PQS Performance Specification

WHO/PQS/E003/ FZ04.1
Original: English
Distribution: General

TITLE: Vaccine freezer or combined vaccine and water-pack freezer: Solar-direct drive

Specification reference:	E003/FZ04.1
Product verification protocol:	E003/FZ04-VP.1
Issue date:	28 November 2022
Date of previous revision:	New specification

Contents

1. Scope **2**

2. Normative references **3**

3. Terms and definitions **4**

4. Requirements **6**

4.1 General 6
4.1.1 Field evaluation *6*

4.2 Performance 6
4.2.1 Operating temperature range *6*
4.2.2 Refrigeration cycle *6*
4.2.3 Voltage *6*
4.2.4 Vaccine storage capacity *6*
4.2.5 Water-pack freezing and storage compartment capacity (optional) *7*
4.2.6 Simultaneous vaccine storage and water-pack freezing warning *7*
4.2.7 Temperature control *7*
4.2.8 Thermostat *7*
4.2.9 Thermometer *8*
4.2.10 Indicator light *8*
4.2.11 Autonomy *8*
4.2.12 Power system requirements *9*
4.2.13 Evaporator configuration, humidity control and defrosting *9*
4.2.14 Lock *10*
4.2.15 Corrosion resistance *10*
4.2.16 Electrical safety rating *10*
4.2.17 Markings *10*
4.2.18 Labelling *10*
4.2.19 Electromagnetic compatibility *11*
4.2.20 Equipment monitoring system *11*

4.3 Environmental requirements 11
4.3.1 Ambient temperature range during transport and storage *11*
4.3.2 Ambient humidity range during transport, storage and use *11*

4.4 Physical characteristics 11
4.4.1 Overall dimensions *11*
4.4.2 Weight *12*

4.4.3 Spacers *12*
4.5 Interface requirements 12
4.5.1 Electrical components *12*
4.5.2 Power switch *12*
4.6 Human factors 12
4.6.1 General design *12*
4.6.2 Control panel, indicator light and thermometer *12*
4.7 Materials 13
4.7.1 Refrigerant *13*
4.7.2 Thermal insulation foaming agents *13*
4.7.3 Other restricted materials *13*
4.7.4 PCM *13*
4.8 Warranty 13
4.9 Servicing provision 13
4.9.1 Essential spare parts and user maintenance tools/supplies *14*
4.10 Disposal and recycling 14
4.11 Instructions 14
4.12 Training 15
4.12.1 Verification *15*
5. Packaging 15
6. On-site installation 16
7. Product dossier 16
8. On-site maintenance 17
9. Change notification 17
10. Defect reporting 17
Annex 1: Temperature zone symbol for vaccine freezers 18
Annex 2: Refrigerant symbols 18
Revision history 19

1. Scope

This specification defines the requirements for vaccine storage freezer appliances powered by a solar direct drive (SDD) electric system with no battery.

These appliances are not suitable for simultaneous frozen vaccine storage and water pack freezing if a single freezer compartment is provided. Optionally, a two-compartment freezer may be provided where one compartment is dedicated for frozen vaccine storage and the second compartment is dedicated to water pack freezing.

Prequalification testing will establish a minimum solar radiation reference period below which the product should not be used. Testing will also establish the maximum autonomy that the vaccine storage freezer can achieve. Three temperature zone designations are described: moderate zone, temperate zone and hot zone. All appliances must fully meet the stated performance requirements for hot zone (+43°C) test temperatures.

PQS specification **WHO/PQS/E003/PV01** specifies a compatible Type 2 solar power system to directly power the appliance.

Appliance design must account for performance degradation over the 10-year target life of the appliance in order to sustain acceptable temperature range for frozen vaccine storage and other appliance features (if included).

