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PQS performance specification

TITLE: Solar Direct Drive Basic Energy Harvest Control devices

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Contents

1. Need and scope

At health facilities with limited or no electrical service there is increasing demand for solar generated electricity for solar direct drive (SDD) vaccine refrigeration and water-pack freezing as well as power for remote temperature monitoring devices. SDD solar power arrays are oversized to assure that safe vaccine storage conditions are sustained and are therefore a potential source of harvestable solar electricity for other unmet immunization and facility needs. Next generation SDD appliances coupled with an optional accessory energy harvest control (EHC) can safely supply some of these power needs while assuring the priority need to keep vaccine within the acceptable temperature range.

A Basic EHC is an accessory control device and/or system to enable the use of harvestable solar electricity for powering remote temperature monitoring devices (RTMD) in addition to an immunization appliance. Three categories of energy harvesting strategies have been identified: Basic, Kit and Custom.

A Basic EHC is the simplest energy harvest strategy, is integrated into the SDD appliance and is limited to 5 V dc and a maximum of 1 amp (i.e.; 5 watts) or less if further limited by the legal manufacturer. The single output is on a USB-A port with protections against electrical overload, short circuit, reverse polarity, high voltage input and damage from high temperatures. Some EHC that include a USB, all Kit EHC and all Custom EHC are more complex, may be standalone from the appliance, are not limited in voltage output(s) and can provide any amount of watt hour per day. A Kit EHC and a Custom EHC must comply with **WHO/PQS/E007/EHC01** specifications and testing per **WHO/PQS/E007/EHC01-VP.1**. The requirements of a Basic EHC as defined in this specification do not apply or modify the testing of any EHC being prequalified per **WHO/PQS/E007/EHC01-VP.1** including those that include only a USB-A output with power output that is not limited per this specification.

The scope of this performance specification is to specify requirements for a Basic EHC that assures the SDD appliance will operate correctly and provide limited solar generated electricity for secondary 5 V dc electric consuming devices (loads) such as remote temperature monitoring devices (RTMD) that comply with **WHO/PQS/E006/TR03** as well as common cell phone recharging. This is generally done with a power management circuit that must simultaneously satisfy: a high voltage input, high efficiency, and high reliability.

A Basic EHC is an optional accessory for SDD appliances prequalified per **WHO/PQS/E003/FZ03** or **E003/RF05**. Specific Basic EHC testing is described in **WHO/PQS/E007/EHC02-VP.1**. Laboratory testing is to be conducted on the Basic EHC when coupled with a specific SDD appliance(s) to assure:

- the Basic EHC does not have an adverse impact on appliance operation;
- if the Basic EHC fails the appliance cooling circuit will remain fully functional;
- if the load is improperly connected to the Basic EHC the appliance is undamaged; and
- harvestable solar electricity of no more than 60 Wh/day can be made available for other uses.

To become prequalified the Basic EHC requires laboratory testing with two full verification protocols:

1. Regular SDD appliance testing modified to include a fixed dc load set to 5 V dc and limited to 5-watt continuously connected throughout all SDD appliance tests: and then assuming the SDD passes all tests
2. Basic EHC testing to assure it operates correctly and has required fail safe features.

The Basic EHC will be required to be tested with at least one compatible SDD appliance where the Basic EHC option will be offered. A specific SDD appliance with a Basic EHC will be tested per the applicable WHO/PQS/E003 appliance verification protocol modified to include a load defined by the legal manufacturer and not to exceed 5 watt (5 Vdc, 1 amp) that will remain continually connected to the appliance through all testing. The Basic EHC will also be required to be tested for fail safe operation and to assure it operates correctly per **WHO/PQS/E007/EHC 02 VP.1**. If multiple different model SDD appliances use the identical Basic EHC, identical cooling system, identical control system and identical solar power system then a single set of tests can be accepted to prequalify multiple SDD appliance models with the identical Basic EHC. Loads are not specified herein, not tested and not prequalified.

Field testing is required of at least one Basic EHC coupled with a prequalifiedE003 SDD appliance. The PQS Secretariat is to pre-approve all field study plans in advance. Any SDD that has also been prequalified with a Basic EHC prior to the publication date of this specification will not be required to undergo further PQS prequalification testing.

Basic EHC design must account for performance degradation over the 10-year target life of the appliance in order to sustain operation and features including USB-A port connection/disconnection durability.

The build quality of the Basic EHC must be consistent with the conditions under which these SDD 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.

