



EO3/RF-04	Date of issue:	Revision Date:
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Title: Refrigerator or Combined Refrigerator-Icepack Freezer, Compression DC, solar powered rechargeable battery operated.		



PQS performance specification

WHO/XXX
Original: English
Distribution: General

TITLE: Refrigerator or Combined Refrigerator-Icepack Freezer, Compression DC, solar powered rechargeable battery operated

<i>Specification reference:</i>	E03/RF04
<i>Product verification protocol:</i>	E03/RF04-VP
<i>Date of origin:</i>	18.10.2006
<i>Date of last revision:</i>	New specification

- **Contents:**

1. **Scope:** This specification defines the requirements for refrigerators or combined refrigerator-icepack freezers, compression direct current (DC). Typically these are powered with a solar electric system. The power system relies on an electrical storage battery recharged by solar power. The PQS E03/RF 06 specification Solar Power System for Vaccine Refrigerator or Combined Refrigerator-Icepack Freezer defines the requirements for solar power systems used to operate vaccine refrigeration systems.
Three optional climate designations are described: moderate (tested at +27°C), temperate (tested at +32°C) and hot (tested at +43°C). An optional rating for cold climate freeze protection is included. Implementation date 18 months after date of origin noted above.
2. **Normative references:**
 - 2.1 DIN 8985:Household Refrigerating Appliances-Testing of Surfaces
 - 2.2 EMAS: European Union Eco-Management and Audit Scheme
 - 2.3 IEC 60335-1:Household and Similar Electrical Appliances-Safety
 - 2.4 ISO 9001: 2000 Quality Management Systems-Requirements
 - 2.5 ISO 14001:2004 Environmental Management Systems-Requirements with guidance for use
3. **Terms and definitions:**
 - 3.1 *Acceptable range +2°C to +8°C:* The specific vaccine storage refrigerator temperature specifications allow brief excursions outside the general target of +2°C to +8°C. During a 5 day period of testing, excursions over +8°C shall not exceed a cumulative 12 hours nor exceed +20°C and excursions below +2°C shall not exceed a cumulative 12 hours nor reach 0°C.
 - 3.2 *Holdover time:* Time in hours without power that all points in vaccine compartment remain between +2°C and +10°C.



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- 3.3 *In writing*: Means communication by letter, fax or email.
- 3.4 *Legal Manufacturer*: The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a product or device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
- 3.5 *Montreal Protocol*: Montreal Protocol on Substances that Deplete the Ozone Layer
- 3.1 *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.

4. **Requirements:** Solar powered DC compression refrigeration equipment is used primarily in areas with unreliable electricity supply (i.e. less than 8 hours of reliable electricity per typical day) or no electricity. Reliability, durability and maintenance are essential for successful installations. Special attention is required to properly design the power system to match both the equipment power consumption and local climate conditions (i.e. ambient temperatures and solar radiation resource). **Consider environmental conditions before final specification (e.g. in dusty conditions avoid using refrigerators with condenser fins requiring electric blower/fan to clean the fins).**

4.1 General: For direct current compression refrigerator or combined refrigerator-icepack freezer compression cycle with one or two compressors. Power source is direct current (DC) electricity, usually nominal 12 Vdc, usually solar powered.

4.2 Performance:

- 4.2.1 *Temperature control*: Refrigerator temperature throughout the area of a full or empty vaccine load must remain in acceptable range +2°C and +8°C throughout the vaccine load at any continuous ambient temperature **test(s)** or day/night cycling temperature **test(s)**. Freezing compartment suitable for storing vaccines must remain below -15°C in the same ambient conditions.
- 4.2.2 *Safe freezing capacity*: (required only for combined units with freezer) At least 1.6 kg and more than 2.4 kg of icepacks per 50 liters of gross freezer volume are to be frozen in 24 hours at ambient temperatures **test(s)** while maintaining the temperature control specified in 4.2.1.
- 4.2.3 *Freezer storage capacity*: (required only for combined units with freezer) No standard set, however it is recommended that the freezer compartment hold a minimum of 16 frozen icepacks (8 kgs) frozen gradually over several days.



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- 4.2.4 *Holdover time*: Holdover time is a minimum 3 hours.
- 4.2.5 *Power consumption*: Less than 0.7 Kwh/24 hours for appliances with a gross volume of less than 50 liters and less than 0.1 KWh per additional 10 liters gross volume, with vaccine load, but without icepack freezing.
- 4.2.6 *Cold climate freeze prevention*: Optional rating. To achieve “cold climate freeze prevention” status refrigerator must maintain the vaccine compartment in acceptable range +2°C and +8°C at ambient temperature down to -10°C. Holdover time requirement applies as specified in 4.2.4.