The build quality of the appliance and all ancillary components must be consistent with the conditions under which these appliances are installed, used and maintained including, but not limited to, the following:

- Transport by air, sea and over rough, dusty road surfaces,
- High temperatures in transport, storage and operation,
- Low temperatures in transport, storage and operation,
- High humidity in transport, storage and operation,
- Operating locations with high wind and high density of dust particles,
- Operating locations near corrosive marine environments,
- Users and technicians with inconsistent training, and/or
- Users with no specific maintenance tools.

2. Normative references

(Use most recent version.)

EMAS: European Union Eco-Management and Audit Scheme.
EN ISO 6270-1 / ASTM D2247 / EN 13523-26: 2017 Determination of resistance to humidity – Part 1: Continuous condensation.
EN ISO 6270-2 / EN 13523-25: 2017 Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres.
Generic Guide for the Field Evaluation of New Technologies for WHO PQS Prequalification.
GHS Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.
IEC 60335-1: 2020 Household and similar electrical appliances - Safety
 Part 1: General requirements.

IEC 60335-2-24: 2020 Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.
IEC 60364-1: 2005 Low -voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.
IEC 61000-6-1 : 2016 Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.
IEC 61000-6-3 : 2020 Electromagnetic compatibility (EMC) Generic standards - Emission standard for equipment in residential environments[1].
IEC 62552-1:2015+AMD1:2020 CSV Consolidated version Household refrigerating appliances - Characteristics and test methods - Part 1: General requirements.Intergovernmental Panel on Climate Change.
ISO 2409: 2020 Paints and varnishes – cross cut test (external cabinet).
ISO 6272 / EN 13523-5: 2014 Impact resistance - external cabinet.
ISO 9001: 2015 Quality Management Systems – Requirements.
ISO 14001: 2015 Environmental management systems - Requirements with guidance for use.
ISO 20282-1: 2006 Ease of operation of everyday products - Part 1: Context of use and user characteristics.
ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories.
WHO/PQS/E003/BC01.1: Global asset identification.
WHO/PQS/E003/FZ04-VP.1: Independent type testing protocol: Frozen vaccine storage freezer: Solar direct drive without battery storage.
WHO/PQS/E003/PV01: Performance specification: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E003/PV01-VP.1: Type-examination protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E003/PV01-VP.2: Quality assurance protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E005/IP01: Water-packs for use as ice-packs, cool-packs and warm-packs.
WHO/PQS/E006/TH02: Fixed gas or vapour pressure dial thermometer.
WHO/PQS/E006/TH06: Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.

3. Terms and definitions

Acceptable temperature range (frozen vaccine): The acceptable temperature range for storing frozen vaccine is -15°C to -25°C.
Autonomy (water pack compartment): For combined vaccine storage freezer with separate water pack freezer compartment the time in hours that a solar direct drive water-pack freezer can maintain the minimum capacity of fully frozen water-packs under low solar radiation conditions (e.g., rain). Autonomy is measured as described in **WHO/PQS/E003/FZ04-VP.1** Test 6.

[1] Note from the IEC: The intention is that all equipment used in the residential, commercial and light-industrial environments are covered by IEC 61000-6-3 or IEC 61000-6-8.

Autonomy (vaccine compartment): Time in hours during which all points in the vaccine compartment remain within the acceptable temperature range. Autonomy is measured as described in **WHO/PQS/E003/FZ04-VP.1** Test 3.
Cool-down time: The time required to initially cool an appliance to achieve stable operating conditions within the acceptable temperature range for frozen vaccine storage and achieve its full autonomy time.
Gross volume: The measured volume of the air space inside the internal compartment(s) with the door or lid shut.
Hot zone: Hot zone appliances must operate at a steady +43°C ambient temperature and over a+43°C/+25°C day/night cycling temperature range.
In writing: Communication by letter, fax or email.
Installation: The appliance specified in this document, connected to a solar power system complying with specification **WHO/PQS/E003/PV01**.
Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of an appliance or device before it is placed on the market under the person's own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.
Moderate zone: Moderate zone appliances must operate at a steady +27°C ambient temperature and over a +27°C/+10°C day/night cycling temperature range.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer and Kigali Amendment 2016.
Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
Net storage capacity: This is the gross volume multiplied by a utilization rate of 0.67.
Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries appliance liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Solar radiation reference period: The minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar-powered appliance, expressed in kWh/m²/day.
Temperate zone: Temperate zone appliances must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.
Vaccine storage capacity: The net storage capacity is the space where it is suitable (both thermally and ergonomically) to store vaccines with any components necessary to operate within the acceptable temperature range fully prepared and in place. If a legal manufacturer would declare more than one vaccine storage capacity for the same internal and external dimensions, they must prequalify with different branding, one model for each different storage volume. This capacity will be published as vaccine volume in litres.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.
Water-pack freezing capacity: The daily maximum weight and number of water-packs which can be fully frozen, in one batch, during a 24-hour freezing cycle when no vaccine is stored in the water-pack freezing compartment. During this period the temperature of the vaccine storage compartment must be at -15ºC or colder.

