

WHO/PQS/E007/EHC01.1

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1. Scope

At health facilities with limited or no electrical services there is increasing demand for solar generated electricity for solar direct drive (SDD) vaccine refrigeration and water-pack freezing, as well as other uses. SDD solar power arrays are oversized to assure that safe vaccine storage conditions are sustained even when providing a potential source of surplus solar electricity for other immunization and facilty needs. Next generation SDD appliances coupled with an optional accessory energy harvest control (EHC) can safely supply some of these power needs while assuring their primary function of keeping vaccines within the acceptable temperature range.

The scope of this performance specification is to specify requirements for an EHC that prioritizes and safeguards appliance operation and provides surplus solar generated electricity for secondary electricity consuming devices (loads). An EHC is an optional accessory for SDD appliances prequalified per WHO PQS E003/FZ03 or E003/RF05. Testing is described in E007/EHC01-VP.1.

Laboratory testing is to be conducted on the EHC when coupled with a specific appliance(s) to assure:

- When the appliance cooling circuit requires electricity the energy harvest control always prioritizes the cooling circuit ahead of all other loads;
- If the EHC fails the appliance cooling circuit will remain fully functional;
- If the EHC is improperly connected to the appliance, the appliance continues to operate correctly and remaims undamaged; and
- Some amount of surplus electricity can be made available for other uses.

To become prequalified the EHC will be required to be tested with all compatible appliances with which the EHC option will be offered, as designated by the Legal Manufacturer. A specific appliance with an EHC will first be tested per E007/EHC01-VP.1 and if successful then tested per the appropriate SDD verification protocol with modifications as noted in Test 10 of E007/EHC01-VP.1. In order to prequalify, the EHC must pass both the E007/EHC01-VP.1 tests and the SDD appliance testing. If multiple, different model appliances use the identical EHC, identical cooling system, identical control system and identical solar power system then a single set of tests can be accepted to prequalify multiple models. Undefined loads and defined loads are not specified herein, not tested and not prequalified.

Field testing is required of each EHC coupled with a prequalified appliance. If the Legal Manufacturer claims to produce multiple, funtionally indistinguishable appliance models (e.g. the same cooling, electric, and control systems), the possibility of testing only a single, representive EHC/appliance combination may be discussed for approval by the PQS Secretariat. The PQS Secretariat is to preapprove all field study plans in advance. EHC design must account for performance degradation over the 10 year target life of the appliance in order to sustain operation and features.

The build quality of the EHC must be consistent with the conditions under which these appliances are used, including, but not limited to, the following:

- Transport by air, sea and over rough, dusty road surfaces.
- High and low temperatures in transport, storage and operation.
- High humidity in transport, storage and operation.
- Operating locations with high wind and high density of dust particles.
- Operating locations near corrosive marine environments.
- Users with inconsistent training.
- Users with no specific maintenance tools.

2. Normative references (use most recent version of each reference)

EMAS: European Union Eco-Management and Audit Scheme.

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

IEC 60335-1: Amendment 1: *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 60364-1: 2005: Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.

IEC 61000-6-1 edition 2.0: 2005: Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.

IEC 61000-6-3 edition 2.1: 2011: Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.

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 20282-1: 2006: Ease of operation of everyday products - Part 1: Context of use and user characteristics.

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

WHO/PQS/E003/FZ03: Performance specification: Water-pack freezer: Solar direct drive without battery storage.

WHO/PQS/E003/FZ03 VP.1: *Independent type testing protocol: Water-pack freezer: Solar direct drive without battery storage.*

WHO/PQS/E003/RF05.4: Performance specification: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage.

WHO/PQS/E003/RF05 VP.4: Independent type testing protocol: Refrigerator or combined refrigerator and water-pack freezer: Solar direct drive without battery storage.

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

WHO/PQS/E007/EHC01-VP.1: *Independent type testing protocol: Solar direct drive surplus energy harvest control and strategy.*

3. Terms and definitions

Appliance: Any SDD vaccine refrigerator, water-pack freezer or combined vaccine refrigerator and water-pack freezer.

