	Yes	No	Yes	Yes	7911.6	EUR	FCA Rotterdam, The Netherlands	30 days	24
Qingdao Aucma Global Medical Co., Ltd	1.45 KW	13 KWh/24h		11A	Yes	No	Yes	Yes	3580	USD	FCA Qingdao Seaport, China	40 days	24
Qingdao Haier Biomedical Co., Ltd	750 W	8.5 KWh/24h		7.5A	Yes	No	Yes	Yes	5265.12	USD	FCA Qingdao Seaport, China	45 days	24
B Medical Systems Sarl	2 KW	11.3 KWh/24h (230V 50Hz) / 12.5 KWh/24h (220V 60Hz)		10A	Yes	No	Yes	Yes	6504	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24

Annex continued

Ultra-low freezers for storing Pfizer-BioNTech COVID-19 Vaccine												
Manufacturer/ supplier	Consumption		Running current	Voltage regulation		With wheels/ casters	Supplied with sets of cryo gloves	Prices		Lead time and FCA point		Warranty period
	Power consumption	Energy consumption		Supplied with voltage stabilizer	Supplied with UPS			Unit price (equipment)	Currency	FCA delivery point	Manufacturer lead time (to FCA delivery point)	
Large volume category ≥ 600 <900 L												
Qingdao Aucma Global Medical Co., Ltd	1.6 KW	15.5 KWh/24h	10A	Yes	No	Yes	Yes	3750	USD	FCA Qingdao Seaport, China	40 days	24
PHC Corporation	0.55 KW	7.7 KWh/24h	4.6A	Yes	No	Yes	Yes	8871.6	EUR	FCA Rotterdam, The Netherlands	30 days	24
B Medical Systems Sarl	2 KW	11.9 KWh/24h (230V 50Hz) / 13.5 KWh/24h (220V 60Hz)	10A	Yes	No	Yes	Yes	6941	EUR	FCA Antwerp Seaport, Belgium	8 weeks	24
Global Cooling Inc./ Stirling Ultracold	1.2 KW	6.67 KWh/24h	5A	No	Yes	Yes	Yes	14250	USD	FCA New York, USA	30 days	24
Qingdao Haier Biomedical Co., Ltd	1000 W	12 KWh/24h	10A	Yes	No	Yes	Yes	6213.76	USD	FCA Qingdao Seaport, China	45 days	24
Portable												
Global Cooling Inc./ Stirling Ultracold	280 W	2.8 KWh/24h	2A	No	Yes	NA	Yes	7215	USD	FCA New York, USA	20 days	24

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