PQS performance specification

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TITLE: Refrigerator or combined refrigerator and water-pack freezer: minimal holdover mains powered, compression cycle

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Contents

1. Scope

This specification defines the requirements for a mains-powered compression cycle appliance including a refrigerator for storing vaccine, a water-pack freezer or a combined vaccine refrigerator and water-pack freezer. Reliable mains power of at least 20 hours per day may be supplied through grid electricity or from a generator on-site. Three temperature zone designations are described: moderate zone, temperate zone and hot zone. However, all appliances are tested at +43°C at minimum. In addition, appliances are tested to establish a minimum rated ambient temperature designation.

Appliance design must account for performance degradation over the 10-year target life of the appliance in order to sustain acceptable temperature range and water-pack freezing capacity 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 used, 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 with inconsistent training.
- Users with no specific maintenance tools.

2. Normative references

EMAS: European Union Eco-Management and Audit Scheme.
EN ISO 6270-1 / ASTM D2247 / EN 13523-26: 2014 Determination of resistance to humidity – Part 1: Continuous condensation.
EN ISO 6270-2 / EN 13523-25: 2014 Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres.
GHS Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.
IEC 60335-1: 2020 Amendment 1: 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: 2006 Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.
IEC 61000-6-1 edition 2.0: 2019 Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.
IEC 61000-6-3 edition 2.1: 2020 Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.
IEC 62552-1: 2015 Household refrigerating appliances – Characteristics/tests.
ISO 2409: 2021 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/E005/IP01: Water-packs for use as ice-packs, cool-packs and warm-packs.
WHO/PQS/E006/TH02.2: Fixed gas or vapour pressure dial thermometer.
WHO/PQS/E006/TH06.2: Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.
WHO/PQS/E003/BC01.1: Global asset identification
WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers

3. Terms and definitions

Acceptable compartment humidity: The acceptable compartment humidity is 55% or lower at +2-8°C during relevant verification testing. However, transient excursions during testing above this value will be tolerated, with the following limits:

- No excursion may exceed 65% at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols.
- The average compartment humidity during relevant verification testing remains 55% or lower at +2-8°C when the appliance is supplied with power and after any initial starting period defined in verification protocols.

Acceptable temperature range: The acceptable temperature range for storing vaccine is +2°C to +8°C. However, transient excursions outside this range will be tolerated, within the following limits:

- No excursion must exceed +20°C (± 0.5°C) for any amount of time.
- No excursion must drop below -0.5°C for any amount of time.
- No excursion must drop below 0°C for longer than 1 hour.
- Following an excursion below 0°C, the appliance must return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours. This duration will be measured from the moment the temperature drops below 0°C and up until it returns to +2°C.

The cumulative effect of any excursions within the above range will be assessed over the five-day period of the *day/night* test. For this test, the calculated mean kinetic temperature (MKT) [1] must remain within the range +2°C to +8°C when the default activation energy is set at 83,144 kJ per mol. Using the recorded temperature data, an MKT figure will be calculated for each sensor. The worst-case result will determine the outcome of the test. Excursions in other tests will be noted and must not exceed the defined upper and lower limits.

Ambient humidity: The relative humidity (%) of the chamber in which the appliance is being tested.

Compartment humidity: The relative humidity (%) of the vaccine compartment of the appliance.

Freezing temperature on walls / lining of vaccine compartment:

For sensors placed in direct contact with the walls /lining of the vaccine compartment, freezing temperature is defined as any of the following conditions:

- Excursion between -0.5°C and 0°C for longer than 1 hour.
- Excursion equal to or below -0.5°C for any amount of time.
- Inability to return to safe operating temperature (i.e., consistently between +2°C and +8°C) within 2 hours following an excursion equal to or below 0°C.

Freeze-protection classification:

- **Grade A,** user-independent freeze protection (UIFP): When the appliance is used within its nominated temperature range (temperature zone +43°C, +32°C or +27°C and minimum rated ambient temperature) there is no intervention required by the user to ensure that the vaccines will not be exposed to temperatures below 0°C whatever the position of the vaccine in the vaccine compartment.
- **Grade B,** user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a

[1] Refer to Seevers, R. et al. The Use of Mean Kinetic Temperature (MKT) in the Handling, Storage and Distribution of Temperature Sensitive Pharmaceuticals. Pharmaceutical Outsourcing, May/June 2009.

procedure provided by the manufacturer and requiring one level of intervention (e.g., the requirement to use baskets or other items) in order to avoid vaccine freezing.

