

POWERING HEALTH: COLD CHAIN AND REFRIGERATION

A cold chain is a series of climate-controlled transport and storage facilities that ensure the viability of testing reagents, medicines, vaccines, and blood products from factory to patient.



POWERING HEALTH

This document is provided as part of USAID's <u>Powering Health</u> toolkit. Health-care facilities require electricity to maintain perishable supplies and power life-saving technologies. Energy is essential for preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combating infectious diseases and pandemics.

Reliable electricity can mean life or death for patients in developing country health-care facilities. However, many of these facilities have little or no access to reliable electricity. USAID supports partner countries in understanding the energy needs of their health-care facilities over the long term. This challenge requires local capacity for careful planning, a commitment to maintenance, and dedicated funding.

USAID uses its experience at the nexus of the health and energy sectors to help international development practitioners and health-care administrators design programs that meet the energy needs of health-care facilities. By applying international best practices and lessons learned, stakeholders can help ensure that health-care facilities are able to power standard appliances, such as lights, life-saving equipment, blood and medicine refrigerators, ventilators, laboratory diagnostic tools, and technology that monitors patients' vital signs.

INTRODUCTION

The COVID-19 pandemic refocused the world on the need for effective cold chains that can deliver testing reagents, vaccines, drugs, and blood products to the remotest regions of the world. Vaccine refrigerators need to maintain internal temperatures between $2^{\circ}C$ and $8^{\circ}C$ or the vaccines will lose potency, and blood bank refrigerators need to maintain an even tighter internal temperature window between $2^{\circ}C$ and $6^{\circ}C$.

A cold chain includes both the refrigeration equipment that chills medical supplies and the operational procedures that ensure these critical supplies maintain the proper temperature. For years, health professionals have struggled to establish effective cold chains in developing countries to ensure that critical medicines and vaccines reach the most isolated populations. Lack of access to electricity and intermittent power supply in many of these countries greatly complicate establishing a cold chain with traditional electrically powered refrigeration.

CONSIDERATIONS WHEN CHOOSING A MEDICAL REFRIGERATOR

When choosing a refrigerator for blood, vaccine, or reagent cold storage, facility managers should consider many specifications that affect the cost of operation and temperature stability.

A refrigerator or freezer must be appropriately sized both to meet the refrigeration needs of the facility and fit within the capacity of the facility's overall energy system. Another key consideration is holdover time, which must be appropriate for the reliability of the facility's energy supply; if the facility receives intermittent power, a longer holdover time will be required. Additional issues include temperature zone (based on the regional climate), daily ice-pack freezing capacity, reliability, and price. A thorough analysis of all these considerations will help ensure the sustainability of the facility's cold chain refrigerator.

SIZE AND ENERGY USE

Refrigeration requires significant energy, and choosing a refrigerator that is appropriately sized for the intended need is critical. In many developing countries, it is common to find oversized medical refrigerators. To choose a unit appropriately sized for the needs of the facility, use the vaccine storage capacity or blood storage capacity of the refrigerator, typically reported in liters or numbers of packs. Manufacturers should state the typical energy consumption, in kilowatt-hours, per 24 hours. This data should be available for both stable running conditions (*i.e.*, maintaining constant temperature) and contents cooldown (*i.e.*, freezing or cooling the refrigerator contents) and should reflect performance at the maximum ambient temperature rating for the equipment (temperature zone rating). Energy consumption will vary based on refrigerator capacity and type; sufficient manufacturer's data should allow for a fair product comparison based on energy consumption. For examples of typical cold chain refrigerators and specific product data, see World Health Organization (WHO) prequalified equipment: refrigerators and freezers. Use the HOMER Powering Health Tool to better understand how refrigeration loads will affect your facility.

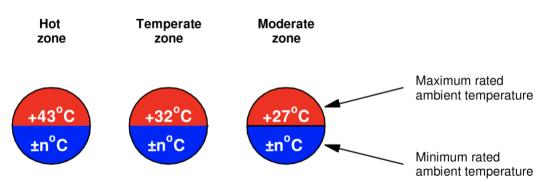
INTENDED USE

The cold chain requirements for blood and vaccines differ slightly; blood must be kept at 2°C to 6°C, while vaccines must be kept at 2°C to 8°C. While this difference may seem minor, it can make a large difference in the delivery of usable blood. If a refrigerator is intended to be used for the storage of blood, a unit designed for that purpose should be chosen, as proper storage conditions cannot be guaranteed otherwise. Frozen vaccines must be kept between -15°C and -50°C and require dedicated freezers. The WHO does not recommend using combined refrigerator/freezer units to store frozen vaccines.