EIA-364-09, Revision D, January 17, 2018 - TP-09D Durability Test Procedure for Electrical Connectors and Contacts
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: 2020 *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 3.0: 2016: *Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.*
IEC 61000-6-3 edition 3.0: 2020: *Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.*
IEC 62552: Parts 1, 2 & 3: *Household refrigerating appliances – Characteristics and test methods.*
ISO 9001: *Quality Management Systems – Requirements*.
ISO 14001: 2015: *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: 2017 *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/E006/TR03.2*:Programmable remote temperature and event monitoring systems*
WHO/PQS/E007/EHC02-VP.1: *Independent type testing protocol: Solar direct drive Basic energy harvest control and strategy.*

3. Terms and definitions

Adverse impact: any cause preventing the appliance from continually sustaining acceptable vaccine storage temperatures and/or water pack freezing performance as defined by applicable PQS appliance performance specification(s).
Appliance: Any solar direct drive (SDD) vaccine refrigerator, water-pack freezer or combined vaccine refrigerator and water-pack freezer.
Basic EHC: an energy harvest control strategy where electrical energy is delivered via one USB A port integrated in a solar direct drive appliance and limited to 5 watt (5 V dc, and 1 amp total) for up to a total of 60 Wh/day.

Custom EHC: an energy harvest strategy where electrical energy is delivered via one or more outputs that may be adjusted or modified to provide differing voltages without specific limitations to watt-hour per day capacity.
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.
Fixed dc load: A laboratory test device to simulate the connection of a continuous direct current load (e.g.; 5 V dc, 5 watt load or less if specified by legal manufacturer).
Harvestable solar electricity: Direct current electricity generated by the solar direct drive appliance solar power system.
In writing: Communication by letter, fax or email.
Kit EHC: An energy harvest strategy where electrical energy is delivered via one or more outputs that are within a pre-packaged kit. Kit EHC may provide multiple voltage outputs through integrated circuits without specific limitations to watt-hour per day capacity. Kit EHC may also provide defined loads (e.g.; lights).
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.
Operate(s) correctly: The component or components being referred to function as normally expected.
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.
Remote temperature monitoring device (RTMD): electrically powered cold chain temperature measuring equipment that uses some means of communication (mobile network, GPRS, UHS, satellite, etc.) to periodically transmit data to the cloud.
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.
SDD: Solar direct drive as defined in **WHO/PQS/E003/RF05** or **WHO/PQS/E003/FZ03**.
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 V dc receptacles as used in vehicles and 120/230 V ac receptacles as used in buildings and electrical generators.
USB-A port: A 5 V dc connection complying with USB.org power specifications specific to USB-A.

4. Requirements

4.1 Operate correctly

In all operational modes the Basic EHC will not cause an adverse impact on appliance ability to sustain WHO PQS prescribed acceptable vaccine storage temperature, water pack freezing requirements or both if appliance is a combined vaccine refrigerator and water packs freezer. During periods of adequate solar radiation, the Basic EHC will make available a load defined by the legal manufacturer not to exceed 5 watt continuously.

4.2 Fail safe operation

The Basic 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 Basic EHC must include a simple and automatic means (requiring no user intervention) to be disconnected or bypassed completely to allow the appliance to continue to operate correctly in the event of Basic EHC failure. Hot swap repair options may be offered by legal manufacturers. The Basic EHC must survive common control fault conditions. Such conditions are as follows but are not limited to: connection errors including reversed load polarity, load voltage mismatch and wiring connections in any sequence possible, high temperature operation, power input over-current conditions and short circuit at the appliance, within the Basic EHC, at load and solar power system. In the event of Basic 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 Basic EHC must manage harvestable solar electricity that can be converted, limited, controlled, diverted to and consumed by other loads.

A Basic EHC and appliance will be tested only with a laboratory supplied fixed direct current (dc) load designed to test the limits of the system.
The energy harvest (in watt-□□□□□hour/average day) must not exceed 60 Wh/day and the energy harvest efficiency must be greater than 80% and will be measured and reported.

4.4 Compatibility and compliance with relevant references

All Basic EHC must be compatible with at least one WHO PQS prequalified SDD appliance and the appliance's required **Type 2** solar power system per WHO/PQS/**E003/PV01**.

4.5 Appliance operation

Appliance/Basic EHC power on/off switch to simultaneously switch off power to both appliance and Basic EHC.

Manufacturer to certify that Basic 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 load battery from powering the appliance under any operating condition.

4.6 Appliance compatibility

All Basic EHC must be integrated in the SDD appliance cabinet and must be compatible with at least one WHO PQS prequalified SDD appliance. The location of the USB-A port cannot interfere with regular appliance operations or routine appliance maintenance and must be accessible without requiring the removal of any appliance parts. See labelling requirement in clause 4.16.

4.7 Solar power system compatibility

All the specific solar power system(s) required by the specific appliance(s) the Basic EHC is prequalified with. All Basic EHC are operated on direct current (dc) electricity generated by the solar power system. The Basic EHC cannot result in a solar power system larger than that required by the SDD appliance alone.

