PQS performance specification

WHO/PQS/E003/FZ01.2
Original: English
Distribution: General

TITLE: Vaccine freezer or combined vaccine and water-pack freezer: compression-cycle

Specification reference:	E003/FZ01.2
Product verification protocol:	E003/FZ01-VP.2
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Contents:

1. Scope:

This specification defines the requirements for compression-cycle vaccine freezers or compression-cycle combined vaccine and water-pack freezers. Three temperature zone designations are described: moderate zone, temperate zone and hot zone.

2. Normative references:

DIN 8985: 1983-05: *Testing the surfaces of installed refrigerators and freezers.*
EMAS: *European Union Eco-Management and Audit Scheme.*
IEC 60335-1: 2006: *Household and similar electrical appliances - Safety - Part 1: General requirements.*
IEC 60335-2-24: 2007 - *Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.*
IEC 62552: 2007: *Household refrigerating appliances – Characteristics and test methods.*
ISO 9001: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*
ISO 20282-1: 2006: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*
WHO/PQS/E006/TH02.1: *Fixed gas or vapour pressure dial thermometer.*
WHO/PQS/E006/TH06.1: *Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.*

3. Terms and definitions:

Holdover time: The time in hours during which all points in the vaccine or water-pack freezing compartment of the freezer remains below -5°C 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.

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.

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.

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.

Water-pack freezing capacity: The maximum weight of water-packs which can be frozen, in one batch, during a 24 hour freezing cycle. During this period the temperature of the vaccine storage compartment must not exceed -15ºC, except during the actual freezing process after unfrozen water-packs have been loaded when a rise to a maximum of -5°C is permitted.

4. Requirements:

4.1 *General:*

Compression-cycle vaccine freezers or combined vaccine and water-pack freezers, powered by mains electricity, are used primarily in areas with a reliable electricity supply (i.e. 20 or more hours of continuous electricity per typical day). Manufacturers may offer products suitable for one or more temperature zones.

4.2 *Performance:*

4.2.1 Operating temperature range:

As indicated on the temperature zone rating sticker attached to the product (see Annex 1).

4.2.2 Refrigeration cycle:

Compression-cycle unit operating on alternating current electricity.

4.2.3 Voltage and frequency:

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

4.2.4 Water-pack freezing:

In combined freezers, not less than 7.2 kg of water-packs must be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.5.

4.2.5 Areas not suitable for vaccine storage:
Areas of an otherwise acceptable appliance which are too warm must be excluded from use by design.

4.2.6 Temperature control:

- **All freezers:** The vaccine load must remain below -15°C during any continuous ambient temperature test(s) or day/night cycling temperature test(s). Combined units must achieve this performance with no water-packs in the water-pack compartment.
- **Combined freezers only:** While freezing a quantity of water-packs equal to its water-pack freezing capacity, the temperature of the full load of vaccines must remain below -5°C and return to below -15°C within the 24 hour freezing cycle under the maximum continuous ambient temperature test conditions of its rated temperature zone.

4.2.7 Thermometer:

- **Option A:** Externally readable cabinet-mounted gas or vapour pressure dial thermometer complying with PQS specification **E006/TH02**.
- **Option B:** Externally readable cabinet-mounted electronic thermometer conforming to PQS specification **E006/TH06**.

4.2.8 Holdover time:
No standard set; however performance data will be published.

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

4.2.10 Power consumption:
No standard set however results will be reported.

4.2.11 Evaporator configuration:
If the evaporator is mounted in shelves the minimum clearance between shelves must be 130 mm.

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

4.2.13 Corrosion resistance:
Internal and external cabinet, lid and frame protected against corrosion to DIN 8985.

4.2.14 Electrical safety rating:
Manufacturer to certify compliance with IEC 60335-1 and IEC60335-2-24.

4.2.15 Markings:
Compressors must be marked with the blue identifying symbol shown in Annex 2. In addition, the freezer 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).

4.2.16 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 freezers:** Vaccine storage instructions and the appropriate temperature zone symbol as Annex 1.
- **Combined freezers:** 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 freezers and near the top of the door on upright freezers. Instructions should be in one of the languages specified in clause 4.11, as indicated by the purchaser at the time of ordering.

4.3 *Environmental requirements:*

4.3.1 Ambient temperature range during transport and storage:
-30°C to +55°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 Voltage stabilizer compatibility:
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 pre-qualified in PQS section E07. 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 least1.5 meters and not more than 2.0 meters in length.

4.6 *Human factors:*

4.6.1 Generally:
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: 2006.

4.6.2 Control panel 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.

4.7 *Materials:*

4.7.1 Refrigerant:

HFC (hydro fluorocarbon) or HC (hydrocarbon) refrigerant. CFC (chlorofluorocarbon) and HCFC (hydrochlorofluorocarbon) gases are not acceptable. 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).

4.8 *Warranty:*

The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship.

