PQS performance specification

WHO/PQS/E004/VC01.2
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Distribution: General

TITLE: Vaccine carrier

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Product verification protocol:	E004/VC01-VP.2
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Contents:

1. Scope:

This specification defines the requirements for thermally insulated vaccine carriers. Vaccine carriers are used to transport vaccines from health facilities with refrigeration to outreach sessions where refrigeration and ice is unavailable. They are typically carried by a single health worker travelling on foot or by other means, where the combined journey time and immunization activity lasts from a few hours to a whole day. Two types of vaccine carrier are described:

- **Short range:** With a minimum cold life of 15 hours.
- **Long range:** With a minimum cold life of 30 hours.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*
ISO 9001: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*
ISO 20282-1: 2006: *Ease of operation of everyday products - Part 1: Context of use and user characteristics.*

3. Terms and definitions:

Cold life: The empty container is stabilized at +43°C and loaded with ice-packs. Cold life is measured from the moment when the container lid is closed until the temperature of the warmest point in the vaccine storage compartment first reaches +10°C, at a constant ambient temperature of +43°C.
Cool life: The empty container is stabilized at +43°C and loaded with cool-packs which have been stabilized at + 5°C for a minimum of 24 hours. Cool life is measured from the moment when the container is closed, until the temperature of the warmest point inside the vaccine storage compartment first reaches +20°C, at a constant ambient temperature of +43°C.

Cool-pack: A water-pack pre-cooled to a temperature between + 2°C to +8°C before use.
Ice-pack: A water-pack frozen to a temperature between -5°C and -20°C before use. Ice-packs are used for the transport of oral polio vaccine (OPV) or stool specimens.
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 his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Phase change material (PCM): A material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.
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.
Vaccine storage capacity: The total volume of the vaccine storage compartment, in litres. The measurement is equal to the volume of the largest rectilinear object that can be inserted into the compartment with all the manufacturer's specified packs in place.
Vaccine storage compartment: The zone within an insulated container which is designated by the manufacturer as suitable for storing vaccine when the container is loaded with the full number of ice-packs required to achieve the cold life specified in this document.
Warm life: The empty container is stabilized at +18°C and loaded with warm-packs which have been stabilized at the same temperature for a minimum of 24 hours. Warm life is measured from the moment when the container is closed, until the temperature of the coldest point inside the vaccine storage compartment first reaches 0°C at a constant ambient temperature of -20°C.
Warm-pack: A water-pack typically stabilized at room temperature, up to a recommended maximum of +24°C. Warm-packs are used for the transport of freeze sensitive vaccines in countries where sub-zero temperatures are common.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying with specification **PQS/E005/IP01**.

4. Requirements:

4.1 *General:*

Short range or long range insulated vaccine carrier, with insulated lid, designed for transporting vaccines. Both rigid non-rigid and semi-rigid designs are acceptable.

4.2 *Performance:*

4.2.1 Vaccine storage capacity:

- **Short range:** 0.5 to 5.0 litres.
- **Long range:** 1.0 to 5.0 litres.

4.2.2 Cold life:

- **Short range:** minimum 15 hours.
- **Long range:** minimum 30 hours.

4.2.3 Cool life:

No standard set; however performance data will be published.

4.2.4 Warm life:

No standard set; however performance data will be published.

4.2.5 Shape:

Vaccine carriers should be substantially square or rectangular in plan and section. Rounded corners are preferred.

4.2.6 Design principles:

The design of the container, including the placement of the packs and of the load, must promote the free circulation of air within the container to ensure minimum temperature stratification. Container design should seek to minimize the weight of ice-packs required to meet the cold life requirement. Non-rigid and semi-rigid designs are acceptable provided they meet the required criteria for robustness.

4.2.7 Lid:

Vaccine carriers must be fitted with an insulated lid which fits securely to the body of the container when closed so as to minimize cold bridging and maximize structural strength. Hinged lids are acceptable, but are not mandatory.

4.2.8 Hinges:

Hinges, where fitted, must allow the lid to open beyond 90° to give full access to the interior of the vaccine carrier. Preferably the hinges must be recessed so that they are fully protected against damage during transport and storage. Hinges must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.9 Closure device:

The lid should be fitted with a mechanism to secure it in place so that the vaccine carrier does not open if it is dropped onto its side or onto its lid when full. Acceptable closure devices include, but are not confined to, magnetic or mechanical catches. It must not be possible for the catch to open accidentally once engaged. Mechanical catches must be recessed so that they are fully protected against damage during transport and storage. Catches must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.10 Carrying device:

The body of the container must be fitted with one or more of the following carrying devices arranged so that the vaccine carrier can be comfortably carried in a substantially upright position:

- **Carrying handle:** A hinged, sliding or moulded-in handle attached to, or forming an integral part of, the container body or lid. When folded away, moveable handles must not extend beyond the maximum length, width or

height of the container. The handle arrangement must not prevent stable stacking of the boxes.