- **Grade C,** user-dependent freeze protection (UDFP): Even if the appliance is used within its nominated temperature range, the user must comply with a procedure provided by the manufacturer requiring more than one level of intervention in order to avoid vaccine freezing. (e.g., the requirement to use baskets and insulation barriers or covers).

Gross volume: The measured volume of the airspace inside the internal compartment of the appliance with the door or lid shut. For combined appliances the gross freezer volume and the gross refrigerator volume are reported separately.
Holdover time: The time in hours during which all points in the vaccine compartment remain between +2°C and +8°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the power supply has been disconnected.
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.
Humidity control: A functional capability of a vaccine storage compartment, by which relative humidity levels are controlled while power is available such that limited or no condensation accumulates on compartment, vial or secondary carton surfaces and mould growth is inhibited.
In writing: means communication by letter, fax or email.
Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Minimum rated ambient temperature: The lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load. All models must be able to operate at a continuous minimum ambient temperature of +10.0°C or lower whilst maintaining the acceptable temperature range.
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.
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.
Primary container: Vial, ampoule, prefilled device, plastic dispenser or tube containing vaccine or diluent. Some products are supplied in a light card carton containing a single vial, ampoule, vial pair, vial-ampoule pair, or prefilled device.
Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
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.
User-dependent freeze protection (UDFP): Refrigeration technology that requires appliance users (e.g., healthcare workers) to perform specific actions (user-interventions) in order to ensure vaccine protection against freezing temperatures (e.g., store vaccines in baskets, away from compartment wall surfaces).

User-independent freeze protection (UIFP): Refrigeration technology that requires appliance users (e.g., healthcare workers) to perform no specific actions (user-interventions) in order to ensure vaccine protection against freezing temperatures.
User-intervention: Any activity that is required to be executed by appliance users in order to ensure vaccine protection against freezing. Activities could include, but are not limited to, basket storage, storage compartment covers, thermostat/fuel adjustment, and combustion component replacement.
Vaccine net storage capacity: The net storage capacity is the space where it is suitable (both thermally and ergonomically) to store vaccines. Where manufacturers are declaring more than one vaccine storage capacity for the same gross volume and external dimensions, manufacturers must prequalify with different branding, one model for each different storage volume.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.
Water-pack freezing capacity: The maximum weight of water-packs which can be fully frozen, in one batch, during a 24-hour freezing cycle. During this period the temperature of the vaccine storage compartment must remain within the acceptable temperature range. The temperature of the water-pack freezing compartment must remain below -3ºC, except during the actual freezing process after unfrozen water-packs have been loaded.
Water-pack storage capacity: The maximum number of fully frozen water-packs that can remain fully frozen at the end of water-pack storage compartment testing.

4. Requirements

4.1 *General*

Mains-powered compression-cycle refrigerators, with or without water-pack freezing compartment, are used primarily in areas with reliable electricity supply (e.g., 20 or more hours of reliable electricity per typical day).

Net vaccine storage capacity bands of the refrigerator are based on the capacity bands prescribed and utilized by UNICEF SD. These are: <30L, 30 L to less than 60 L, 60 L to less than 90 L, 90 L to less than 120 L, 120 L to less than 150 L, 150 L and above.

4.2 Design criteria

4.2.1 Operating temperature range

As indicated on the temperature zone rating sticker attached to appliance front (see **Annex 1**). All must be suitable for operation in the hot zone (+43°C) and at a minimum rated ambient temperature of +10°C or lower whilst maintaining the acceptable temperature range in the vaccine storage compartment.

4.2.2 Refrigeration cycle

Compression-cycle unit operating on alternating current electricity.

4.2.3 Design of vaccine storage compartment

The vaccine storage compartment must be designed so that no part, which is outside the acceptable temperature range, can be used to store vaccines either by inadvertent or deliberate misuse.

As per the classification of freeze prevention features (Section 3, Terms and definitions) appliances complying with this requirement without demanding any intervention from the user will be published as Grade A. Others will be published as Grade B or Grade C depending on the level of interventions required.

