



TITLE: Water-pack freezer: solar direct drive

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1. Need:

Recent reports from the field have identified the need for solar direct drive (SDD) water-pack chilling and water-pack freezing equipment to complement sites where SDD refrigerators are installed. An SDD freezer allows a health facility to provide outreach services and enables district level stores to provide coolant for vaccine transport. In addition, district level SDD freezers would be able to service one or more long-term passive devices at their peripheral health facilities.

Initial first generation SDD refrigerators were not able to provide separate freezing capacity. This technical hurdle can and has been overcome. The majority of PQS prequalified SDD appliances are refrigerators with no freezer. Initial field experiences with first generation SDD water-pack freezers are limited however users report acceptable performance.

The purpose of this preliminary Target Product Profile is to propose the scope of a new PQS category for SDD water-pack freezers (WHO PQS E003 FZ03) and to initiate a consultation process with industry which will lead to a PQS performance specification and verification protocol.

2. Normative references:

DIN 8985: 1983-05: *Testing the surfaces of installed refrigerators and freezers.*

GHS Rev 5. United Nations: *Globally Harmonized System of Classification and Labelling of Chemicals.*

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/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*

WHO/PQS/E003/RF05.2: *Performance Specification: Refrigerator or combined refrigerator and water-pack freezer: compression-cycle. Solar direct drive without battery storage.*

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

WHO/PQS/E003/PV01-VP1.2: *Type-examination protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*

WHO/PQS/E003/PV01-VP2.2: *Quality assurance protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.*

3. Terms and definitions:

Autonomy: Time in days that a solar water-pack freezer can maintain all ice-packs in a fully frozen state under low solar radiation conditions (e.g. rain). The measured autonomy period ends immediately when the first recorded temperature within an ice-pack exceeds 0°C or indicates phase change from solid to liquid has occurred. Freezer autonomy is measured as described in E003/FZ03.0-VP.1 (in development). Installation site autonomy is determined as described in E003/PV01 – Section 4.1.2.

Coolant-pack:

- A generic PQS prequalified water-pack complying with specification PQS/E005/IP01.
- A purpose designed PCM-pack complying with this specification.
- A purpose designed leak-proof container, filled with water, complying with this specification.

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.

Ice-pack: A water-containing coolant-pack frozen to a temperature between - 5°C and -25°C before use, to the point where there is no remaining liquid water

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 their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.

Manufacturer's gross volume: The manufacturer's stated gross volume or, for purposes of comparison, the internal free volume, including the space occupied by the freezing compartment, and the volume occupied by shelves, but excluding the space taken by the ice-lining or other type of thermal storage, if present.

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 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 storage capacity: The net capacity in an appliance available for the storage of water- or ice-packs. It is measured by loading the freezer compartment with WHO PQS specification water-packs per manufacturer's loading instructions, including any rack or structure provided for holding water-packs. The total volume of water-packs, in litres, represents the net volume available for the storage of water-packs.

Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification PQS/E005/IP01.

Water-pack freezing capacity: The maximum net amount of solid ice-packs which remain fully frozen at the end of a night phase in the water-pack freezing test expressed as kg. Partially frozen water-packs will not be included in the water-pack freezing capacity report.

4. Design criteria:

4.1 General

Solar direct drive (SDD) equipment is typically deployed at the district store and health facility level where mains electrical supply is unavailable or highly unreliable (i.e. less than 8 hours of continuous electricity per typical day).

Minimum water-pack freezing capacity is 1.6 liters per day. Minimum ice-pack or water-pack storage capacity is two times the actual water-pack freezing capacity.

All appliances must fully meet the stated performance requirements with a minimum solar radiation reference period of 3.5 kWh/m²/day or less.

Manufacturers may offer products suitable for one or more temperature zones and all must be suitable for Hot Zone (+43°C).

These units are not suitable for storing vaccine.

Reason: To provide PQS prequalified SDD water-pack freezer options for countries and provide certainty for manufacturers.

Timing for PQS Inclusion: 2015, subject to change upon further discussions.

4.2 Operating temperature range

All SDD freezers must prequalify for the Hot Zone (+43C).

4.3 Refrigeration cycle

Electrically driven freezing will be considered including compression cycle and thermoelectric freezers.