TEMPERATURE ZONES

It is necessary to understand temperature zones when selecting refrigerators and freezers. Refrigerator and freezer temperature zones are outlined by the WHO's Expanded Programme on Immunization (EPI). If ambient temperatures are too high or too low, then there is danger that compartment temperatures may move outside the temperature window required for vaccine storage. The WHO rates equipment according to its ability to maintain vaccine storage temperatures in three climate types: hot, temperate, and moderate. Equipment rated for hot, temperate, and moderate zones must be able to maintain the compartment temperature below 8°C when the ambient temperature is 43°C, 32°C, and 27°C, respectively.

To prevent their contents from freezing, hot-, temperate-, and moderate-zone refrigerators are also rated with a minimum ambient temperature of 25°C, 15°C, or 10°C, respectively. However, some refrigerators with the ability to heat the storage compartment can prevent vaccines from freezing; these refrigerators can be rated for ambient temperatures as low as -10°C. Freezers do not have a minimum temperature rating because there is no need to protect their contents from freezing. Determinations for temperature and geographic zone should be based on the prevailing climate of the area. The figure below shows the WHO temperature-zone labeling requirements. Hot-zone equipment can be used in temperate zones, but equipment for temperate zones should not be used in hot zones.



Temperature Zone Symbols for Vaccine Refrigerators

REPRINTED, WITH PERMISSION, FROM WORLD HEALTH ORGANIZATION, E003.6.4 PQS SPECIFICATIONS: REFRIGERATOR TEMPERATURE ZONE SYMBOLS

DAILY ICE-PACK FREEZING CAPACITY

Capacity is crucial if large quantities of frozen ice packs are needed and/or when the appliance is also used for vaccines. If the program requires only ice-pack freezing, and capacity is not a major concern, any locally available residential or commercial freezer with low power consumption can be used. According to WHO standards, dedicated vaccine/ice pack freezers should have a daily freezing capacity of 7.2 kilograms (kg), while ice pack–only freezers should freeze 2.4 kg/day.

POWER SOURCE AND QUALITY

Equipment should be selected that is compatible with the available power supply. Refrigerators typically run on either 110–120 volt (V) or 220–240 V alternating current (AC) power at 50 or 60 hertz, and these operating specifications should match the power supplied to the facility. If the facility is connected to the grid or a generator, voltage stability may be an issue. If the power supply frequently generates surges, dips, or other fluctuations in voltage, the refrigerator may be damaged. In this case, an automatic voltage regulator (AVR) should be connected to the refrigerator to ensure that it is protected from damage resulting from low-quality power. Some refrigerator and freezer manufacturers offer AVRs as an optional accessory. Refrigerating equipment designed specifically for use with a dedicated solar system runs on 12 V or 24 V direct current (DC) power.

HOLDOVER TIME DURING POWER FAILURES

Continuous refrigeration is required for vaccine storage, and it is often difficult to ensure this in areas where power or fuel sources are intermittent. Ice-lined refrigerators, which provide significantly longer holdover time than non-lined refrigerators, can provide stable internal temperatures, even in areas with intermittent power. The longer the holdover time of the refrigerator, the more likely it is that the vaccine will survive a power outage. According to WHO standards, a standard compression medical refrigerator should have a holdover time of no less than 4 hours. Ice-lined refrigerators should have a holdover time of 3 hours if connected to a battery and 20 hours if directly supplied by photovoltaic (PV) panels (*i.e.*, no battery).

RELIABILITY AND SPARE PARTS

When selecting equipment, it helps to know the availability of spare parts and the proximity of repair facilities. Spare parts and repairs account for 40 to 50 percent of the lifetime cost of a refrigerator. Manufacturers should suggest necessary spare parts. Typical spare parts include thermostats, compressors, and fans. To avoid shortages later, purchase these spares at the time the equipment is purchased.