4.9 *Servicing provision:*

The product is to be designed to achieve a maintenance-free life of not less than 10 years apart from routine de-frosting and cleaning and replacement of batteries (if any).

4.10 *Disposal and recycling:*

The 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 the European Union WEEE compliance in accordance with European Union Directive 2002/96/EC is mandatory.

4.11 *Instructions:*

User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The instructions are to be written for users and repair technicians and are to cover the following topics:

- installation procedures;
- compatible types of voltage stabilizer;
- temperature adjustments (if applicable);
- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance checks;
- diagnostic and repair procedures;
- itemized list of spare parts including part numbers;
- end-of-life resource recovery and recycling procedures.

4.12 *Training:*
Not required.

4.13 *Verification:*
In accordance with PQS Verification Protocol **E003/FZ01-VP.2.**

5. Packaging:
Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol. 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 pre-qualification 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.
- Where available, 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 2000).

8. On-site maintenance:
Maintenance will be carried out by the end-user and/or his agents.

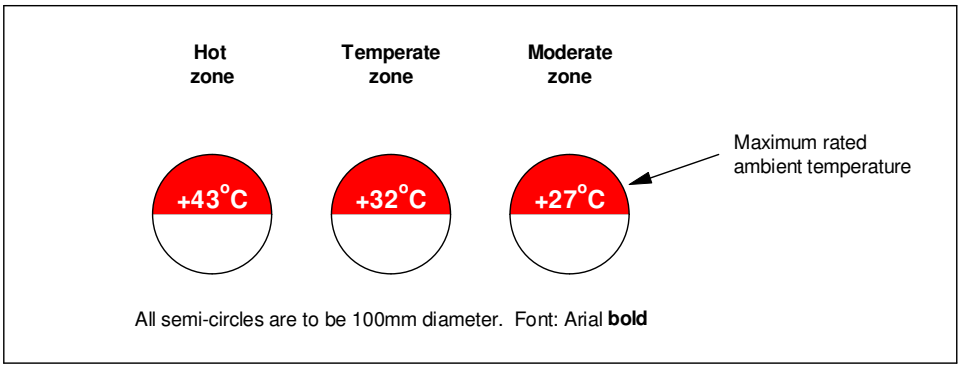
9. Change notification:

The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E003/FZ01-VP.2** will result in a request for the product to be retested.

10. Defect reporting:

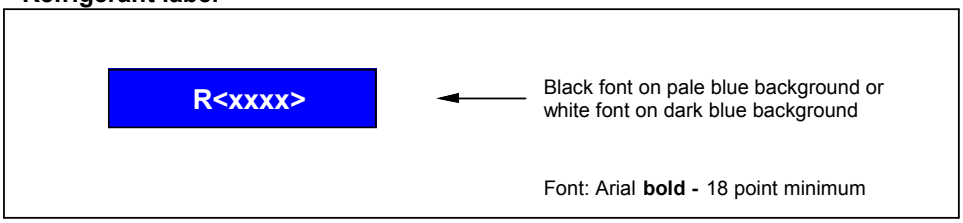
The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer is to submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Annex 1 – Temperature zone symbol for freezers

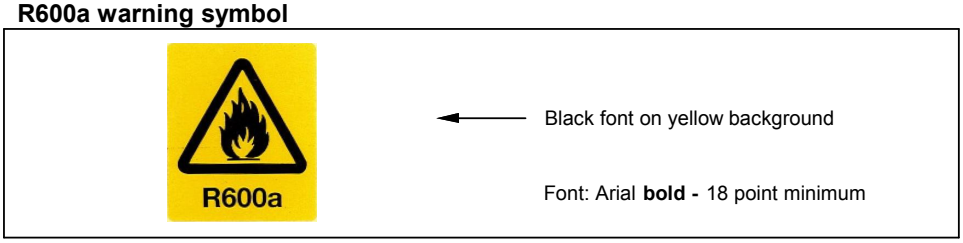


Annex 2 - Refrigerant symbols

Refrigerant label



R600a warning symbol



Revision history:			
Date	Change summary	Reason for change	Approved
07.03.2007	General edit with additional clauses plus Annexes 1 and 2.	Final revisions to PQS format.	UK
23.03.2007	Further minor revisions following comment round		UK
23.05.2007	4.2.5: New clause.		UK
02.08.2007	4.2.12: Lock spec changed. 4.4.1: Dims clarified.	Response to manufacturer's comment.	UK
06.07.2010	'Icepack' changed to 'water-pack'. 2: Normative references updated. 3: Holdover time max temp changed to -5°C. Water-pack freezing compartment definition added. 4.2.4: Clause title changed. 4.2.7: Option A & B amended. 4.4.1: Clause amended. 4.4.2: Clause amended. 4.6.1: Clause amended. 4.6.2: Clause amended. 4.7.1: GWP amendment. 4.9: Clause amended. 4.13: VP ref updated. 7: ISO 9001 waiver omitted. Annex 2: Symbols amended.	Response to comments from manufacturers, testing laboratories and others.	