Further, the vaccine storage compartment must provide some means, such as baskets, to enforce physical separation between the vaccines and any surfaces that potentially have condensate on them, such as the floor, ceiling and/or walls of the compartment. Those are not optional but have to be provided.

4.2.4 Vaccine freeze protection classification

As indicated on the freeze protection classification sticker attached to appliance front (see Annex 4). The amount of user-intervention required to ensure that the vaccines will not be exposed to freezing temperatures when the appliance is used within its nominated temperature range and minimum rated ambient temperature will be classified and reported as Grade A, Grade B, or Grade C.

4.2.5 Water-pack freezing capacity (combined units only)

In combined units with freezer compartment, a minimum of 1.6 kg and not less than 2.4 kg per 50 litres of gross freezer volume must be frozen per 24 hours.

Additionally, a new methodology for measurement of ice production is presented in Annex 3. This will be reflected in the verification protocol for freezers.

4.2.6 Water-pack storage compartment capacity (combined units only)

The freezer compartment to hold a minimum of 3.2 kg of fully frozen water-packs and at least twice the daily water-pack freezing capacity determined by **E003/RF01-VP.4**. The water-packs must comply with **E005/IP01**.

4.2.7 Temperature control

Refrigerator compartment: The zone within the vaccine compartment that is designated for vaccine storage must remain within the acceptable temperature range during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined units must achieve this performance with or without water-packs in the water-pack compartment.

Water-pack *freezing compartment:* The water-pack freezing compartment (if present) must remain below -3°C under the same ambient conditions and the minimum weight of water-packs described in clause 4.2.5 must remain fully frozen at the end of the power-off cycle.

4.2.8 Thermostat

The thermostat must be set to prevent freezing in any part of the vaccine storage compartment. The thermostat must be effective throughout the ambient operating temperature range (down to the minimum rated ambient temperature – see clause 4.2.13). It 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 Temperature monitoring and thermometer

The refrigerator compartment must be equipped with a temperature monitoring device that supports the transfer of data to another system for analysis purposes and with a display that can be read without opening the appliance.

Two types of temperature monitoring systems are permitted for use:

- Externally readable cabinet-mounted electronic thermometer conforming to PQS specification **E006/TH06** with a 30-day temperature logger placed either inside the vaccine compartment or externally if supplied with probe and wire.
- An integrated remote temperature monitoring device conforming with PQS specification **E006/TR03** with external display or coupled with a device that has a display.

The temperature monitoring device currently required is the currently prequalified disposable 30-day temperature logger, certified by WHO PQS as complying with PQS specification **E006/TR06**, with or without an external sensor lead, located in an integrated holder within the vaccine storage compartment. The holder must be positioned so that the device can easily be read by the health worker, and must be located so that temperature readings are taken in the coldest temperature spot within the compartment.

Integration of temperature monitoring devices with the refrigerator must satisfy the following requirements:

- The display must be visible to the healthcare worker from outside the refrigerator. In case the integrated device has no display, it must be coupled to another device that has an external display.
- In accordance with WHO policy, a backup system of temperature display must be provided in the form of digital or a stem or vapour thermometer.
- If the manufacturer ships temperature monitoring devices with refrigerators, the temperature monitoring device and its battery are not adversely impacted by the shipping and storage conditions as specified in Clause 4.3.
- If the manufacturer ships temperature monitoring devices separately, they should arrive at the same destination as the refrigerator shipment, on the same date, and addressed to the same consignee. This is necessary to allow for smooth in-country receipt and assembly of the refrigerators and temperature monitoring devices. Separate shipments of temperature

monitoring devices must be tracked and coordinated by the refrigerator manufacturer.

- The refrigerator manufacturer must also provide the consignee with replacement temperature monitoring devices throughout the 10-year expected lifetime of the refrigerator, so that the temperature monitoring device is always active on-site. This cost is expected to be included in the upfront price of the refrigerator that is quoted to WHO PQS. Scheduled replacement dates of the temperature monitoring devices must also be mentioned by the refrigerator manufacturer in the instructions (see clause 4.11).