- **Shoulder strap:** An adjustable strap arrangement which allows the vaccine carrier to be carried over the shoulder.
- **Backpack:** An adjustable padded strap arrangement which allows the vaccine carrier to be carried as a backpack.

All carrying devices must be robustly constructed and firmly attached in order to survive rough handling.

4.2.11 Vial holder (Optional):

The vial holders, if offered, must be located immediately below the lid and above the vaccine storage compartment. It should be designed to hold a maximum of five opened vaccine vials for use during immunization sessions when the lid of the vaccine carrier is open. The vial holder must fully close off the vaccine storage compartment so that there is minimal loss of cold life. Design solutions may include, but are not limited to, the following:

- Soft foam plastic pad, moulded to receive vaccine vials. The indentations must be designed so that vials are held from below and cannot be pushed through the pad.
- Moulded plastic tray with indentations to receive vials.
- Moulded plastic tray as previously described, but forming a separately hinged inner lid to the vaccine carrier.

The vial holder must be able to hold vials, with capacities ranging from one to fifty doses, in a stable position and without risk of overturning the vial.

4.2.12 Vaccine storage advice:

Vaccine carriers must carry factory-fitted non-removable labels designed to last the lifetime of the appliance. Labels should be in the UN language most appropriate to the country of use (Arabic, English, French, Mandarin Chinese, Russian or Spanish, or other language, by special order) and should carry the following information.

- **On the outside of the lid, and/or on the front face of the vaccine carrier:** As Annex 1.
- **On the inside of the lid:** As Annex 2

4.2.13 Stacking:

The design of the base and lid of rigid containers should include moulded features that allow multiple units of the same model to be stacked on top of one another in a safe and stable manner. The base of the container must be designed to withstand repeated dragging across hard rough floor surfaces.

4.2.14 Corrosion resistance:

All metallic components and their fixings must be constructed in stainless steel or a suitable non-ferrous metal.

4.2.15 Chemical resistance:

The external and internal surfaces of the container must be resistant to chemicals used for disinfecting (e.g. sodium hypochlorate, 5.25% in water).

4.2.16 IP rating:

Protection of the container with lid closed and latched not less than IEC 60529: IP55.

4.2.17 Robustness:

The container must withstand a one meter drop onto each face, edge, and corner at its rated fully-loaded weight. At the end of the test there must be no

damage that affects the performance of the product and the lid must still close and latch correctly.

4.3 *Environmental requirements:*

4.3.1 Ambient temperature range during transport, storage and use:
-30°C to +55°C.

4.4 *Physical characteristics:*

4.4.1 Overall dimensions:
In conformity with clause 4.5.1 to 4.5.3.

4.4.2 Weight:
The weight of the container must not exceed the following figures:

- **Short range:** Maximum loaded weight, inclusive of the recommended number of water filled packs: 7.0 kg.
- **Long range:** Maximum loaded weight, inclusive of the recommended number of water filled water-packs: 8.0 kg.

4.5 *Interface requirements:*

4.5.1 Dimensional compatibility with packs:
The internal dimensions of the container must be compatible with any of the three standard types of water-pack specified in **E005/IP01**. However, it is acceptable for the product to achieve its designated cold life at its designated vaccine storage capacity using only one of these three types.

4.5.2 Dimensional compatibility with vaccine packaging:
Vaccine carriers are generally used to transport vaccine in individual vials. The net dimensions of the storage compartment (length, breadth and height, with water-packs in place) should accommodate all types of pre-filled vaccine presentation and the complete range of standard vaccine vials and ampoules up to 50 dose size.

4.5.3 Dimensional compatibility with distribution vehicles:
Vaccine carriers must be designed so that they can easily be strapped, upright, to the luggage rack of a bicycle or light motorcycle.

4.6 *Human factors:*

4.6.1 Generally:
The product must be designed in accordance with the general usability principles laid out in ISO 20282-1: 2006.

4.6.2 Portability:
All vaccine carriers must be designed so that they can comfortably be carried, when fully loaded, for periods of several hours by a male or female health worker wearing traditional dress. Backpack units may be incompatible with some types of clothing.

