PQS performance specification

WHO/PQS/RF04.2
Original: English
Distribution: General

TITLE: Refrigerator or combined refrigerator and water-pack freezer: compression-cycle. For solar powered rechargeable battery storage

Specification reference:	E003/RF04.2
Product verification protocol:	E003/RF04-VP.2
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Contents:

1. Scope:

This specification defines the requirements for compression-cycle vaccine refrigerators or combined vaccine refrigerator and water-pack freezers powered by a solar electric system with rechargeable batteries. PQS specification **E003/PV01.2** specifies a compatible **Type 1** solar power system. 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:

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/E003/PV01.2: *Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*
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.*

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.

Autonomy: Time in days that a solar refrigerator, or combined refrigerator and water-pack freezer, can maintain the vaccine load within the acceptable temperature range under low solar radiation conditions (e.g. rain). Autonomy is determined as described in **E003/PV01** – Section 4.1.2**.**

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 power supply has been disconnected.

Hot zone: Hot zone units 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.

Installation: The refrigerator specified in this document, connected to a solar power system complying with specification **E003/PV01**.

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: 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.

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[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.

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.
Solar radiation reference period: The minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar refrigerator, or combined refrigerator and water-pack freezer, expressed in kWh/m²/day.
Temperate zone: Temperate zone units 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. Water-packs in the water-pack freezing compartment must remain fully frozen, except during the actual freezing process after additional unfrozen water-packs have been loaded.

4. Requirements:

4.1 *General:*
Solar powered DC compression vaccine refrigerators are used primarily in areas without any electricity or where there is less than 8 hours of reliable electricity over a typical day. Reliability, durability and effective maintenance is essential for a successful installation. The associated power system must be designed to match both the refrigerator power consumption and local climate conditions (i.e. ambient temperatures and solar radiation resource). 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, with one or two compressors, operating on direct current electricity.

4.2.3 Voltage and frequency:
Generally 12-24 volt DC, supplied from a solar powered battery set. Other voltages may be acceptable.

4.2.4 Water-pack freezing:
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 whilst maintaining the temperature control specified in 4.2.5.

4.2.5 Water-pack storage in combined units:
No standard set, but it is recommended that the freezer compartment holds a minimum of 8 kg of water-packs complying with PQS section **E005**. These may be frozen gradually over several days.

4.2.6 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.

4.2.7 Temperature control:

Refrigerator compartment: The entire vaccine load 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: Water-packs in the water-pack freezing compartment (if present) must remain fully frozen under the same ambient conditions.

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 4.2.11). 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.

4.2.9 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, powered off the battery set. Dry cell batteries must not be used.

4.2.10 Holdover time:

Holdover time must be a minimum of 3 hours.

4.2.11 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.

4.2.12 Power consumption:

To be less than 0.7 kWh per 24 hours for appliances with a gross volume of less than 50 litres and less than 0.1 kWh per additional 10 litres gross volume, with a full vaccine load, but without water-pack freezing.

4.2.13 Defrost switch:

The defrost switch (or switches if dual compressors are employed) must accessible to the user without tools but must be protected from accidental changes in position.

4.2.14 Lock:

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

4.2.15 Corrosion resistance:

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

4.2.16 Electrical safety rating:

Manufacturer to certify compliance with IEC 60335-1 and IEC60335-2-24.

4.2.17 Markings:

Compressors operating 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.

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 Battery charge regulator compatibility:

All electrical components must be compatible with the battery charge regulator specified in specification **E003/PV01**.

4.5.2 Alarm:

The alarm system will normally be part of the battery charge regulator. However, if it is incorporated into the refrigerator casing, the control panel must have a colour-coded voltmeter, LEDs, or other indicators to show:

- Array charging (green).
- Low battery (orange or yellow), with a clearly labelled warning: *Do not freeze water-packs* in the appropriate language.
- Load disconnect (red).

An acoustic alarm may be included as a supplementary high/low battery and/or load disconnect warning device.

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, must not contain lead (except in batteries), 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 low-maintenance life of not less than 10 years apart from routine de-frosting, cleaning, solar array shading

prevention, battery water addition and replacement of batteries in the associated battery set.

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;
- temperature adjustments (if applicable);
- prevention of vaccine freezing;
- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance checks;
- diagnostic and repair procedures;
- battery replacement;
- 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/RF04-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.
- Full details of the recommended compatible solar power system (see specification **E003/PV01.2**).
- 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.