4.2.10 Humidity control

NOTE: As of the publishing of this specification version, refrigerators will be required to be tested for humidity control as part of the laboratory verification protocol, but compliance with the requirement directly below will not be required until publishing of an updated version of this specification document. The intended time frame will be to require compliance as of January 2023, pending review of equipment performance tests up to that time and publication of updated specifications and verification protocols.

Refrigerator compartment: The refrigerator compartment must have humidity control. The zone within the vaccine compartment that is designated for vaccine storage must remain within acceptable compartment humidity levels during humidity control testing as specified in the verification protocol. Combined units must achieve this performance with or without water-packs in the water-pack compartment.

Water-pack freezing compartment: Not applicable

4.2.11 Indicator light

A minimum of one green LED indicator light 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 is to go off when the compressor or cooling system is off.

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

4.2.12 Holdover times

Minimum 4 hours in continuous hot zone (+43°C) ambient temperature.

4.2.13 Minimum rated ambient temperature

All models must be able to operate at a continuous minimum ambient temperature of +10.0°C or lower whilst maintaining the acceptable temperature range. The maximum performance rating is achieved if the vaccine load remains within the acceptable temperature range at -10°C. A freeze-prevention circuit may be required to protect against freezing at low ambient temperatures.

4.2.14 Power system requirements and consumption

Direct supply of mains electricity. Options for 220-240-volt 50/60 Hz and 100-127-volt 50/60 Hz are to be offered. Performance is to be identical for all options, regardless of the nominal voltage and frequency rating of the appliance.

At 22% below manufacturers stated voltage, 10 out of 10 cold starts and 10 out of 10 hot starts must all be successful.

No standard set, however electricity consumption will be reported.

4.2.15 Condensation management and defrosting

The environmental conditions within the vaccine storage compartment must be designed so that vaccine primary containers and vaccine cartons are not exposed to levels of humidity which may cause damage to cartons or primary container labels or create a risk of mould growth.

To alleviate humidity damage legal manufacturers are to include refrigerator design features and/or provide containers for vaccine storage. Condensate and defrost drainage must be provided in all refrigerator and freezer compartments.
If used, the defrost switch (or switches) must be accessible to the user without tools but must be protected from accidental changes in position.

4.2.16 Lock

The door or lid must be fitted with a lock. Two keys are to be supplied with every unit.

4.2.17 Corrosion resistance

Legal manufacturer must certify compliance that internal and external cabinet, lid and frame 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.**

4.2.18 Electrical safety rating

Legal manufacturer must certify compliance with **IEC 60335-1, IEC 60335-2-24** and **IEC 60364-1.**

4.2.19 Markings and labelling

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 operating on R600a must be marked with the warning symbols shown in Annex 2.

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**.

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.

This label to remain readable for the expected life of the appliance.

All appliances require an asset identification label (bar code) as specified in **WHO/PQS/E003/BC01:** Global asset identification. Effective date June 30, 2020.

4.2.20 Vaccine storage advice

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

- *Vaccine refrigerators:* Vaccine storage instructions and the appropriate temperature zone symbol as Annex 1.
- *Combined units:* Vaccine storage instructions, water-pack freezing instructions and the appropriate temperature zone symbol as Annex 1.

The instructions should be fixed to the lid of chest refrigerators and near the top of the door on upright refrigerators. Instructions should be in one of the languages specified in Clause 4.11, as indicated by the purchaser at the time of ordering. If the appliance is graded other than "A" and removable baskets are supplied, fix a multi-lingual warning within the refrigerator instructing users to *Store vaccine in baskets only* or other appropriate instruction.

4.2.21 Electromagnetic compatibility

Legal manufacturer to certify compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**.

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport and storage

-30°C to +70°C when the product is inactivated.

4.3.2 Ambient humidity range during transport, storage and use

5% to 95% RH, non-condensing.

4.4 Physical characteristics

4.4.1 Overall dimensions

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the product (either length, width or height) should not exceed 710mm; exceptionally a minimum dimension up to 830mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension must not exceed 1700mm and the maximum diagonal (corner to corner) dimension must not exceed 1850mm.

4.4.2 Weight

Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that the refrigerator 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.