PRICE

In addition to the cost of the refrigerator and spare parts, include freight costs and freight times in cost evaluations. When placing an order, include a request for a thermometer and an AVR for electrical equipment if local conditions require one.

TRAINING

It is important that the users and those in charge of maintenance of the clinic cold storage equipment are properly trained. The importance of user and technician training is often underestimated and therefore underbudgeted. A cold chain system with good equipment but insufficiently trained staff may seriously hamper an immunization program. Remember to specify the language needed for the user's manual and service manual. For more information, see the WHO's <u>Manual on the management</u>, maintenance and use of blood cold chain equipment.

REFRIGERANT SELECTION

Older refrigerants contain chlorofluorocarbons (CFCs), which are chemicals that contribute to ozone depletion in the upper atmosphere. Refrigerants that do not meet the Montreal Protocol standards are slowly being phased out of production, affecting refrigerator operators' ability to source replacement refrigerants for older refrigerator models. Only refrigerators that use compliant refrigerants such as R134-A and R410-A should be purchased for use in health-care facilities.

TYPES OF COLD CHAIN REFRIGERATORS

A health-care facility should have a range of powered and passive cold chain elements. A variety of different technologies have been developed, including 12 V electric, liquefied petroleum gas (LPG), gas/electric hybrid, and kerosene-powered models, to provide powered refrigeration in areas with limited electricity service. A cold box passively keeps vaccines at the required temperature for between two and seven days and is needed in case of interrupted power supply or equipment maintenance. It can also be used to transport and temporarily store vaccines, blood, and reagents in health posts without refrigeration, provided the medical supplies are used immediately.

Each of the refrigeration technologies listed below has advantages and disadvantages, and there is considerable debate among health professionals concerning the most reliable technology.

MEDICAL-GRADE VAPOR COMPRESSION

MINIMUM HOLDOVER TIME:

ADVANTAGES:

• 4 hours

- Many third-party service companies
- Mass produced



DISADVANTAGES:

 Requires AC power source

Vapor compression refrigerators and freezers require a source of electricity to run a compressor. Grid-powered vapor compression refrigerators and freezers are designed for on-grid use but can be run by any source of AC power; inverters and diesel generators are alternative sources of AC power. Vapor compression refrigerators for medical use are heavily insulated and include cooling fans and temperature-monitoring equipment. Some medical refrigerators have two compressors to provide redundancy in case one compressor fails. Grid-powered vapor compression is the most common refrigeration technology and is usually less expensive than the other technologies listed here. Compression refrigerators are the best option when there is a high-quality electricity supply, either from the grid or an on-site energy supply system specifically designed to meet refrigeration loads.

Residential refrigerators are not as reliable or efficient as medical refrigerators but are often more readily available and less expensive. Because domestic refrigerators are usually poorly insulated, internal temperatures can rise quickly during power failures and result in uneven temperature distribution, including hot or cold spots in different parts of the unit. Domestic refrigerators should not be used for blood, vaccine, or testing reagent storage.

SOLAR-POWERED VAPOR COMPRESSION

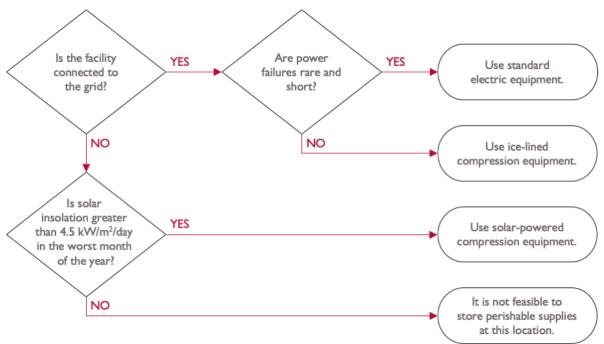
MINIMUM HOLDOVER TIME:

- ADVANTAGES:
- With battery: 3 hours
- Without battery: 20 hours
- Does not need grid connection or generator
- No additional electricity or fuel cost

DISADVANTAGES:

- High capital cost
- Requires solar availability analysis
- With battery: must regularly replace battery
- Few third-party service companies

Solar electric refrigerators are a subset of compression refrigerators. They are highly insulated refrigerators that typically include a top-opening refrigerator to minimize chilling loads when the unit is opened. Solar electric refrigerators are coupled to DC-powered motors that are powered by solar panels and occasionally batteries for backup power. Solar refrigerators require careful study of the refrigeration requirements, number of sunlight hours, and a specification for the number of days of storage during cloudy periods. The figure below outlines some important considerations when determining if a solar refrigerator is an appropriate cold chain solution.



