Vaccine Carrier - PQS performance specification

PQS performance specification

TITLE: VACCINE CARRIER

Specification reference: <PQS category>/<unique reference>

Product verification protocol: <PQS category>/<unique reference>

Date of origin: <17.12.04>

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- Contents: <list the specification content down to level 1.1.1>

1. Scope: <briefly describe the intent of the specification>
   This document describes the performance specification to be complied with by a portable container called VACCINE CARRIER that is to be used for the transport of vaccines by an individual from one point to another, and to maintain the vaccine temperature with acceptable limits during the transport and immunisation activity typically from a few hours to whole day.

2. Normative references: <list ISO/IEC and other standards that apply to the specification and list any relevant WHO product verification protocols; cross-refer to any other relevant performance specifications>
   Previous equipment performance specifications: E4/VC.0, E4/VC.1 & E4/VC.2
   No associated ISO or international standard has been found.

3. Terms and definitions: <define any specific terms used in the specification, particularly terms which may not be widely understood>
   Green highlight: suggested values based on recommendations received from expert advice.
   To add relevant parts from Terms and Definitions after adaptation when finalised.

4. Requirements

4.1 General: <state what is generally required of the product, but not how this is to be achieved; briefly describe the context in which the product is to be used>
   The device should be a thermally insulated portable container with an internal vaccine storage volume between 0.5 L and 3 L for the short range type and between 1L and 3 L for the long range type, excluding space required by the recommended number of water packs of standard approved type.
   The device must safely maintain the vaccines within the recommended temperature limits (+2°C to +8°C), using the recommended number of IP/CP and for the period it is designed for.

4.2 Performance: <set out the specific performance characteristics required, including limits on energy consumption, where relevant>
The internal thermal insulation should have sufficiently low thermal conductivity to assure the required cold life of at least 12 hours for short range type and 24 hours for long range type of vaccine carriers.

Cool life: No specification set but measured results to be reported in PQS database.

Warm life: No specification set but measured results to be reported in PQS database.

4.3 Environmental requirements: <quantitatively define the operating environment in respect of temperature range, humidity, shock, vibration, etc.>

The device should withstand storage and usage at external ambient temperatures between -10°C and 45°C.
The device should be robust enough to withstand shocks caused by accidental drops or knocks and should not be damaged by vibrations of the type caused by road transport. The device should have an external lid that can be safely closed and remain closed during accidental drops and knocks.

4.4 Physical characteristics: <set out critical physical characteristics such as limits on weight, size, etc., but only to the extent that these data are essential to satisfy human factors and/or interface requirements>

Depending of the type of vaccine carrier, the following conditions should be met:

<table>
<thead>
<tr>
<th>Type</th>
<th>Vaccine storage capacity (L)</th>
<th>Minimum cold life (hours)</th>
<th>Max. Loaded weight (kg)</th>
<th>Maximum Weight when empty (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short range</td>
<td>0.5 to 3 litres</td>
<td>12 hours</td>
<td>2.5 kg</td>
<td>2 kg.</td>
</tr>
<tr>
<td>Long range</td>
<td>1 to 5 litres</td>
<td>24 hours</td>
<td>7 kg</td>
<td>4 kg.</td>
</tr>
</tbody>
</table>

4.5 Interface requirements: <describe form and fit requirements to the extent that these impact on other related products; for example, size of icepacks to suit a specific range of cold boxes>

The internal dimensions of the device should be sufficient to accommodate the largest tolerance of the WHO approved standard IP/CP (PQS #XYZ) and accommodate the number of IP/CP as recommended by the manufacturer.
The device should have an internal foam lid to position opened vaccine vials with the external lid removed during an immunization session.

4.6 Human factors: <describe ergonomic requirements, including percentile of users; ‘Universal Design’ principles; health and safety issues, etc.>

For convenience of transport the device should have a handle for holding and/or strap to hang across the shoulder.
The design should permit easy stacking of the device in a stable condition.

4.7 Materials: <specify materials that are to be used or excluded only to the extent that this is absolutely necessary; for example to ensure adequate corrosion or wear resistance, to minimize toxicity, or to comply with international agreements (e.g. the Montreal Protocol)>

The thermal insulation should be produced using chemicals that do not belong to the family of CFC (chemicals specified in annexures A & B of the Montreal Protocol) which are ozone depleting, and should preferably have minimum global warming potential.
4.8  **Reliability:** <define reliability requirements in quantitative terms and define the conditions under which these requirements must be met>

**Robustness:**
The device shall withstand a one meter drop on every face, edge, and corner. As a result the maximum acceptable damage to the casing should be easily repairable (rating 2) and the hinges and catches get undone in the worst case (rating 2).