4.5 *Interface requirements*

4.5.1 Electrical components

Every appliance must be provided with either an integrated or a standalone voltage stabilizer. The voltage stabilizer must be certified by WHO PQS as complying with PQS specification **E007/VS01**.

All electrical components must be compatible with voltage stabilizers that use tap-changing technology. If the product contains components that are incompatible with this type of voltage stabilizer it must be supplied with an appropriate device of equivalent performance to those voltage stabilizers that are currently prequalified in PQS section E007. A warning must be affixed to the unit stating the type(s) of voltage stabilizer that may be used and the user's manual and spare parts list must clearly record this warning.

4.5.2 Power lead

The product is to be supplied with a power lead with a sealed-on plug compatible with the electricity socket standard in the country where the equipment is to be installed. The power lead must be at least 1.5 meters and not more than 2.0 meters in length.

4.6 Human factors

4.6.1 General design

The product 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 people without glasses, in accordance with the general principles laid out in **ISO 20282-1**.

4.6.2 Control panel, indicator light, and thermometer

Controls, 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-off and/or defrost switch, if present, should be recessed or otherwise protected so that it is not possible inadvertently to activate it.

4.6.3 PQS stickers

In addition to the PQS temperature zone sticker the device should carry the following additional information:

- 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 fixed to the front of the cabinet.
- An operations and maintenance pictogram fixed to the lid or near the top front of chest refrigerators and near the top of the door on upright refrigerators.

PQS stickers should remain readable for the expected age of the equipment.

4.7 Materials

4.7.1 Refrigerant

Appliances are required to use HC refrigerants such as R600a or other gases with GWP ≤11 and zero ODP.

Existing appliances with HCFC refrigerants including R134a will be phased out over a transition period of four years from the issue date of this publication.

The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to products 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.

4.7.3 Other restricted materials

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

4.7.4 PCM

Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. The buffer material may be PCM-based but if so, must comply with **WHO/PQS/ E005/PCMC0.1**– PCM specification for phase-change material containers.

4.8 *Warranty*

The product is to be covered by a minimum three-year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The warranty period begins on the date of shipment (EXW) from the legal manufacturer.

4.9 *Servicing provision*

The product must be designed, and components selected, with the aim of achieving a zero-repair life of not less than 10 years.

4.9.1 Essential spare parts and user maintenance tools/supplies

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

Legal manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 appliances and power systems. Legal manufacturer must ensure supply of spare parts for a minimum of 5 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 is to provide information to the buyer on 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*

Printed user, installation, and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information should be summarized on a single sheet fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the product and must be available in Arabic, Mandarin Chinese, English, French, Russian, and Spanish. 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.

The manufacturer can maintain a core set of manuals in one language, but must be able to provide translations in any of the aforementioned UN languages if requested. The manufacturer can also store the manuals on their websites, with links that are shareable when requested.

The user, installation, and maintenance documents must address five aspects:

Introductory information. This should consist of the following:

- Title page with image of unit, supplier name, supplier model #, PQS code, and version number
- Table of contents
- General information on unit, its functionality, and intended use
- Relevant warnings related to transportation, any corrosive or toxic substances in the construction of the appliance, power source, or disposal

Model specifications and details. This should include the following:

- Detailed technical specifications, including wiring diagram
- Parts and equipment list
- Detailed technical specifications, including wiring diagram
- Safety procedures, including warranty information and supplier contact information
- Directions for safe transportation

Installation and operation. This aspect must cover the following:

- Detailed installation procedure, including installation checklist
- Detailed operational procedures covering both vaccine storage, as well as icepack / cold-pack preparation
- Disposal guidelines

Maintenance. This component should consist of the following:

- Detailed guidance on preventative maintenance, including checklists and standard operating procedures (SOPs)
- Trouble-shooting guide for corrective maintenance, including table detailing common issues and step-by-step remedial actions
- Typical replacement cycle for spare parts
- Recommended replacement dates for temperature monitoring devices (see Clause 4.2.9).

Format and usability. The document developer should keep in mind the following aspects:

- Include clear graphics to illustrate tasks, with multiple view-points (e.g. top, side) and clear labelling
- Be published in English, with translations readily available in all UN languages (Arabic, English, French, Mandarin, Russian, and Spanish).