Compression Technology Decision Tree

ADAPTED, WITH PERMISSION, FROM WHO-EPI PRODUCT INFORMATION SHEETS, 2000

Solar refrigerators are an excellent option for remote facilities without access to reliable electricity or fuel supplies if all the conditions for maintaining and sustaining the solar systems are in place. Solar-powered vaccine refrigerators endorsed by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) are typically the most successful examples of solar power application in rural health facilities. These systems are more sustainable than standard clinic-wide solar photovoltaic (PV) systems for the following reasons:

- **Dedicated Load** Solar-powered systems are typically well designed (oversized) for the vaccine refrigerator, and no other load is allowed to be connected. This prevents system overloading, which results in the failure of many clinic-wide systems.
- **Maintenance Staff** WHO/UNICEF cold chain programs typically train local technicians who are responsible for the cold chain. These technicians make periodic checks of each cold chain system, including the solar system. Technicians are often supported by a national-level cold chain technician who can provide support when difficult problems are encountered.

Solar-powered refrigerators can be equipped with and without batteries.

BATTERY STORAGE SOLAR SYSTEMS

Battery storage solar systems require proper PV panel and battery bank sizing to provide power for periods without sufficient sunlight. Such systems rely on energy stored in the batteries, rather than the holdover time of the refrigerator, to ensure that temperatures are maintained.

DIRECT DRIVE SOLAR SYSTEMS

Direct drive solar systems, those that do not contain any battery storage, require greater holdover time and are also specified based on autonomy. Autonomy is the number of days that the refrigerator can maintain required interior temperatures when solar radiation is low. For instance, if a refrigerator requires a minimum of 3.5 kilowatt-hours per square meter per day (kWh/m2/day) of solar irradiance in order to perform properly, the autonomy is the number of days that interior temperatures will be maintained if solar irradiance is below that minimum condition.

ICE-LINED VAPOR COMPRESSION

MINIMUM HOLDOVER TIME:

• 20 hours

ADVANTAGES:

- Maintains temperature during short power outages
- No battery replacement cost
- Many third-party service companies

DISADVANTAGES:

- Must have AC source
- Higher cost than regular vapor compression refrigerators

Ice-lined refrigerators are designed to have a longer holdover time than non-ice-lined refrigerators. Unlike standard vapor compression refrigerators, ice-lined variants may hold the temperature below $+10^{\circ}$ C for many days following a power outage. This is achieved by lining the cabinet with water/ice containers or freezer sections with ice packs positioned adjacent to the storage area. During periods of power failure and load shedding, the ice packs act as a means of cold storage to protect the medical supplies stored in the refrigerator. Ice-lined refrigerators are strongly recommended for facilities located in areas with intermittent power supply (*i.e.*, eight or more hours of reliable electricity per day) and frequent power cuts, typically in district or regional centers.

ABSORPTION

MINIMUM HOLDOVER TIME:

I.5 hours

ADVANTAGES:Does not need electricity

connection

- DISADVANTAGES:
- Must have low-cost heat source
- Few third-party service companies
- Energy inefficient

Absorption refrigerators require a heat source, which is typically either a natural gas, kerosene, or propane burner or an electric resistive heater. Kerosene refrigerators are more difficult to control than propane refrigerators, and electric absorption refrigerators are less efficient than electrically powered vapor compression refrigerators. Absorption refrigerators are an excellent option for areas with no electrical power service and poor conditions for solar refrigeration, but reliable access to fuel. However, budgeting funds to continually purchase fuel, can be a serious constraint.

HYBRID

MINIMUM HOLDOVER TIME:

• 1.5 hours

ADVANTAGES:

• Runs on either electricity or gas

DISADVANTAGES:

- Mechanically complex
- Not widely available

Hybrid absorption/compression refrigerators can operate on either electricity or gas. These refrigerators offer the flexibility of operating on whichever energy source is available at the lowest cost. They are a good option for any type of small facility with inconsistent electrical power. Supply of fuel is still an issue, however, as hospital staff often consider it a "backup" and do not prioritize refilling canisters. WHO standards for absorption refrigerators apply to hybrid refrigerators.