4. Requirements

4.1 General

Solar powered vaccine storage freezers will be used primarily where there is no electricity or where the electricity is unrealiable. These freezers are not to be used for simultaneous vaccine storage and water-pack freezing unless provided with separate dedicated compartments with separate cooling and control systems. These freezers are not for ultra-low temperature storage (i.e. -40°C or colder). The associated power system must be designed to match both the freezer energy consumption and local climate conditions (i.e. ambient temperatures and solar radiation resource). All appliances must fully meet the stated performance requirements with a minimum solar radiation reference period of 3.5 kWh/m²/day and hot zone (+43°C) test temperatures. In addition, manufacturers may offer appliances suitable for hot zone and a lower temperature zone and/or lower solar radiation reference period.

4.1.1 Field evaluation

At the discretion of the WHO PQS Secretariat and prior to PQS prequalification a WHO PQS pre-approved field evaluation may be required in accordance with the requirements of the *Generic Guide for the Field Evaluation of New Technologies for WHO PQS Prequalification***.**

4.2 Performance

4.2.1 Operating temperature range

The operating temperature range is indicated on the temperature zone symbol attached to the appliance (see **Annex 1**). All appliances must be suitable for hot zone (+43°C). Solar direct drive (SDD) vaccine freezers are not required to indicate a minimum rated ambient temperature (note: some other products in the WHO PQS E003 appliance category are required to indicate this rated temperature).

4.2.2 Refrigeration cycle

Electrically powered compression-cycle, Stirling engine, thermoelectric freezers operating with input of direct current (DC) electricity. Other technologies with equal or better performance may be considered.

4.2.3 Voltage

Solar power system input voltage up to 45 Voc is acceptable.

4.2.4 Vaccine storage capacity

Areas of an otherwise acceptable appliance which are too warm for vaccine storage must be excluded from use by design.

No minimum vaccine storage capacity volume is specified. Net vaccine storage capacity volume will be established and reported per **WHO/PQS/E003/FZ04/VP.1**.

4.2.5 Water-pack freezing and storage compartment capacity (optional)

If included, the water-pack freezing compartment shall be capable of freezing a minimum mass of water based on the volume of the compartment over a 24-hour period. For gross water-pack freezing compartment volume of less than 50 litres, the appliance shall be capable of freezing a minimum of 1.6 kg of water. For compartments greater than 50 litres the appliance shall be capable of freezing a minimum of 2.4 kg per each 50 litres of gross storage volume.

The water-pack freezing compartment shall hold a minimum of 3.2 kg of water-packs and at least twice the daily water-pack freezing capacity determined by **WHO/PQS/E003/FZ04//VP.1**. The water-packs must comply with **WHO/PQS/E005/IP01**.

4.2.6 Simultaneous vaccine storage and water-pack freezing warning

These appliances are not suitable for simultaneously storing frozen vaccine and water-pack freezing unless separate compartments (i.e. at least one compartment being dedicated to vaccine storage and other compartments dedicated to water pack freezing), with separate temperature control systems, are provided. All appliances must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the words: '*When storing frozen vaccine do not freeze water-packs or store any other items in the vaccine storage compartment*' in letters no smaller than 20 mm high in the languages specified in clause 4.11. The label should be fixed to the lid of chest freezers and near the top of the door on upright freezers.

