PQS performance specification

WHO/PQS/E003/FZ02.2
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TITLE: Water-pack freezer: absorption cycle

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Product verification protocol:	E003/FZ02-VP.2
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Contents

1. Scope

This specification defines the requirements for absorption-cycle water-pack freezers. Three temperature zone designations are described: moderate zone, temperate zone and hot zone. These units are not suitable for storing vaccine.

2. Normative references

BS2869:2006: Specification for fuel oils for agricultural, domestic and industrial engines and boilers.
DIN 8985: 1983-05: Testing the surfaces of installed refrigerators and freezers.
EMAS: European Union Eco-Management and Audit Scheme.
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/TH02.2: Fixed gas or vapour pressure dial thermometer.
WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers
WHO/PQS/E003/BC01.1: Global asset identification

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.
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.
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

Absorption-cycle water-pack freezers are used primarily in areas without a reliable electricity supply (i.e. less than 8 hours of continuous electricity per typical day). Manufacturers may offer products suitable for one or more temperature zones. Fuel supply is natural gas, propane or kerosene. These units

are not suitable for storing vaccine. Supplementary electric power is allowed but not required. If it is offered, performance under electrical power may be tested by prior agreement between WHO and the manufacturer.

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

Absorption-cycle unit designed to operate on natural gas, propane or kerosene. Multi-fuelled products, including an electric-powered option are allowed but not required.

4.2.3 Water-pack freezing

Not less than 2.4 kg of water-packs must be frozen per 24 hours. The freezer should accommodate a minimum of 8.4 kg of frozen water-packs.

4.2.4 Temperature control

No specific requirement, subject to achieving the performance described in clause 4.2.3.

4.2.5 Thermostat/flame control device

An adjustable thermostat is permitted for gas-fuelled units. Kerosene-fuelled units must have an easy-to-operate flame adjustment control and/or a two-position day-night regulator. All units should be designed to minimise the need for further intervention by the operator once an optimum internal temperature setting has been achieved at the installation site.

4.2.6 Flame failure device (gas units)

Natural gas and propane units must be fitted with an automatic flame failure device.

4.2.7 Holdover time

No standard set; however, performance data will be published.

4.2.8 Lock

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

4.2.9 Fuel quality

If kerosene is used see Annex 2 for recommended fuel quality.

4.2.10 Fuel consumption

No standard set; however, performance data will be published.

4.2.11 Corrosion resistance

Internal and external cabinet, lid and frame protected against corrosion to **DIN 8985**.

4.2.12 Thermometer

A thermometer is not specifically required. However, if an externally readable cabinet-mounted thermometer is fitted it must be a gas or vapour pressure dial thermometer complying with PQS specification **E006/TH02**.

4.2.13 Electrical safety rating

For products with relevant electrical components only: Manufacturer to certify compliance with **IEC 60335-1** and **IEC 60335-2-24**.

4.2.14 Markings

The freezer cabinet must be permanently marked with the chemical name of the refrigerant, or with the refrigerant number, formula or proportion (for blended refrigerants). If units contain hexavalent chromium as a corrosion inhibitor there must be an appropriate hazard warning label on the cabinet to indicate its presence. The label 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. Effective date June 30, 2020.

4.2.15 Vaccine storage advice

All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the words: *'Do not store vaccine in this freezer'* in letters a minimum of 20mm high. The label should be fixed to the lid of chest freezers and near the top of the door on upright freezers. The wording 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 (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 Power lead

If the product is supplied with an electrical power lead it must have a sealed-on plug compatible with the electricity socket standard in the country where the equipment must 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 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 long-sighted people without glasses, in accordance with the general principles laid out in **ISO 20282-1: 2006**.

4.6.2 Control panel

The control panel and thermostat 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 gas isolating valve/kerosene burner control knob must be easily accessible to the operator without need to move the unit.

4.7 Materials

4.7.1 Refrigerant

Ammonia-water. 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 must not contain lead, mercury, cadmium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE). Hexavalent chromium is permitted as a corrosion inhibitor in absorption cycle freezers, but for no other purpose.

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 must be covered by a three-year replacement warranty in the event of any component failure arising from defective design, materials or workmanship.

4.9 Servicing provision

The product must be designed to achieve a maintenance-free life of not less than 10 years apart from re-fueling, wick replacement and trimming (kerosene units), gas burner maintenance (gas units), flue cleaning, routine de-frosting and cleaning.

4.10 Disposal and recycling

The manufacturer must provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal.

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;
- 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/FZ02-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 must 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, the thermostat and the burner controls.
- 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.