Defined load: Specific load(s) matched to the EHC and supplied by the Legal Manufacturer/Reseller. The defined load(s) would be permanently connected to the EHC or would connect to the EHC with a unique, non-standard electrical connector to restrict the addition of undefined loads with standard electrical connectors.

Energy harvest: The collection, distribution and use of surplus solar electricity for loads in addition to an immunization appliance.

Energy harvest control (EHC): Accessory control device and/or system to enable the use of surplus solar photovoltaic electricity for powering other electricity consuming devices (loads) in addition to an immunization appliance. An EHC may harvest surplus electricity when the active cooling circuit is off and/or when the active cooling circuit is on and sufficient surplus electricity is available.

In writing: 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 her/his own name, regardless of whether these operations are carried out by that person or on her/his behalf by a third party.

Load: Any end-use device in an electrical circuit (other than the primary appliance and EHC) that can consume power when the electrical circuit is energized. Two categories of electrical loads are considered: defined loads and undefined loads. Operate(s) correctly: The component or components being referred to function as normally expected. More explicitly with respect to the appliance, the cooling circuit functions as required by the thermostat.

Preventive maintenance: Activities associated with the upkeep of an appliance or solar power system to protect against normal wear and tear. This type of maintenance requires minimal skills and training, and is usually scheduled for regular intervals (daily, weekly, or monthly). On-site workers who have received appropriate training are responsible for preventive maintenance.

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 power simulator (SPS): A supply of power intended to simulate solar array output at specific instantaneous solar radiation values.

Solar power system: An assembly of solar module(s), electrical cabling and support structure complying with WHO PQS E003/PV 01.

Standard electrical connector: Common electrical connectors including all USB receptacles, 12 VDC receptacles as used in vehicles and 120/230 VAC receptacles as used in buildings and electrical generators.

Surplus solar electricity: Any electricity the SDD appliance cannot use because:

- The appliance does not require electricity at that instant; or
- Electricity being generated is insufficient to power the appliance at that instant; or
- Electricity is powering the appliance and there is surplus electricity that the appliance cannot use at that instant.

Undefined load: User selected load devices that are not supplied by the Legal Manufacturer/Reseller as a defined load with the appliance and EHC system.

Uninterrupted: With respect to an electronic component or device, to operate continually, without pause.

Variable DC load: A laboratory test device to simulate the range of secondary loads.

4. Requirements

4.1 Appliance prioritization

In all operational modes the EHC prioritizes appliance operation over other loads.

4.2 Fail safe operation

The EHC must be designed so that if for any reason it fails, safe and adequate power is still supplied to the appliance for continuous operation. The EHC must include a simple and intuitive mechanism to be disconnected or bypassed completely to allow the appliance to continue to operate correctly in the event of EHC failure. The EHC must survive common control fault conditions. Such conditions are as follows but not limited to: connection errors including reversed polarity, voltage mismatch and wiring connections in any sequence possible, high temperature operation, power input overcurrent conditions and short circuit (appliance, EHC, load and solar power system). In the event of EHC failure, the appliance will continue to operate correctly as prequalified and remain safely connected to the solar power system.

4.3 Energy harvest

The EHC must manage surplus solar electricity that can be controlled, diverted to and consumed by other loads.

An EHC must be specified by manufacturers for either undefined loads selected by the user or for defined loads provided by the manufacturer. In both cases the EHC and appliance will be tested only with a laboratory supplied variable direct current (DC) load designed to test the limits of the system.

The energy harvest (in watt-hours per day on average) and the energy harvest efficiency have no set criteria but will be measured and reported. Manufacturers are to state the minimum daily quantity of harvested energy (Wh/day) available based on the Day/Night test at the minimum solar radiation reference period.

Manufacturer to provide clear examples of energy harvest available for users (e.g., X quantity of Y device in operation for Z hours per day).

4.4 Compatibility and compliance with relevant references

The EHC must be compatible with at least one WHO PQS prequalified appliance and the appliance's required **Type 2** solar power system per **E003/PV01**. When possible it is recommended that load batteries comply with **E003/PV01**.

4.5 Appliance operation

The SDD appliance power switch (as required in **PQS E003 RF05.4**, section 4.5.2) must simultaneously disconnect both the EHC and the SDD appliance to prevent accidental or intentional power diversion to secondary load(s) through the EHC when the SDD appliance is switched off.