4.2.7 Temperature control

- **All freezers:** The vaccine load must remain within the acceptable temperature range during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined freezers must achieve this performance with no water packs in the water-pack compartment.
- **Combined freezers only:** While simultaneously freezing a quantity of water-packs equal to its water-pack freezing capacity, the temperature of the full load of vaccines must remain at -15°C or colder under the maximum continuous ambient temperature test conditions of its rated temperature zone. Dedicated water-pack freezing compartments must remain at -5°C or colder during freezing operations.

4.2.8 Thermostat

A thermostat must be provided that is effective throughout the ambient operating temperature range. A vaccine compartment thermostat must be

designed so that it cannot be adjusted by the user. A means for adjustment by a technician is acceptable provided the device is protected from user interference (e.g. by location within the appliance cabinet). Alternatively, programmable thermostats may be password-protected. Bulb and capillary tube thermostats are not acceptable.

4.2.9 Thermometer

- **Option A:** Electronic thermometer powered by a photovoltaic cell which forms part of the device. This type draws no power from the appliance in which it is installed.

- **Option B:** Externally readable cabinet-mounted electronic thermometer.

4.2.10 Indicator light

A minimum of one green LED indicator light per vaccine storage compartment is required to be located on the front or top of the appliance to alert users that the cooling system is actively operating. A constant green LED light is required to indicate that the compressor or cooling system is active, and the light must go off when the compressor or cooling system is off.

Optionally, additional indicator lights may be added to indicate other operating conditions including water pack freezing operations, temperature and faults.

4.2.11 Autonomy

All solar direct drive (SDD) vaccine freezers or combined vaccine freezer and water-pack freezer must have a minimum autonomy of three days at the minimum solar radiation reference period and when tested for the hot zone unless an alternative autonomy (of greater days) for a specific location(s) can be calculated using one of the two methods defined in the normative reference: Toma, H. and Markvart T. *Solar Autonomy Calculation Tool*, University of Southampton, UK, 2009. If an autonomy of greater than three days can be calculated for a specific location(s) then the installation(s) must then be sized to provide the required autonomy at the specified location(s). In no case can the solar powered frozen vaccine storage freezer have an autonomy of less than three days. The two autonomy calculation methods are:

1. selection of autonomy for the specific locations listed in the supporting document to the *Solar Autonomy Calculation Tool*[2] or

2. calculation of autonomy using the formulas and the required long term daily solar radiation data as described in the *Solar Autonomy Calculation Tool*[2].

Autonomy of appliance is determined by testing in accordance with **WHO/PQS/E003/FZ04/VP.1**.

4.2.12 Power system requirements

PQS specification **WHO/PQS/E003/PV01** specifies a compatible Type 2 solar power system to directly power the appliance.

A battery powered/assisted cooling system for freezer operation will not be accepted.

Ancillary power storage systems (e.g. capacitor) for nonessential cooling functions may be included provided these have a minimum guaranteed design life of 10 years under the environmental conditions for which the freezer is prequalified.

Solar module voltage up to 45 volts open circuit (Voc at Standard Test Condition of solar radiation 1000 W/m², cell temperature +25°C, air mass 1.5) is acceptable provided all electrically powered system components are integrated in such a way that performance and component life is not reduced by voltage input from the solar array.

4.2.13 Evaporator configuration, humidity control and defrosting

If an evaporator is mounted in shelves the minimum clearance between shelves must be 130 mm.

Freezer may be defrosted manually or have automatic defrosting.

Defrost drainage must be supplied by design or by including a drain with plug where condensate can accumulate.

If active defrost used, the defrost switch(es) and heaters must be accessible to the user without tools but must be protected from accidental changes in position.

