PQS performance specification

WHO/PQS/E003/RF02.2
Original: English
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TITLE: Refrigerator or combined refrigerator and water-pack freezer: absorption cycle

Specification reference:	E003/RF02.2
Product verification protocol:	E003/RF02-VP.2
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Contents:

1. Scope:

This specification defines the requirements for absorption cycle refrigerators or combined refrigerator and water-pack freezers for storing vaccine. Three temperature zone designations are described: moderate zone, temperate zone and hot zone. In addition appliances are tested to establish a minimum rated ambient temperature designation.

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 62552: 2007: *Household refrigerating appliances – Characteristics and test methods.*
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.*
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.*

3. Terms and definitions:

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.
- No excursion must reach 0°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.

Holdover time: The time in hours during which all points in the vaccine compartment remain between +2°C and +10°C, at the maximum ambient temperature of the temperature zone for which the appliance is rated, after the fuel supply has been switched off.

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.

Minimum rated ambient temperature: In addition to the day/night test, all appliances will be challenged by reducing the ambient temperature in 5°C increments below the lower limit for the model's rated temperature zone, down to a minimum of -10°C. This test is designed to determine the lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load. Once established, this figure will be displayed in the blue sector of the Annex 1 temperature zone symbol. This will enable purchasers in countries with low winter temperatures to select the most appropriate models.

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 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

[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.

compartment must remain below 0ºC, except during the actual freezing process after unfrozen water-packs have been loaded.

4. Requirements:

4.1 *General:*

Absorption-cycle vaccine refrigerators or combined vaccine refrigerator and 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) and where solar units are unsuitable. Manufacturers may offer products suitable for one or more temperature zones. Fuel supply is natural gas, propane or kerosene. Supplementary electric power is allowed but not required. If it is offered, performance under electrical power may also 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:

In combined units with freezer compartment, a target minimum of 1.6 kg of water-pack should be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.5. For freezers with at least 50 litres of gross freezer volume a target minimum of 2.4 kg of water-pack should be frozen per 24 hours whilst maintaining the temperature control specified in 4.2.5. If this target minimum performance cannot be achieved, the maximum weight that can be frozen in a 24 hour period must be stated in the manufacturer's pre-qualification dossier.

4.2.4 Areas not suitable for vaccine storage:

Areas of an otherwise acceptable appliance which are too warm or too cold must be excluded from use by design – for example: baskets may be used to define safe storage zones and door storage shelves and vegetable storage compartments may be eliminated.

4.2.5 Temperature control:

- **Refrigerator compartment:** The entire vaccine load must remain within the acceptable temperature range during the continuous ambient temperature test(s), day/night cycling temperature test(s) and down to the minimum rated ambient temperature in the minimum rated ambient temperature test (see clause 4.2.10). Combined units must achieve this performance with or without water-packs in the water-pack compartment.
- **Water-pack freezing compartment:** No specific requirement, subject to achieving the performance described in clause 4.2.3.

4.2.6 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.

4.2.7 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 maximum-minimum thermometer conforming to PQS specification **E006/TH06.**

4.2.8 Flame failure device (gas units)

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

4.2.9 Holdover time:

Minimum 1.5 hours at the appliance's maximum rated ambient temperature (Moderate zone: +27ºC, Temperate zone: +32°C, Hot zone: +43°C).

4.2.10 Minimum rated ambient temperature:

All models will be tested to establish their minimum rated ambient temperature. The minimum acceptable performance rating is achieved if the product passes the day/night test for its nominal temperature zone. 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.

4.2.11 Lock:

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

4.2.12 Fuel quality:

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

4.2.13 Fuel consumption:

No standard set; however performance data will be published.

4.2.14 Corrosion resistance:

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

4.2.15 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**.

4.2.16 Electrical safety rating:

For products with relevant electrical components only: Manufacturer to certify compliance with IEC 60335-1 and IEC60335-2-24.

4.2.17 Markings:

The 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.

4.2.18 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 removable baskets are supplied fix a multi-lingual warning within the refrigerator instructing users to *Store vaccine in baskets only* or other appropriate instruction.

4.3 *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 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 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 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:
The thermostat, 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 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 refrigerators, but for no other purpose.

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 re-fueling, wick replacement and trimming (kerosene units), gas burner maintenance (gas units), flue cleaning, 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.

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);
- prevention of vaccine freezing;
- 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/RF02-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, 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.

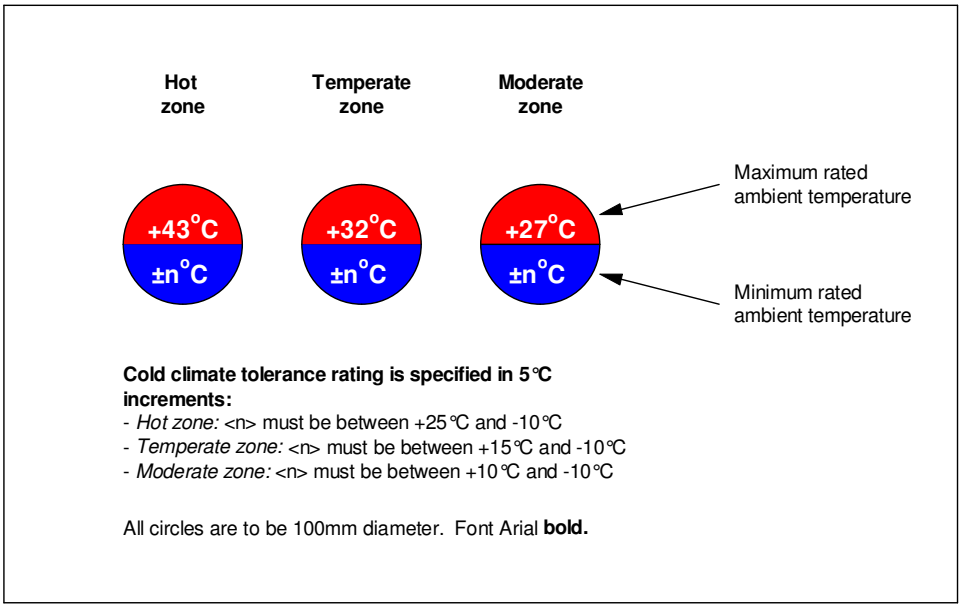
9. Change notification:

The legal manufacturer or reseller 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/RF02-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 refrigerators



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. 4.2.5: Amended. Reference to thermostat (previous clause 4.2.6) omitted.		UK
02.08.2007	4.2.10: 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: Acceptable temperature range and holdover time definitions changed. Water-pack freezing capacity definition added. 4.1: Conditions for testing supplementary electrical power added. 4.2.3: Clause title changed. Water-pack freezing performance relaxed. 'Target' added. 4.2.5: Water-pack freezing compartment requirement changed. 4.2.6: Thermostat/flame control device clause added. 4.2.7: Option A amended. 4.2.9: Holdover time changed from 3 to 1.5 hrs. 4.2.12: Typo. 4.2.15: Clause added. 4.2.16: Clause added. 4.2.17: Requirement for hexavalent chromium hazard warning label added. 4.2.18: Clarification. 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. 7: ISO 9001 waiver omitted. Annex 2: Omitted. Annex 3: Renumbered.	Response to comments from manufacturers, testing laboratories and others.	