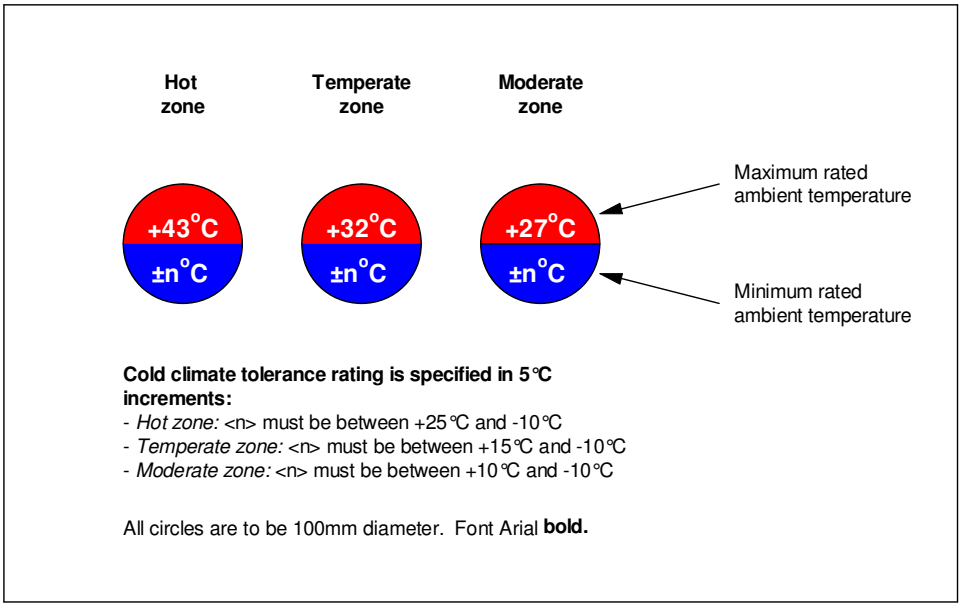
9. Change notification:

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/RF04-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



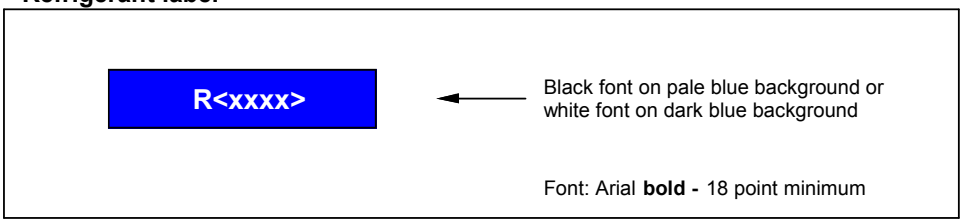
Cold climate tolerance rating is specified in 5°C increments:

- *Hot zone:* <n> must be between +25°C and -10°C
- *Temperate zone:* <n> must be between +15°C and -10°C
- *Moderate zone:* <n> must be between +10°C and -10°C

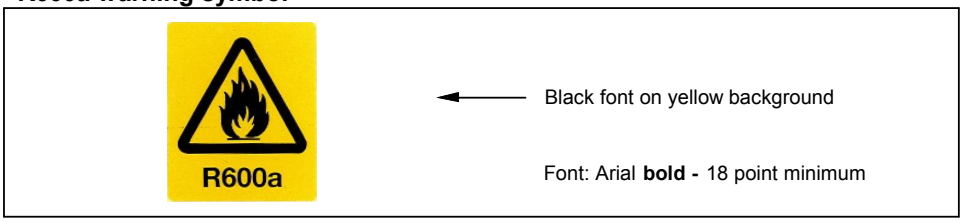
All circles are to be 100mm diameter. Font Arial **bold.**

Annex 2 - Refrigerant symbols

Refrigerant label



R600a warning symbol



Revision history:			
Date	Change summary	Reason for change	Approved
05.03.2007	General edit with additional clauses plus Annexes 1 and 2.	Final revisions to PQS format.	UK
09.05.2007	Revised to SMc comments & teleconference UK, SMc, AG 26.04.07		UK
16.05.2007	Final review version		UK
23.05.2007	4.2.6: New clause. 4.2.8: Minor correction 4.11: Minor addition	Consistency with other specs.	UK
08.08.2007	Autonomy definition clarified. 4.2.5: 'No' added before 'standard'. 4.2.13: 'but must be protected from accidental changes in position' added. 4.2.14: Lock spec changed. 4.4.1: Dims clarified. 4.5.2: 'LEDs or other indicators' added. 4.5.2: Last sentence: 'low' changed to 'high/low'.	Response to manufacturer's comment.	UK
06.07.2010	'Icepack' changed to 'water pack'. 2: Normative references updated. 3: Acceptable temperature range and holdover time definitions changed. Water-pack freezing capacity definition added. 4.2.3: Clause amended. 4.2.4: Clause title changed. 4.2.5: Clause title changed. 4.2.7: Temperature requirement changed to 'fully frozen'. 4.2.9: Option A & B amended. 4.2.17: Clause amended for R600a. 4.2.18: Typo corrected. 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. 4.11: Clause amended. 4.13: VP reference updated. 7: ISO 9001 waiver omitted. 9: VP reference updated. Annex 2: Symbols amended.	Response to comments from manufacturers, testing laboratories and others.	