If a separate compartment for water pack freezing is provided legal manufacturers are to propose water-pack placement instructions, racks and/or structure to prevent frozen water-packs from adhering to other water-packs or adhering to freezer walls and/or other surfaces.

Spare parts will be required for all drain plugs, switches and heaters.

[2] Instructions for Autonomy Calculation, Table 1 includes a subset of sites for which the data are considered to be sufficiently accurate for solar vaccine storage applications.

4.2.14 Lock

The door or lid must be fitted with a lock or a means of locking (e.g. with a padlock). Two keys are to be supplied with every unit.

4.2.15 Corrosion resistance

The legal manufacturer must declare compliance that internal and external components are protected against corrosion as appropriate to **EN ISO 6270-1 / ASTM D2247 / EN 13523-26**, **EN ISO 6270-2 / EN 13523-25**, **ISO 6272 / EN 13523-5** and **ISO 2409.** Evidence for compliance shall be demonstrated.

4.2.16 Electrical safety rating

The legal manufacturer must declare compliance with **IEC 60335-1**, **IEC 60335-2-24** and **IEC 60364-1**. Evidence for compliance shall be demonstrated.

4.2.17 Markings

If used, compressors must be marked with the blue identifying symbol shown in **Annex 2**. In addition, the cabinet must be permanently marked, near the compressor position, with the chemical name of the refrigerant, or with the refrigerant number, formula or proportion (for blended refrigerants).

Appliances not utilizing compressor-based cooling methods must be marked identifying any refrigerant and/or heat transfer fluids used including, but not limited to, the chemical name, formula or proportion (for blended refrigerants).

All appliances to label hazardous materials and include a Safety Data Sheet. Label and Safety Data Sheet must comply with the Globally Harmonized System for the Classification and Labelling of Chemicals **GHS Rev.5**.

All appliances require an asset identification label (bar code) as specified in **WHO/PQS/E003/BC01.1:** Global asset identification.

4.2.18 Labelling

All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the following information:

- All freezers: Warning against simultaneous frozen vaccine storage and water-pack freezing in same compartment per clause 4.2.6. Warning against storing ultra-low temperature vaccines.

- Vaccine freezers: Vaccine storage instructions and the appropriate temperature zone symbol as **Annex 1**.

- Combined freezers: Vaccine storage instructions, water-pack freezing instructions, simultaneous vaccine storage and water-pack freezing warning and the appropriate temperature zone symbol as **Annex 1**.

All key information must be pictorial and summarized on a single sheet fixed onto the appliance cabinet. The sheet should be sufficiently durable to last the life of the appliance.

The instructions should be fixed to the lid of chest freezers and near the top of the door on upright freezers. Labelling must be available in the languages as specified in clause 4.11.

The appliance must carry the following additional information fixed to the front of the cabinet: manufacturer and model number (unless already located on the front of the unit), serial number, date of manufacture, PQS identification number, applicable service phone number and website URL.

4.2.19 Electromagnetic compatibility

The legal manufacturer must declare compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**. Evidence for compliance shall be demonstrated.

4.2.20 Equipment monitoring system

Future revisions of this specification will require that the legal manufacturer must certify compliance with the requirements of the latest edition of **WHO/PQS/E006/EMS 01**.

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport and storage

The ambient temperature range during transport and storage is -30°C to +70°C when the appliance is inactivated.

4.3.2 Ambient humidity range during transport, storage and use

The ambient humidity range during transport, storage and use is 5% to 95% RH, non-condensing.

4.4 Physical characteristics

4.4.1 Overall dimensions

To allow for maneuvering through corners, corridors and doorways, the minimum dimension of the appliance (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can

be installed. The maximum dimension must not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm.

4.4.2 Weight

Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that the freezer and any associated components should be designed for lifting in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group.

4.4.3 Spacers

If air clearances around or on particular sides are critical for appliance performance (e.g. to protect the condenser), *spacers* or similar must be provided (e.g. as screw-in rods). For clearances greater than 50 mm (e.g. for side venting) prominent warning signs in letters no smaller than 20 mm high must be provided. If no spacers or warning signs are provided, then it can be assumed that air clearances are not critical.