4.4 Refrigerant

As specified in WHO/PQS/E003/RF05.3 and RF06.2 the WHO is proposing that future specifications require the use of HC refrigerants such as R600 or other gases with GWP ≤ 11 and zero ODP, while R134a will be phased out over a transition period of two years in accordance with the next publication of WHO/PQS/E003/RF05 or RF06. 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).

Reason: To provide visibility to manufacturers into the WHO's future refrigerant specifications.

Timing for PQS Inclusion: 2015.

4.5 Water-pack freezing

A minimum of 1.6 kg litres must be frozen per 24 hours. The packs must remain fully frozen overnight.

Reason: Use of fully frozen coolant-packs with future PQS prequalified freeze-free carriers is considered a simpler operation with fewer decisions for users.

Fully frozen packs will provide increased cold life in passive devices.

Some passive devices require fully frozen packs.

Accurate prediction of cooling capacity with partially frozen packs cannot be made.

4.6 Freezer storage volume

The freezer should accommodate a minimum of two times the actual water-pack freezing capacity of the freezer.

4.7 Temperature control

The freezer must be capable of producing ice for use by health workers at the beginning of each working day. Under the day/night cycling and water-pack freezing tests, the temperature of the freezer compartment is permitted to exceed 0°C during the night phase of the test provided all ice-packs remain fully frozen at the start of the day cycle.

4.8 Thermostat

Thermostat must be pre-set at the factory. The thermostat must be effective throughout the ambient operating temperature range. It must be designed so that it cannot be adjusted by the end-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, adjustable thermostats may be password-protected.

4.9 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. Dry cell batteries must not be used.

4.10 Humidity control

Manufacturers are to propose water-pack placement instructions, racks and/or structure to prevent frozen packs from adhering to other packs or adhering to freezer walls and/or bottom surface. Defrost drainage must be supplied.

Reason: Instances have occurred where ice-packs adhere to the cabinet making them difficult to remove without excessive and potentially damaging force.

Timing for PQS Inclusion: 2015.

4.11 Defrost

Defrosting requiring no user intervention is preferred and will be reported as Grade A.

Defrosting that requires any user intervention will be reported as Grade B.

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

4.12 Power source

Direct supply from a photovoltaic panel array in compliance with WHO/PQS/E003/PV01.

An ancillary battery for freezer operation will not be accepted. Other power storage systems (e.g., capacitor) with charge level indicator may be included provided these have a minimum guaranteed design life of 10 years under the environmental conditions for which the SDD freezer is prequalified.

A system that is able to provide spare power for other approved facility electrical loads (e.g. rechargeable cold chain support devices such as temperature monitoring devices, mobile phone charging, computing, and lighting) is acceptable provided the freezer is always prioritized ahead of other power uses.

Reason: Because most SDD refrigerators and SDD freezers now operate without ancillary batteries, the option for devices with ancillary batteries will not be allowed. Ancillary power storage systems (e.g. capacitors) must have the same design life as the product.

Timing for PQS Inclusion: 2015

Reason: There is increasing demand for solar power for other uses in health facilities. Next generation SDD power supply specifications need to acknowledge this requirement while assuring the priority need to keep freezer operation prioritized.

Timing for PQS Inclusion: 2017, subject to change upon further discussions.

4.13 Power consumption

No standard set; however performance data will be published.

4.14 Input voltage

Solar module voltage up to 45 volts open circuit (Voc) is acceptable provided all electrically powered system components are integrated in such a way that performance and component life is not reduced by voltage input from the solar array.

Reason: Compressors and other cooling systems can utilize a range of input voltages including 30 to 36 volts now commonly available in solar modules that may have economic advantages owing to their very wide scale use with grid-connected systems. Higher input voltage may also reduce solar array cable costs and/or improve energy efficiency when compared to lower input voltage.

Timing for PQS Inclusion: 2015.

4.15 Autonomy

All solar direct drive freezers must pre-qualify with at least a minimum autonomy of 3 days at the minimum solar radiation reference period of 3.5 kWh/m² day in the Hot temperature zone. Freezer autonomy is determined by testing in accordance with E003/FZ03.1-VP.1. Site autonomy is determined by the methods described in E003/PV01.2 clause 4.1.2. Installation site conditions may require autonomy of more than 3 days.