Manufacturer to certify that EHC design prevents simultaneous initial starting of appliance and load. Manufacturer to certify that EHC design prevents loads with a battery from powering the appliance under any operating condition.

Certifications to include a description of the method(s) used to prevent simultaneous initial starting of appliance and loads and methods to prevent load battery from powering the appliance under any operating condition.

4.6 Appliance compatibility

The EHC must be compatible with at least one WHO PQS prequalified appliance.

4.7 Solar power system compatibility

The EHC must be compatible with the specific solar power system(s) required by the specific appliance(s) with which the EHC is prequalified. All EHCs are operated on direct current (DC) electricity generated by the solar power system. The energy harvest system cannot result in a solar power system larger than that required by the SDD appliance alone.

4.8 Load compatibility

Legal Manufacturer/Reseller are to clearly indicate if the EHC is designed for use with a defined load or an undefined load. Legal Manufacturer/Reseller are to clearly note any incompatible load types including external battery charge regulator type (e.g. maximum power point tracking, pulse width modulated, series, shunts). It is recommended that all EHCs with load outputs of 12 VDC or higher be compatible with all common solar battery charge regulator types.

4.9 Available energy harvest and energy efficiency

Manufacturer to state the minimum average daily Watt hours (Wh/day) of energy available to users based on the day/night test at the minimum solar radiation reference period and provide clear examples for users (e.g., X quantity of Y device in operation for Z hours per day).

An EHC with a defined load will report only the energy used for the defined load. Any additional energy will not be reported. Results will be published for the minimum available Wh/day and overall energy efficiency (estimated as the available Wh/day divided by the possible average surplus solar electricity as measured in the day/night appliance testing).

4.10 <u>Electrical safety rating</u>

Legal Manufacturer/Reseller to certify compliance to IEC 60335-1, IEC 60335-2-24 and IEC 60364-1.

4.11 Electromagnetic compatibility

Legal Manufacturer/Reseller to certify compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**.

4.12 Restricted materials

The EHC and its constituent components must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or

polybrominated diphenyl ethers (PBDE). The only exception will be for loads requiring a recyclable lead acid battery.

4.13 Maintenance and servicing provision

The EHC and load(s) cannot impact the day-to-day operation of the appliance or increase preventive appliance maintenance. The EHC is to be designed to achieve a no-maintenance life of no less than 10 years.

4.14 Essential spare parts

Based on EHC design and requirements the type and quantity of spare parts, basic installation tools/supplies, and user and technician maintenance manuals (see 4.16 Instructions) must be determined and agreed upon in advance of order placement. As a minimum each EHC is to be supplied with 10 spare fuses of all fuse size and types used in the EHC and, if supplied, used by any defined load(s). The spare fuses are to be attached within or on the EHC and, if supplied, the defined load(s).

Legal Manufacturer/Resellers are to publish a list of spare parts recommended for purchases of 10 and 50 EHCs and, if supplied, defined load(s). Legal Manufacturer/Reseller must ensure supply of spare parts for a minimum of 5 years from the time of cessation of the last production of equipment. Spare parts are to be provided in kit form for storage in appropriate quantities at National or Subnational level in the purchasing country, as agreed with the purchasing agency.

4.15 <u>Disposal and recycling</u>

The Legal Manufacturer/Reseller is to provide information to the buyer on the hazardous materials contained within the EHC and, if supplied, the defined load(s) with suggestions for resource recovery/recycling and/or environmentally safe disposal. For Legal Manufacturer/Resellers from the European Union WEEE compliance in accordance with European Union Directive 2002/96/EC is mandatory.

4.16 Instructions and labelling

Each EHC must include a separate user manual and technician installation manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of laboratory testing. 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;
- Basic operations description;
- Correct handling to avoid damage to the EHC;
- Loads that are compatible and not compatible;
- Minimum average daily Wh of energy available to user based on the minimum solar radiation reference period and clear examples for users (e.g., X quantity of Y device in operation for Z hours per day);
- Preventive maintenance tasks (e.g., daily, weekly, and monthly);
- End-of-life resource recovery and recycling procedures.