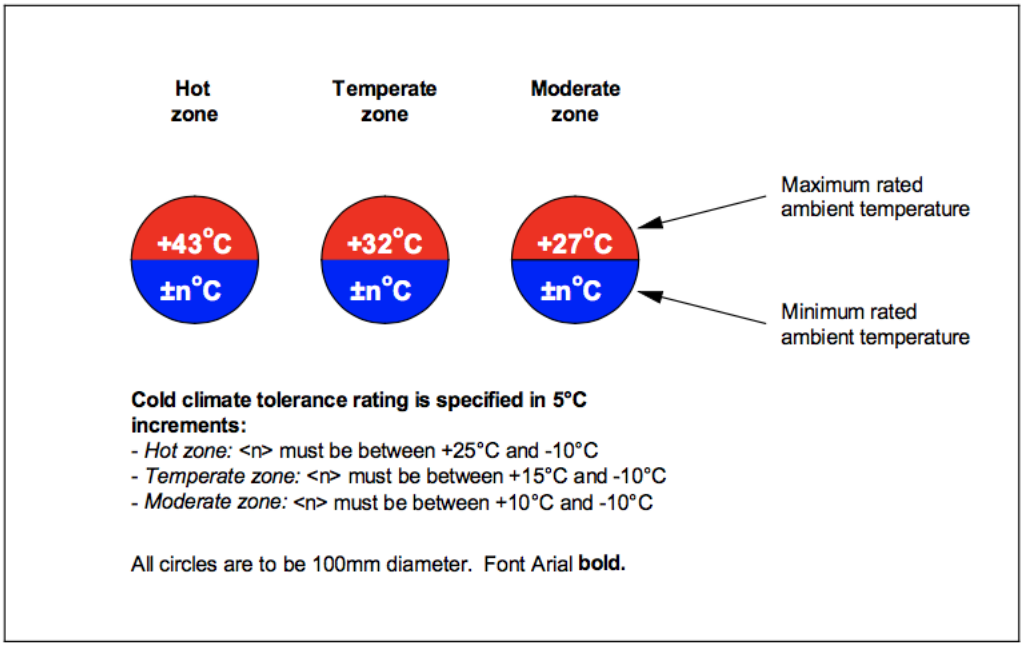
9. Change notification

The legal manufacturer or reseller must 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/FZ02-VP.2** will result in a request for the product to be re-tested.

10. Defect reporting

The legal manufacturer or reseller must 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 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 freezers



Annex 2 – Kerosene quality

The quality of kerosene recommended for wick burning stoves and refrigerators should have the following characteristics:

Minimum smoke point:	35 mm
Maximum char value:	10 mg/kg
Distillation: maximum % recovery at 200°C:	60% Flock
test:	Negative
Maximum sulphur content:	0.04%

Note: Specification details for kerosene to **BS2869**, Class C1 have been altered in the current 2006 version of the standard. After consultation with industry, and to reflect field conditions in the developing world, the standard set out in the 1998 PIS Annex 6 has been retained as the minimum required. Kerosene to this old standard should be used for testing appliances.

Revision history			
Date	Change summary	Reason for change	Approved
23.05.2007	General edit with additional clauses plus Annexes 1, 2 and 3.	Final revisions to PQS format.	UK
31.05.2007	SMc comments incorporated. 4.2.4: Temperature control method clarified.		UK
02.08.2007	4.2.7: Lock spec changed. 4.4.1: Dims clarified. Annex 3 wording changed back to 1998 PIS wording. Clarification note added	In response to comments from manufacturers.	UK
06.07.2010	'Icepack' changed to 'water-pack'. 2: Normative references updated. IEC 60335 added. 3: Holdover clarified and temperature changed to -3°C. Water-pack freezing capacity definition added. 4.1: Conditions for testing supplementary electrical power added. 4.2.3: Title changed. 4.2.4: Requirement for non- adjustable control system removed. 4.2.5: Thermostat/flame control device clause added. 4.2.9: Typo.	Response to comments from manufacturers, testing laboratories and others.	

	4.2.12: Clause amended. 4.2.13: Clause added. 4.2.14: Requirement for hexavalent chromium hazard warning label added. 4.4.1: Clause amended. 4.4.2: Clause amended. 4.5.1: Clause added. 4.6.1: Clause amended. 4.6.2: Clause amended. 4.7.1: Ammonia-water refrigerant permitted. GWP amendment. 4.7.3: Hexavalent chromium allowed as corrosion inhibitor. 4.9: Gas burners added. 4.13: VP reference updated. 7: ISO 9001 waiver omitted. Annex 2: Omitted. Annex 3: Renumbered.		
21.09.2018	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
21.09.2018	Clause 4.7 (Materials) 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
08.09.2020	Formatting and small edits for style	N/a	I.Gobina