4.5 Interface requirements

4.5.1 Electrical components

All electrical components must be compatible with a Type 2 solar power system as specified in specification **WHO/PQS/E003/PV01**.

4.5.2 Power switch

Each appliance to provide an on and off power switch that is readily accessible to the user either on the outside of the appliance cabinet or in a wall-mounted switch within one meter of the appliance. Switches must be rated for DC voltage and currents required by the SDD appliance. Plug and play solar array cable connectors (i.e. locking female and male coupler system) are not acceptable for on and off switching of the solar power system or appliance.

4.6 Human factors

4.6.1 General design

The appliance must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including colour blind users and long-sighted (hyperopia) people without glasses, in accordance with the general principles laid out in **ISO 20282-1: 2006**.

4.6.2 Control panel, indicator light and thermometer

Controls panel, indicator light, thermometer and other visual displays may be positioned on the front of the unit preferably as close to eye level as possible.

Alternatively, they may be mounted on top of the unit at a height not exceeding 1.3 metres. If a low-level position is essential, the display should be aligned so that it can easily be read without the user having to squat or kneel down. The on and off switch and/or defrost switch, if present, should be recessed or otherwise protected from accidental change in position so that it is not possible to inadvertently activate it.

4.7 Materials

4.7.1 Refrigerant

Refrigerants with global warming potential (GWP) ≤ 11 and zero ozone depletion potential (ODP) must be used.

The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to appliances that use gases with low global warming potential (GWP).

4.7.2 Thermal insulation foaming agents

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals with global warming potential (GWP) ≤ 11 and zero ozone depletion potential (ODP) must be used and clearly specified.

4.7.3 Other restricted materials

The appliance and its constituent components must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.7.4 PCM

Integrated phase change materials (PCM) may be used for thermal purposes and must comply with **WHO/PQS/ E005/PCMC0.1** specification for phase-change material containers.

4.8 Warranty

The appliance must be covered by a three-year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. Ancillary power storage (e.g. capacitors) to be covered by a 10-year warranty. Solar power system warranties as required per **WHO/PQS/E003/PV01**.

4.9 Servicing provision

The appliance and solar power system must be designed to achieve a low-maintenance life of not less than 10 years (with the exception of routine defrosting, cleaning and solar array cleaning and shading prevention).

4.9.1 Essential spare parts and user maintenance tools/supplies

Based on design and requirements of appliance and solar power system the type and quantity of spare parts, basic installation tools/supplies, user and technician maintenance manuals (see clause 4.11), must be determined and agreed upon in advance of order placement.

As a minimum, each appliance and solar power system is to be supplied with 10 spare fuses of all fuse size and type used in the appliance. The spares fuses are to be attached within or on the appliance. Each appliance with drain plugs and active defrost components will be supplied with a minimum of one spare drain plug and one set of active defrost components (e.g. switches and defrost heater).

Legal manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 appliance and solar power systems. The legal manufacturer must ensure supply of spare parts for a minimum of five years from the time of cessation of the last production of equipment. Spare parts are to be provided in kit form for storage in appropriate quantities at National or Sub-national level in the purchasing country, as agreed with the purchasing agency.

4.10 Disposal and recycling

The legal manufacturer must provide information to the buyer on proper disposal, including child-proofing the cabinet, the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For legal manufacturers from the European Union WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.11 Instructions

Each freezer to include a separate user manual and technician installation manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of laboratory testing. Instructions to include easy to understand visuals whenever possible to avoid reliance on text.

The user manual must include the following information:

- Health and safety guidance;
- Basic operations description;
- Warning against simultaneous frozen vaccine storage and water-pack freezing;
- Warning against storing refrigerated vaccines, refreezing vaccines and storing ultra-low temperature vaccines;
- If PCM included then safe PCM handling in case of leakage; and
- Preventive maintenance tasks (e.g. daily, weekly, and monthly).