ICE PACK FREEZERS

MINIMUM HOLDOVER TIME:

- ADVANTAGES:
- Not applicable
- Lower temperature-management requirements
- Low cost

- DISADVANTAGES:Not appropriate for vaccine,
 - reagent, or blood storage

Ice pack freezers are available as either compression or absorption units. These freezers are generally only suitable for freezing and storage of ice packs, although some compression models are also designed for simultaneous freezing of vaccines and ice packs. Because ice pack storage is not as critical as vaccine or blood storage, these units are typically less complex and have less stringent requirements than medical-grade freezers. There are WHO standards in place for ice pack freezers, but no minimum holdover time is specified.

COLD BOXES AND VACCINE CARRIERS

MINIMUM HOLDOVER TIME:

- Cold Box: 48–96 hours
- ADVANTAGES:
- Vaccine Carrier: 15–30 hours
- Low cost
- No moving parts

DISADVANTAGES:

- Only used for transportation and very short-term storage
- Must have access to other cold storage technology

Cold boxes and vaccine carriers are not refrigerators but are highly insulated containers used to transport vaccines from one facility to another or from a facility to the point of use. These containers are rated by their cold life, or the number of hours they can maintain required internal temperatures (much like holdover time). Cold-life ratings can be further divided by long range and short range, which indicate the relative distance over which they can be relied on for transport.

TEMPERATURE-MONITORING EQUIPMENT

Temperature monitoring is a crucial part of the cold chain. There are many methods to monitor temperature during the transport and storage of medical products.

Temperature-monitoring techniques can range from manual temperature readings written down twice a day to automatic data loggers that continuously record temperatures. Either can be accurate and effective, but both require defined procedures and appropriate equipment. Many cold chain refrigerators have integrated temperature measurement systems, and they should be closely evaluated when choosing a refrigerator.

Following are a few of the available temperature-monitoring technologies. For more information on these technologies and temperature-monitoring devices, visit the <u>World Health Organization list of prequalified equipment</u>.

PORTABLE ELECTRONIC THERMOMETER

Portable thermometers are a simple and inexpensive solution to cold chain temperature monitoring. When used as part of a well-organized temperature-monitoring protocol, involving twice-daily temperature recordings, these devices can effectively track temperature across multiple cold chain storage units. While the devices themselves are quite accurate, the necessary opening and closing of cooling compartments when taking measurements can lead to inaccurate results. Other drawbacks are that a portable device can be lost or stolen and does not allow for continuous temperature recording, leaving the monitoring program open to human error.

FIXED PRESSURE DIAL THERMOMETER

A fixed pressure dial thermometer is an analog device that displays the temperature in a single refrigerator at all times. This dedicated device allows for the manual recording of refrigerator temperature, without the drawback of having to open the cabinet door.

INTEGRATED ELECTRONIC THERMOMETER

An integrated electronic thermometer is similar to the fixed dial thermometer above, but it has a digital temperature display. Some dedicated electronic thermometers also record the minimum and maximum temperature within the storage cabinet over a period of time, giving greater assurance that storage temperatures have not gone outside the required temperature range.

THERMOGRAPH

A thermograph is an analog device that continuously records temperature over a period of time, typically 24 hours or 7 days. These devices allow for a complete record of storage temperature for one or multiple refrigeration units. One major drawback is the need for special recording paper, pens, and ink, which can run out over time, rendering the device useless.

TEMPERATURE DATA LOGGER

A temperature data logger allows for continuous temperature monitoring. Much like a thermograph, a data logger can track the temperature for one or more refrigeration units, maintaining a constant temperature record for each. The advantage of a data logger is that it does not require consumables like ink and paper, as does a thermograph. However, access to a computer and appropriate data-logging software are essential.

ALARM

An alarm is an audible or visual indicator that alerts facility personnel if the temperature within a storage unit is outside the required temperature range. Alarms can also be used to indicate when a refrigerator door has been left ajar or a unit experiences a loss of power.