Translations to other languages specific to certain countries are to be provided if requested by the buyer

- Be specific to a given model and avoid covering multiple devices in same document
- Have a clear and consistent structure that covers installation, operation, and maintenance and repair
- Be accessible and downloadable from a central repository.

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 product and its power system.

4.12 *Training*

Not required.

4.13 *Verification*

In accordance with PQS Verification Protocol **E003/RF01-VP.4.**

5. Packaging

Manufacturers must be aware that products may be exposed to very high temperatures during shipping and dockside storage and must take appropriate actions to mitigate this risk.

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

The packaging is to 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 is to 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 is to provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Brand name of the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- A comprehensive set of photographs showing all external surfaces of the unit, the interior layout, the compressor and a close-up of the thermometer and the control panel.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's **ISO 9001** quality system certification.
- Where relevant, 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 product specifications.
- Indicative cost of the product per unit, per 10 units and per 100 units, EXW (Incoterms 2010).

8. On-site maintenance

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

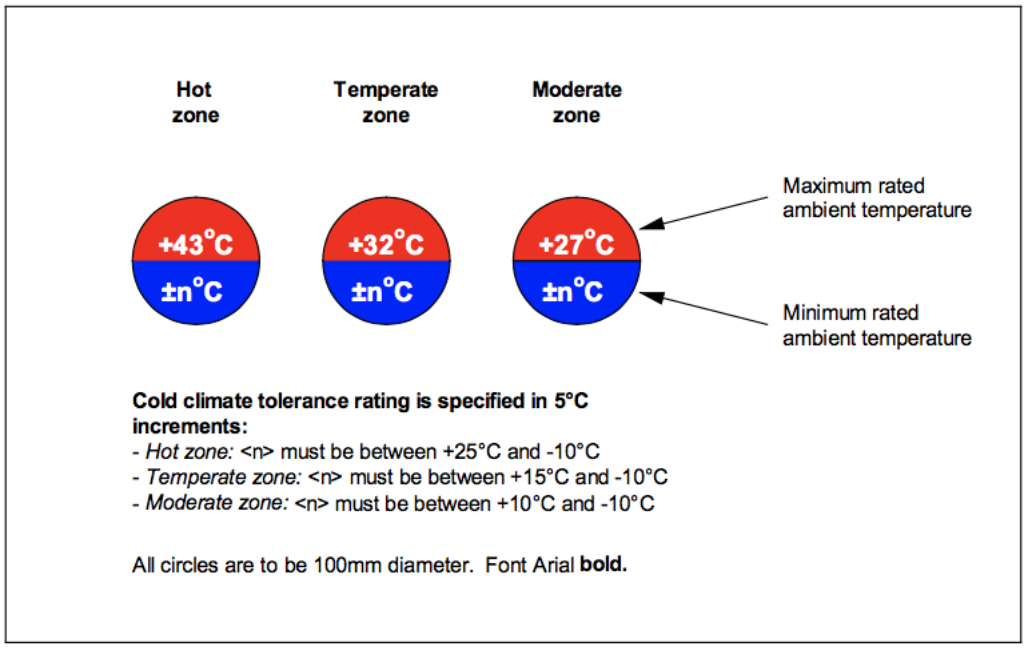
9. Change notification

The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E003/RF01-VP.4** will result in a request for the product to be retested.