Reason: Freezer operation requires predictability. A minimum autonomy requirement is proposed as 3 days. However 5 day autonomy is suggested since there is evidence there are locations where more than 3 days of autonomy are required.

Request for cost information: WHO PQS requests manufacturers indicate estimated cost differences for identical freezers produced with overnight autonomy, 3 day autonomy and 5 day autonomy.

4.16 Performance degradation

Product design must account for performance degradation over the target life of the product in order to sustain acceptable water-pack freezing temperatures and other product features (if included).

Reason: Certain insulation materials and other components may degrade over time potentially impacting temperature control and energy consumption.

Timing for PQS Inclusion: 2015.

4.17 Lock

The door or lid must be fitted with a lock or a means of locking (e.g. with a padlock). Two keys are to be supplied for every lock.

4.18 Corrosion resistance

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

4.19 Electrical safety

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

4.20 Markings

Appliances utilizing compressors 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.

Appliances not utilizing compressors-based cooling methods must be marked identifying the refrigerant and/or heat transfer fluids. 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) and/or chemical name and formula of other heat transfer fluids.

All appliances to label hazardous materials and include a Safety Data Sheet. Label and Safety Data Sheet must comply with the Globally Harmonized System for the Classification and Labelling of Chemicals.

4.21 Vaccine storage warning

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 the local language specified at time of ordering.

Graphic to be supplied by WHO.

4.22 Instructions

Each freezer to include a separate user manual and technician's installation manual in the language most appropriate to the installation site. Instructions to include easy to understand visuals whenever possible to avoid reliance on text.

The user manual must include the following information:

- Health and safety guidance;
- Routine maintenance tasks (e.g., daily, weekly, and monthly).

The technicians' installation manual must include the following information:

- installation procedures;
- correct handling to avoid product damage and for safety of persons;
- compatible types of solar power system;
- simple daily, weekly and monthly maintenance tasks;
- periodic preventative maintenance procedures;
- diagnostic and repair procedures;
- itemized list of spare parts including part numbers;
- end-of-life resource recovery and recycling procedures;
- user training guidance.

Printed user and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information should be summarized on a single sheet fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the product and must be in a locally-understood language. In addition supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.

Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the installation teams in installation standards and practices specific to the product and its power system.

Reason: High quality instructions are a pre-requisite for high quality installations and good routine maintenance. Increasingly, countries are using video instructions for training purposes.

Timing for PQS Inclusion: 2015.

4.23 User-centred design features

Products must be designed for simplified maintenance and troubleshooting, such that there is a minimum requirement for work by trained technicians, and should include a minimum number of components requiring service actions.

Control panels and integrated thermometers must be able to present legible information to a reader at a standing position. For example, the product could make use of a larger and/or higher contrast LCD screen to enable better legibility.

Reason: In response to end users demand. Control panels close to floor level are inconvenient, even if the panel is tilted.

Timing for PQS Inclusion: 2017, subject to change upon further discussions.

In addition to the PQS temperature zone sticker and vaccine storage warning the device should carry the following additional information:

- Near-Term: Manufacturer and model number (unless already located on the front of the unit), serial number, data of manufacture, PQS identification number, applicable service phone number, and website URL fixed to the front of the cabinet.
- Near -Term: An operations and maintenance pictogram fixed to the lid or near the top front of chest freezers and near the top of the door on upright freezers.
- Long-Term: The above information, plus a bar code to identify the freezer (actual definition of bar code TBD) fixed to the front of the cabinet.

Given the large amount of information, it is expected that separate stickers could convey the totality of information.

PQS stickers should be readable for the expected age of the equipment.

Reason: To simplify data gathering for in-country equipment inventories.

Timing for PQS Inclusion: Near-Term 2015.

Long-Term 2019, subject to change upon further discussions.

4.24 Build quality

The build quality of the product and all ancillary components must be to a standard consistent with the conditions under which these appliances are used, including, but not limited to, the following:

- Transport over rough road surfaces.
- High temperatures in transport and operation.
- Low temperatures in transport and operation.
- Operating locations with high wind and high density of dust particles.
- High humidity.