4.7 *Materials:*

4.7.1 Casing material selection:
Internal and external casing materials and all joints between the moulded components must be water and vapour proof, must resist UV degradation, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Chlorinated plastics and composites containing epoxy resins are not permitted.

4.7.2 *Thermal insulation foaming agents:*
Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals. Cyclopentane and similar foaming agents with a low global warming potential (GWP) are preferred.

4.7.3 *PCM:*
Integrated thermal buffer materials may be used to prevent freezing temperatures from propagating to the vaccine storage compartment or for other thermal purposes. The buffer material may be PCM-based but if so, must comply with WHO/PQS/ E005/PCMC0.1– PCM specification for phase-change material containers.

4.8 *Warranty:*
The product is to be covered by a two year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. The manufacturer should state the time period over which the rated cold life is assured.

4.9 *Servicing provision:*
The product is to be designed to achieve a maintenance-free life of not less than 5 years, apart from routine cleaning.

4.10 *Disposal and recycling:*
The manufacturer is to provide information to the buyer on any hazardous materials contained within the product and suggestions for resource recovery/recycling and/or environmentally safe disposal.

4.11 *Instructions:*
User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The instructions need not repeat the information shown on the permanent labels, but must include guidance on how to repair minor damage.

4.12 *Training:*
No requirement. Training on prevention of vaccine freeze damage and correct use of ice-packs, cool-packs and warm-packs is the responsibility of the purchaser.

4.13 *Verification:*
In accordance with PQS Verification Protocol **E004/VC01-VP.2.**

5. Packaging:
Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol. The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. In-coming inspection:
A random visual inspection of each batch of vaccine carriers will be conducted by purchasing agencies. This inspection will generally be based upon

E004/VC01-VP.2 clause 5.3.1 (Test 1: Type examination), but may include other tests.

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.
- A set of digital photographs showing a three-quarter view of the unit with the lid closed, and three-quarter view with the lid fully opened and a top view of the interior with the full compliment of water-packs in place.
- Certified photocopies of all type-approvals obtained for the product.
- Certified photocopies of the legal manufacturer's current ISO 9001 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.
- Indicative cost of the product per unit, per 10 units and per 100 units, including water-packs, EXW (Incoterms 2000).

8. On-site maintenance:

The product is to be designed to be maintenance-free apart from repair of minor impact damage caused by dropping and the like.

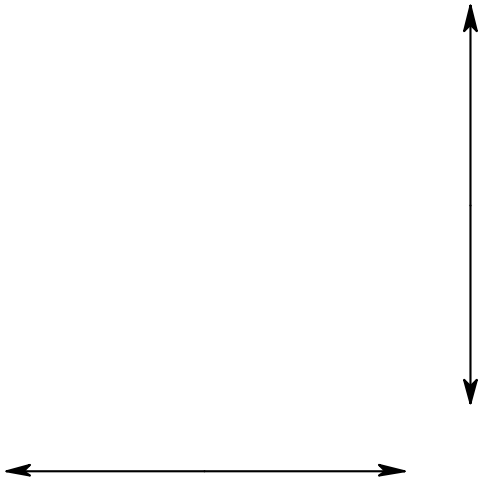
9. Change notification:

The legal manufacturer or reseller must advise WHO in writing of any changes in form, fit or function which may affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