The technician installation manual must include the following information:

- Health and safety guidance;
- Detailed operations description;
- Correct handling to avoid appliance damage and for the safety of handling persons;
- If PCM included then safe PCM handling in case of leakage;
- Warning against simultaneous frozen vaccine storage and water-pack freezing;
- Warning against storing ultra-low temperature vaccines;
- Installation procedures;
- Compatible solar power system voltage;
- Technical maintenance tasks (e.g. daily, weekly and monthly);
- Periodic preventive maintenance procedures;
- Corrective maintenance, diagnostic and repair procedures;
- Itemized list of spare parts including part numbers;
- End-of-life resource recovery and recycling procedures; and
- User training guidance.

Printed user operations and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information must be summarized on a single sheet pictogram fixed onto the appliance cabinet per clause 4.2.18 - Labelling; the sheet should be sufficiently durable to last the life of the appliance.

Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the installation teams in installation standards and practices specific to the appliance and its power system. In addition, supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.

4.12 Training

If requested, all legal manufacturers are required to have the capability of providing in-person training in the countries where their product is deployed. Training may be delivered by the legal manufacturer, manufacturer's representative or reseller. The legal manufacturer must provide user training guidance to enable installation technicians to present user training. In addition, supporting video material supplied on DVD and/or online can be supplied to assist the instructor when delivering on-site user training.

4.12.1 Verification

In accordance with PQS Verification Protocol **WHO/PQS/E003/FZ04-VP.1.**

5. Packaging

Materials used for packaging the finished appliance are to be free of ozone-depleting compounds as defined in the Montreal Protocol and Kigali Amendment 2016.

The packaging must be a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. The packaging must be not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).

To avoid destructive unpacking prior to installation, legal manufacturers are encouraged to add a re-sealable observation opening in their packaging to aid inspectors in finding labelling and/or placing additional markings prior to installation. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. On-site installation

Not required.

7. Product dossier

The legal manufacturer or reseller must provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information, including names and addresses, of the legal manufacturer, the reseller and all other parties concerned with the manufacture and sale of the product.
- Unique identification reference for the appliance type.
- Brand name of the appliance.
- Full specifications of the appliance being offered, covering all the requirements set out in this document, including details of appliance marking and traceability.
- Full details of the recommended compatible Type 2 solar power system (see specification **WHO/PQS/E003/PV01**).
- A comprehensive set of photographs including a views of all external sides of the appliance with the door open. Take additional photographs showing the interior layout including optional configurations (e.g with baskets or shelves) the compressor or cooling system and a close-up of the thermometer, indicator light(s), the control(s), control panel and any special features.
- Certified copies of all type-approvals obtained for the appliance, including UL marking, CE marking and the like.
- Certified copies of the legal manufacturer's **ISO 9001** quality system certification.
- Certified photocopies of the legal manufacturer's **ISO 14001** certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.

- Laboratory test report(s) proving conformity with the appliance specifications as tested by a PQS accredited laboratory.
- Indicative cost of the appliance per unit, per 10 units and per 100 units, EXW (Incoterms 2015) including appliance and solar power system.

All documents, like the above, supporting the submission must be clearly referenced against the specification clause to which they apply. All documents originally not in English or French must have a notarized copy in English or French.

8. On-site maintenance

Maintenance will be carried out by the end-user and/or their agents.

9. Change notification

The legal manufacturer or reseller must advise WHO in writing of all changes which affect the performance of the appliance after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E003/ FZ04-VP.1** will result in a request for the appliance to be retested.