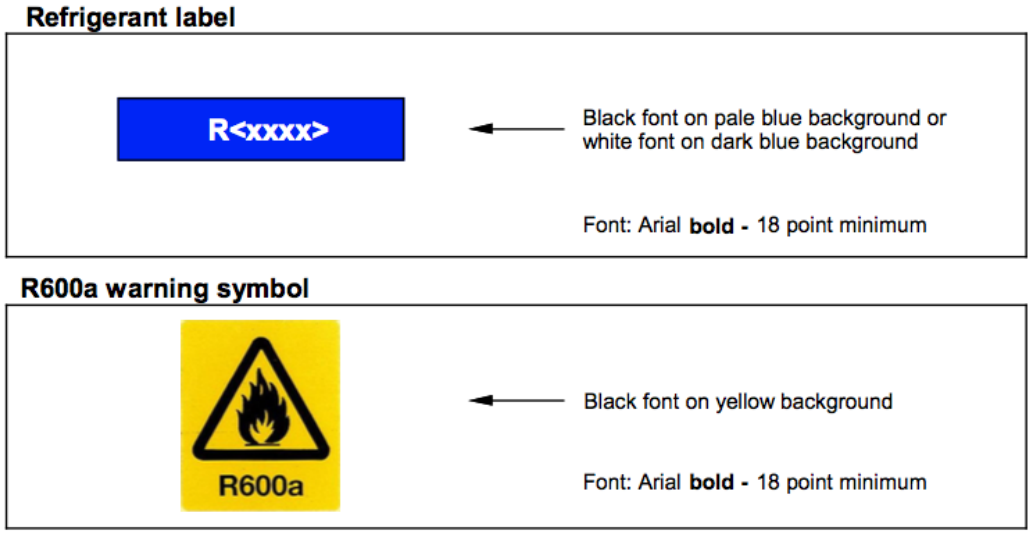
10. Defect reporting

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. If requested to do so by WHO/UNICEF, the manufacturer is to 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 refrigerators



Annex 2: Refrigerant symbols



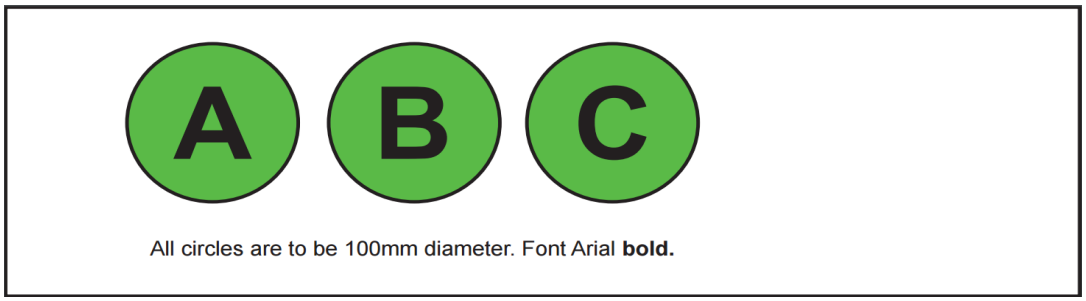
Annex 3: Fully frozen water-pack determination

The following tests are used to determine whether a water-pack is fully frozen, partially frozen, or unfrozen. While the assessment is not 100% accurate, misclassifications are usually conservative in nature: water-packs that are fully frozen are sometimes classified as partially frozen rather than partially frozen water-packs being classified as fully frozen. A fully frozen water-pack contains only ice. A partially frozen water-pack contains both ice and water. An unfrozen water-pack contains only water.

Perform the all of the following tests on the water-pack:

- Shake test - Shake the water-pack while holding the water-pack near the assessor's ear. If the sound of water sloshing in the water-pack is heard, then the water-pack fails the shake test.
- Tilt test – Tilt the water-pack back and forth while looking for the movement of air or water in the water-pack. If the movement of air or water is observed, then the water-pack fails the tilt test.
- Bulge test – Water expands when it freezes. Examine the water-pack for localized bulging near the centreline of the water-pack when viewing the water-pack from the side. If localized bulging is not present, then the water-pack fails the bulge test.
- Classify the water-pack as follows:
    - If the water-pack passes all three tests, then the water-pack is fully frozen.
    - If the water-pack fails one or more tests, then the water-pack is partially frozen or unfrozen and fails the test.

Annex 4: Freeze protection classification symbol for refrigerators



Revision history (revision since December 10, 2016):			
Date	Change summary	Reason for change	Approved
27.08.2018	Section 4.7 edited to include a definition of PCM	Reflects change to allowance of PCM-based buffer materials.	I.Gobina
24.10. 2019	Addition of bar code requirements	Supports more effective CCE management and tracking	I.Gobina
10.09.2020	Clause 3 (Terms and definitions) PCM definition edited in line with other specs	Reflect change to allowance of water-based and PCM-based buffers	I.Gobina
15.09.2020	Terms & definition updated to include humidity-control	Reflect requirements included in the 2020 Humidity Control TPP	I. Gobina
15.09.2020	Clause 4.2.10 added on Humidity Control	Reflect requirements included in the 2020 Humidity Control TPP	I. Gobina