Reason: Specific issues noted with current prequalified refrigerators include: insufficient robustness to withstand transport; deformation of thermal storage components affecting use of the vaccine storage baskets; failure of bulb and capillary tube thermostats; poorly routed and retained wiring; component corrosion; and accessibility for service.

Timing for PQS Inclusion: 2015, note that with no specific standards this is communicated only as a goal.

4.25 Service provision

The product must be designed, and components selected, with the aim of achieving a zero-repair life of not less than 10 years.

Maintenance activities should be confined to tasks that can be carried out by the health worker or storekeeper; these tasks should be confined to routine de-frosting and cabinet cleaning and solar array cleaning.

The installation kit provided for each site must include the specialized maintenance supplies and/or tools needed to carry out these routine tasks. Wherever possible, the means for routine maintenance should be built into the product: for example, a drainage tray or spout for defrosting.

Reason: Equipment breakdowns compromise immunization programs and skilled maintenance staff are frequently not available in resource-poor settings.

Timing for PQS Inclusion: 2015.

4.26 Shipping, storage and use conditions

Ambient temperature range during transport and storage: -30°C to +70°C when the product is inactivated.

Ambient humidity range during transport, storage and use: 5% to 95% RH, non-condensing.

Manufacturers must be aware that products may be exposed to very high temperatures during shipping and dockside storage and must take appropriate actions to mitigate this risk.

Reason: Instances have occurred where SDDs have been damaged during transit and storage due to exposure to high ambient temperatures in shipping containers.

Timing for PQS Inclusion: 2015.

4.27 Accessories

Specialized tools and materials required for installation and/or required for technical maintenance are to be clearly identified to prospective buyers and offered as an option by the manufacturer.

Accessories not required for regular operations and/or not required for routine user maintenance are to be offered as an option by the manufacturer.

Items that are required for regular operation and routine maintenance are not considered accessories and must be included as standard with each appliance supplied.

Reason: To avoid appliances being provided without items required for regular operations and maintenance such as ice scrapers for defrosting and condensate catchment pans. These items and specialized installation tools and materials are not always readily available in the area of installation and additional funds may not be available for installer or user purchases.

Timing for PQS Inclusion: 2015.

4.28 Spare parts

Attached within each water-pack freezer there must be a set of 10 spare fuses for each fuse size and type used.

Manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 units. The minimum spare parts for 10 freezers are:

- 1 compressor or complete cooling unit, to suit supplied freezer.
- 1 electronic unit (compressor control or cooling system control).
- 1 thermostat (or temperature control components).
- 1 x 100 g canister of R600a, if used.
- 1 fan, if used.

Reason: To avoid appliances being provided without spare fuses and fuse types not always readily available in the area of installation. Spare parts can be assessed at time of purchase based on manufacturer specific requirements, country conditions, existing spare parts stocks and geographic distribution of installations.

Timing for PQS Inclusion: 2015.

4.29 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 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension must not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm.

4.30 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 ergonomically designed so no single worker is required to carry more than 25 kg while working on their own, or in a group.

4.31 Electrical components

All electrical components must be compatible with a **Type 2** solar power system as specified in specification **E03/PV01**.

4.32 Human factors:

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.

4.33 Control panel, thermometer and switch locations

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.

4.34 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).

4.35 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.

4.36 Disposal and recycling

The manufacturer is to provide information to the buyer on childproofing the cabinet at time of disposal and information on 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.

4.37 Verification

In accordance with PQS Verification Protocol **E003/FZ03-VP1** (to be developed).

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 assistance:

Training is not required of manufacturer. Specific user training is recommended for the responsible, on-site freezer user. Manufacturers to provide user training guidance. User training conducted by installers at time of installation is recommended

Installation is not required of manufacturers. Manufacturers to provide contact information for installation sources.

Maintenance is not required of manufacturers. Maintenance will be carried out by the end-user and/or their agents.

Reason: User training has not been systematically addressed. Installers are guaranteed to be on site and must be prepared to provide user training.

Timing for PQS Inclusion: 2015.

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 and TPP 02.1**).
- 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 2010).

8. **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/FZ03-VP1.0** will result in a request for the product to be retested.

9. **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.

10. **Revision history:**

Date	Change summary	Reason for change	Approved