The technician installation manual must include the following information:

- Health and safety guidance;
- Detailed operations description;
- Correct handling to avoid damage to the EHC;
- Loads that are compatible and not compatible;
- Installation procedures;
- Compatible appliance(s);
- Compatible solar power system voltage;
- Minimum average daily Wh of energy available to user based on the minimum solar radiation reference period and clear examples for users (e.g., X quantity of Y device in operation for Z hours per day);
- Preventive maintenance procedures (e.g., daily, weekly and monthly);
- Corrective maintenance tasks;
- 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 operations and maintenance instructions specifically directed at the health facility or store staff must be pictorial. All key information is to be summarized on a single pictogram sheet fixed onto the EHC lid or near the top front of chest appliances and near the top of the door on upright appliances. The sheet is to be sufficiently durable to last the life of the appliance.

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 EHC and, if supplied, defined load(s).

The EHC must be labelled to assure correct connection to appliance, load and solar power system.

4.17 Training

If requested, all Legal Manufacturers/Resellers are required to have the capability of providing in-person training in the countries where their product is deployed. Training may be delivered by the Legal Manufacturer/Reseller or a manufacturer representative. The Legal Manufacturer/Reseller must provide user training guidance to enable installation technicians to train users. 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.

4.18 Human factors

An EHC should be simple to understand, simple to install, simple to use and require minimal maintenance. The EHC should be repairable on-site or replaceable on-site.

4.19 Warranty

EHC warranty to be a minimum of five years.

4.20 Ambient temperature range during transport and storage

Ambient temperature range during transport and storage to be -30° C to $+70^{\circ}$ C when the product is inactivated.

4.21 Ambient humidity range during transport, storage and use

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

4.22 Protection against dust and water ingress

A stand-alone EHC that is not part of the appliance design could be installed in dusty environments. The design of the enclosure should ensure that the EHC is not damaged by dust penetration or splashing water. A minimum of IP54 rating is required. This IP rating requirement does not apply for an EHC that is integrated into the appliance design (i.e., within the body of the appliance).

4.23 Verification

In accordance with PQS Verification Protocol E007/EHC01.1-VP.1.

5. Packaging

Materials used for packaging the finished EHC are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

The packaging is to be of a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. The packaging is to be not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).

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/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 and any Reseller(s), including name and address.
- Unique identification reference for the EHC type.
- Brand name of the EHC.
- Full specifications of the EHC being offered, covering all the requirements set out in this document, including details of EHC marking and traceability.
- Full details of the compatible appliance(s) and certification of appliance conformance with specification **E003/FZ03** or **E003/RF05**.

- Full details of the compatible **Type 2** solar power system and certification of conformance with specification **E003/PV01**.
- A comprehensive set of photographs including a three quarter view of the EHC. Additional photographs showing all external surfaces of the EHC, the interior, defined loads, connection points/cables and any special features.
- Certified photocopies of all type-approvals obtained for the EHC and/or its components, including CE marking and the like.
- Certified photocopies of the Legal Manufacturer/Reseller's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the Legal Manufacturer/Reseller'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.
- Laboratory test report(s) proving conformity with the equipment specifications.
- Indicative cost of the EHC per unit, per 10 units and per 100 units, EXW (Incoterms 2010) including appliance and solar power system.

8. On-site maintenance

Maintenance will be carried out by the end-user and/or their agents.

9. Change notification

The Legal Manufacturer/Reseller is to advise WHO in writing of any changes which affect the performance of the EHC after PQS pre-qualification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol E007/EHC01-VP.1 will result in a request for the EHC to be retested.

10. Defect reporting

The Legal Manufacturer/Reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related EHC 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.

Revision history:						
Date	Change summary	Reason for change	Approved			
05/02/2017	Scope changed to include field testing of each EHC and SDD.	Future EHC and/or SDD changes may require field evaluation.				
05/02/2017	New wording added as the first sentence 4.5 Appliance operation.	To prevent solar power from accidentally or intentionally bypassing the SDD appliance and powering the secondary load.				
05/02/2017	Replace term "accessory" with "EHC" throughout the document.	It is more accurate to describe as EHC.				