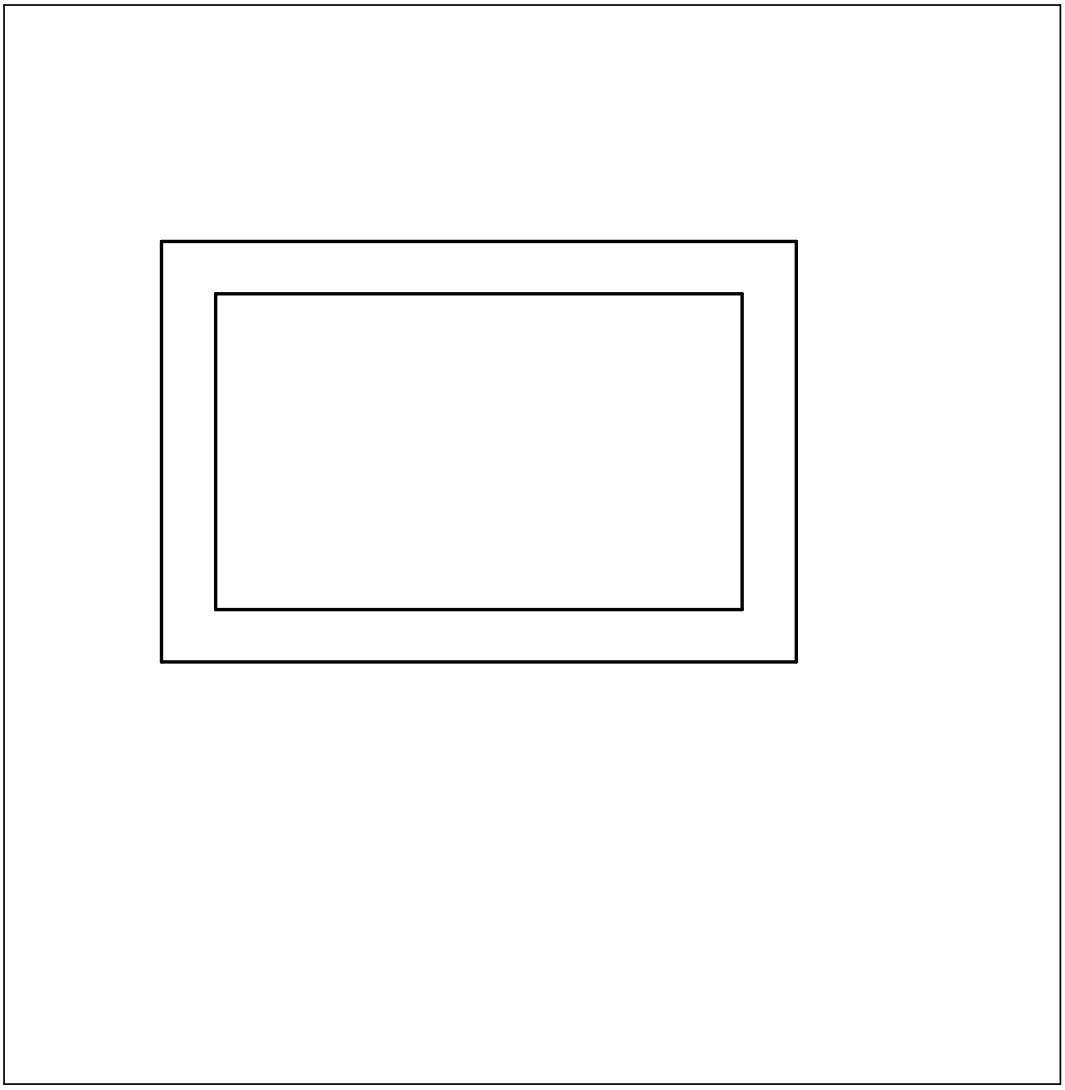
The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – Label on outside of the lid, and/or front face of vaccine carrier



Notes:
1. Language: As required – see clause 4.11.

Annex 2 – Label on inside of lid



Notes:

2. The layout of the label must suit the shape of lid in order to ensure maximum legibility.
3. Language: As required – see clause 4.11.
4. Optionally, the manufacturer's name, model number and date of manufacture/serial number may be permanently fixed elsewhere on the container instead of inside the lid.

Revision history:			
Date	Change summary	Reason for change	Approved
23.04.2008	4.2.6: Minimization of icepack weight added. 4.2.12: Stacking and handling amendment.	Version for final approval	UK
04.09.2008	Minor editions for consistency of terminology used	Comments received from Steering Committee	UK
03.11.2008	4.2.10: Handle specification amended. 4.7.3: omitted. 7: 'including CE marking and the like' omitted. Annex 2: Note 3 added.	Manufacturer's further review comments	UK
08.12.2008	4.2.15 IP rating has changed to IEC 60529: IP55	Manufacturer's further review comments	UK
21.05.2010	'Packs' changed to 'water-packs'. 2: Normative references updated. 3. Vaccine storage capacity and Vaccine storage compartment definitions changed. 4.1: Non-rigid and semi-rigid options added. 4.2.6: Non-rigid and semi-rigid options added. 4.2.11: Vial holder added 4.3.2: Clause omitted. 4.7.1: Requirement added 6. Incoming inspection added. 7. ISO 9001 wording amended. Annex 1: Minor change to label wording.	Policy decision. Comments received. Response to new product types. Response to new product types. Comments received. Comments received. Comments received. Comments received. Comments received.	DM
27/08/2018	Clause 3 (Terms and definitions) edited to amend and remove some PCM-related terms and definitions	Reflect changes to allowable use of PCM materials/packs as described the new draft PCM specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*
27/08/2018	Clause 4.7.3 (Materials) added: definition of PCM	Reflect change to allowance of water-based and PCM-based buffers and added reference to new PCM draft specification	*Revised by: Steve DeSandis* *Approved by: Isaac Gobina*