4.8 Load compatibility

Basic EHC are limited to 5 V dc loads through one USB A port where the total daily output is limited to 60 Wh/day. It must be clearly labelled that the USB-A port is 5 Vdc and primarily intended for RTMD power.

Legal manufacturer to certify that the USB-A connector shall be of the ruggedized version rated to 10,000 cycles as certified by EIA-364-09. Legal manufacturer/reseller are to clearly note any incompatible load types.

4.9 Available energy harvest and energy efficiency

The USB-A port output must not exceed 60 Wh/day. Manufacturer to state the minimum average daily watt hour (Wh/average day) of energy available to user based on the measured results from **WHO/PQS/E003** SDD appliance day/night test at the minimum solar radiation reference period of 3.5 kWh/m^2 day and provide clear examples for users (e.g., X quantity of Y device in operation for Z hour per day). Results will be published for the total available Wh/average day as measured in the Day/night appliance testing.

4.10 Electrical safety rating

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 Basic EHC and its constituent components must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.13 Maintenance and servicing provision

The Basic EHC is to be designed to achieve a no-maintenance life of not less than 10 years. If necessary, any preventive maintenance required by the Basic EHC and load(s) cannot create an adverse impact on the appliance causing it to not operate correctly.

4.14 Essential spare parts

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

Legal manufacturer/resellers are to publish a list of spare parts recommended for purchases of 10 and 50 SDD appliances with a Basic EHC. 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 Sub-national level in the purchasing country, as agreed with the purchasing agency.

4.15 Disposal and recycling

The legal manufacturer/reseller is to provide information to the buyer on the hazardous materials contained within the Basic EHC with suggestions for resource recovery/recycling and/or environmentally safe disposal. For legal manufacturer/resellers from the European Union must certify WEEE compliance in accordance with European Union Directive **2002/96/EC** is mandatory.

4.16 Instructions and labelling

Each SDD with an integrated, Basic EHC shall include a separate section dedicated to the Basic EHC use and operations in the applicable manuals and documentation. These sections shall be found in the user manual and technician installation manual and be provided 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 shall include the following information specific to the Basic EHC:

- Health and safety guidance as applicable;
- Basic operations description;
- Correct handling to avoid damage;
- Loads that are compatible and are 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 hour per day); and
- End-of-life resource recovery and recycling procedures for separate Basic EHC componentry.

The technician installation manual shall include the following information:

- Health and safety guidance as applicable;
- Detailed operations description;
- Correct handling to avoid damage;
- Loads that are compatible and are not compatible;
- 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 X device in operation for X hours per day).
- Corrective maintenance tasks;
- Diagnostic and repair procedures;
- Itemized list of spare parts including part numbers;
- End-of-life resource recovery and recycling procedures for separate Basic EHC componentry; and
- 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 appliance 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.

The USB-A port is to be labelled “5 V dc” and the appropriate value for “ X watts” as determined by the legal manufacturer and not to exceed 5 watts.

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 accessory.

The USB A port must be labelled to assure correct connection to load.

4.17 Training

If requested, legal manufacturer/reseller is 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 manufacturer's representative. Legal manufacturer/reseller to 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

Basic EHC should be simple to understand, simple to use and require minimal or no maintenance. The Basic EHC should be repairable on-site or replaceable on-site.

4.19 Warranty

Basic 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°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

The design of the enclosure should ensure that the Basic EHC is not damaged by dust penetration or splashing water.

4.23 Verification

In accordance with PQS Verification Protocol **WHO/PQS/E007/EHC02-VP.1.**

5. Packaging

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

6. On-site installation

Basic EHC to be factory integrated in the appliance. On-site installation not required.

7. Product dossier

The legal manufacturer/Reseller is to provide WHO with a prequalification 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 Basic EHC type.
- Brand name of the Basic EHC.
- Full specifications of the Basic EHC being offered, covering all the requirements set out in this document, including details of Basic EHC marking and traceability.
- Full details of the compatible appliance(s) and certification of appliance conformance with specification **WHO/PQS/E003/FZ03** or **E003/RF05**.
- Full details of the compatible **Type 2** solar power system and certification of conformance with specification **WHO/PQS/E003/PV01**.
- A comprehensive set of photographs including a three-quarter view of the Basic EHC. Take additional photographs showing all surfaces of the Basic EHC, the interior, USB-A port connection points/cables and any special features.
- Certified photocopies of all type-approvals obtained for the Basic 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 prequalified SDD appliance including solar power system and optional Basic EHC (cost per unit, per 10 units and per 100 units, EXW Incoterms 2010).

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 adversely affect the performance of the Basic EHC after PQS prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **WHO/PQS/E007/EHC02-VP.1** will result in a request for the accessory to be retested.

10. Defect reporting

The legal manufacturer/reseller is to advise WHO and the UN purchasing agencies in writing within 30 days after the event of safety related Basic 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