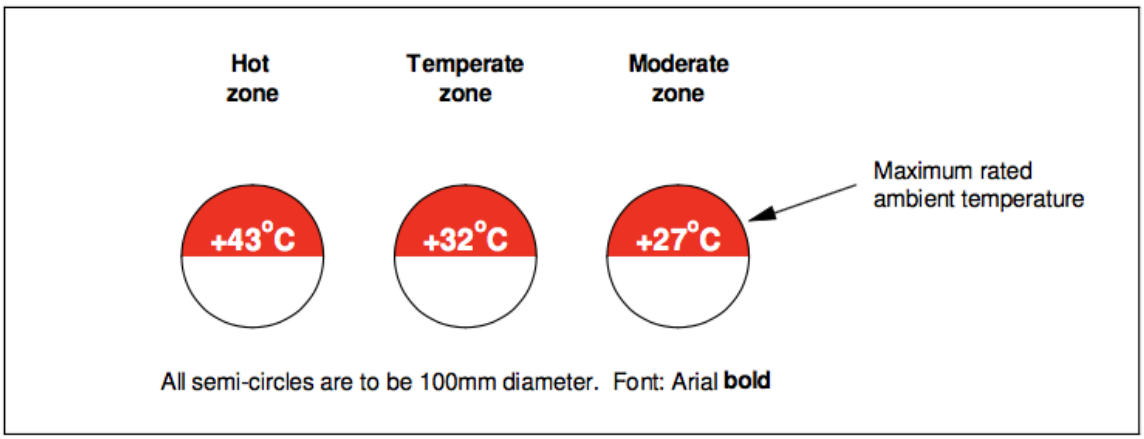
10. Defect reporting

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events

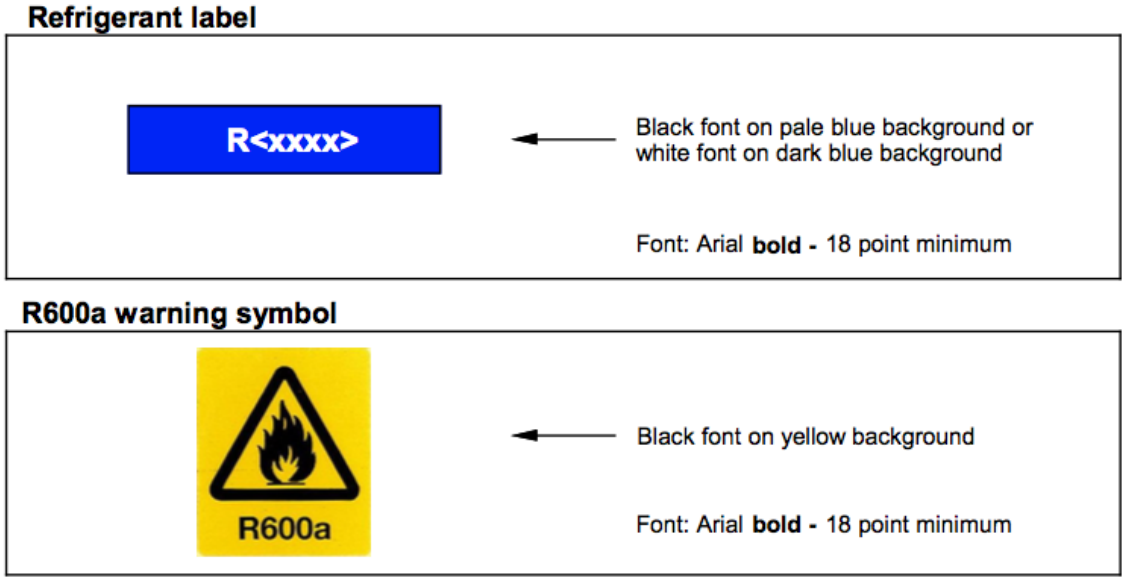
The legal manufacturer or reseller must advise WHO and the UN purchasing agencies in writing in the event of safety-related appliance and/or solar power system recalls, defects and other similar events within 30 days after the first known event.

If requested to do so by WHO/UNICEF, the manufacturer must submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Annex 1: Temperature zone symbol for vaccine freezers



Annex 2: Refrigerant symbols



Revision history			
Date	**Change summary**	**Reason for change**	**Approved**