4.3 Environmental requirements:

4.4 Physical characteristics:

- 4.4.1 *Refrigerant type*: Must be CFC-free (chlorofluorocarbon-free) with HFC (hydro fluorocarbon) or HC (hydrocarbon) refrigerant. The acceptability of alternative refrigerant gases will however continue to be assessed.
- 4.4.2 *Thermal insulation foaming agent*: Can be any gas complying with the limitations and deadlines set by the Montreal Protocol on the ban of CFC gases.
- 4.4.3 *Corrosion resistance*: Internal and external cabinet, lid and frame protected against corrosion to DIN 8985.
- 4.4.4 *Electrical safety rating*: Manufacturer to certify compliance with IEC 60335-1 Edition 4.1 Household and Similar Electrical Appliances-Safety.

4.5 Interface requirements:

- 4.5.1 *Vaccine storage protection advice*: All units to display vaccine storage and vaccine freeze protection instructions affixed at factory. If removable baskets are supplied affix a multi-lingual warning within the refrigerator instructing users to store vaccine only within the basket.
- 4.5.1 *Thermostat*: A thermostat that is not user-adjustable and set to prevent freezing in any part of the refrigerator must be included. Technician adjustment is acceptable provided the thermostat is protected from user adjustment by location (e.g. in machine cabinet) or password (i.e. for programmable thermostats).
- 4.5.2 *Thermometer*: All units to include external reading thermometer in compliance with PQS E06 standards.
- 4.5.3 *Markings*: Compressors operating on R 134a refrigerant should be marked with a blue disk painted or otherwise securely attached on their visible side. The disk should have a minimum diameter of 100 mm (see Annex 1). All units are to be marked with a refrigerant chemical name, refrigerant number, formula and proportion (for blended refrigerants).
- 4.5.4 *Alarm*: Indicator lights (LED or LCD) or alarms must be included to display 1.) load disconnect (e.g. red LED), 2.) array charging (e.g. green LED) and 3.) low battery (orange or yellow LED with clearly labeled warning “Do not freeze icepacks” in an appropriate language). To operate



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from system storage battery only. Alarm may be part of battery charge regulator.

4.5.5 *Battery charge regulator:* All battery charge regulators must comply with PQS E03/RF06 Solar Power System for Vaccine Refrigerator or Combined Refrigerator-Icepack Freezer.

4.6 Human factors:

4.6.1 *Door lock:* Door lock and two keys required.

4.6.2 *Defrost switch:* Defrost switch (or switches if dual compressor are employed) shall be accessible to the user without tools. No other power switch shall be installed.

4.7 Materials:

4.8 Reliability: Any component of the system which fails due to defective design, materials or workmanship will be covered by a warranty for replacement. The minimum period of the warranty shall be 2 years.

4.9 Maintainability: These systems require maintenance including battery care. If routine maintenance including battery care is unavailable consider solar battery-less refrigerators in PQS E03/RF-05.

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: If unit to be exported then the instructions are to be included in the relevant language - English, French, Spanish, Russian or Arabic. Separate users instructions and separate technicians instructions are required.

Instructions shall be provided with each unit with clear descriptions for users and technicians of:

- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance checks;
- diagnostic and repair procedures;
- prevention of vaccine freezing;
- installation procedures;
- itemized list of spare parts including part number
- resource recovery and recycling procedures

4.12 Training:

4.13 Verification: Satisfactory completion of a single type-examination in accordance with PQS Verification Protocol E03/RF04-VP

5. **Packaging:** Maximum dimensions of appliance (minus packing) width or depth to be less than 780mm to allow delivery through common doors. No package shall be larger or heavier than can be handled manually in the country of use. Labels bearing instructions shall be highly visible and printed clearly. Sea



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- crating to be provided.
6. **On-site installation:**
 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
 - Confirmation of the 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 trace ability
 - Certified photocopies of all type-approvals obtained for the product, including CE marking and the like
 - Certified photocopies of the legal manufacturer's ISO 9001:2000 or ISO 9001:1994 quality system certification
 - Where relevant, certified photocopies of the legal manufacturer's ISO 14001:2004 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.
 8. **On-site maintenance:**
 9. **Change notification:** All product changes are to be reported to WHO/UNICEF. Any change that can alter the test results per PQS E03/RF04-VP will cause the product to be retested.
 10. **Defect reporting:** The manufacturer is to provide WHO/UNICEF with immediate notification of any component recall or defect or similar event. **If requested by WHO/UNICEF**, the manufacturer is to submit a report to WHO/UNICEF with the number of systems provided, number of component repairs/replacements provided and any field reports including successes and failures.

Annexes: Annex 1: R134a Marking

Revision history:

Date	Change summary	Reason for change	Approved
dd.mm.yy	< change item> < etc.>	< reason for change> < etc.>	<name>



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REVISION HISTORY FORM

(Form number: FCH/IVB /ATT/GEN/F002)

SOP Number

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REVISIONS

Date

Reason

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and Name)