**Cold Life:** Min cold life of 12 hours for short range and 24 hours for long range type of vaccine carriers, without opening.

**Cool life:** using chilled water packs should be reported but no specification.

**Warm life:** No specifications, to report only

4.9  **Maintainability:** <define maintainability issues in as quantitative manner as possible; for example, mean time between maintenance, level of maintenance skill needed, etc.>

To check regularly that the lid closes properly on the carrier. The carrying strap and the internal foam lid, if provided, are not damaged.

4.10  **Disposal and recycling:** <state specific requirements relating to end-of-life disposal, including any requirements for recycling of materials or components>

The Manufacturer should state life span over which the measured / claimed cold life performance is assured, and how to dispose off device at end of life without polluting the environment.

4.11  **Instructions:** <if user and/or maintenance instructions are required, state in which languages they are to be supplied>

The device should have graphics on the exterior to inform the user about contents and the safe temperature range within which it should be maintained. Specific messages should include:
1) Device’s minimum cold life and cool life in hours
2) Date of manufacture
3) CFC free technology

In addition, specific additional instruction should be provided in form of laminated sheet affixed on one of the exterior sides. This should include the following information in the 6 UN languages: Arabic, Chinese, English, French, Russian and Spanish.
1) Frozen IP should be used only for OPV
2) Freezing harms some vaccines (list names)
3) Loading pattern of ice/cool packs and vaccines

4.12  **Training:** <if user training is required, state who is to be trained and for what purpose>

Training on means of prevention of freeze damage to vaccine and proper use of cool packs to cold store personnel responsible of handling the vaccines and cold boxes.

4.13  **Verification:** <state how product performance is to be verified, by citing the relevant type-testing, type-examination or full quality-assurance protocol>

Type Examination Protocol: #

5.  **Packaging:** <state any specific requirements for packaging>
6. **On-site installation**: <where a product requires on-site installation (e.g., a standby generator) clearly define who is to be responsible for each stage in the process, such as:

- designing the installation;
- identifying a suitable space or building to house the installation;
- inspecting and approving the space or building;
- making necessary physical changes to prepare for the installation;
- inspecting and approving the changes;
- carrying out the installation;
- testing and commissioning the installation.>

7. **Product dossier**: <state what supporting information and/or samples the manufacturer (legal manufacturer or re-seller) or approved installer is to provide when submitting a product for pre-qualification, including details of quality systems (QA) in place>

The dossier submitted by the manufacturer should contain the following:

1. Sample of the device with the required standard IP/CP
2. Manufacturer’s data on the following:
   - a. External and internal measurements
   - b. Vaccine storage capacity and IP/CP load
   - c. Weight Empty
   - d. Weight when fully loaded
3. Manufacturer’s test results for the following:
   - a. Cold life, cool life, and warm life
   - b. Ice melting rate
   - c. Results of drop test
3. Manufacturer’s own QA standard and procedures

8. **On-site maintenance**: <if on-site maintenance is required state the desired performance criteria with regard to response rate and the like>

9. **Change notification**: <state how the manufacturer or approved installer is to report future changes in product specification, manufacturing location and manufacturing methods to WHO/UNICEF and define the conditions under which re-testing may be required>

Manufacturers should keep WHO informed of any change in the design of the box that affect the compliance with the specification and/or is likely to alter performance.

10. **Defect reporting**: <state how the manufacturer or approved installer is to notify purchasers, end-users and WHO/UNICEF in the event of safety-related product recalls, component defects and other similar events>

WHO PQS secretariat should be informed of such event as soon as they are identified - in writing by mail or email.

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1 This section may have to take the form of a guideline to the ‘client’ who draws up a site-specific specification. See for example WHO/V&B 02.33. *Equipment performance specifications and test procedures. E1: Cold rooms and freezer rooms.*

2 This process includes establishing the required ‘capacity’ of the installation: for example the kVA rating of a generator, the internal volume of a cold room, etc. In some cases this may entirely be the responsibility of the installer. In other instances, responsibility may be split between ‘client’ and installer.