



TITLE: Vaccine cold box

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1. Scope:

This specification defines the requirements for thermally insulated cold boxes. These are typically used to maintain the cold chain when vaccines are transported in bulk from one fixed vaccine store to another. Two types of cold box are described:

- **Short range:** With a minimum cold life of 48 hours.
- **Long range:** With a minimum cold life of 96 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: 2000: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO/IEC 17025: 2000: *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 frozen 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 **pack** pre-cooled to a temperature between + 2°C to +8°C before use.

Ice-pack: A **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.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

Pack: As in **ice-pack**, **cool-pack** or **warm-pack**. A flat, leak proof, plastic container, filled with tap water, complying with specification **PQS/E05/IP01**.

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.

Secondary packaging: A carton which contains a number of individual vaccine vials or vial pairs. Most countries store and distribute vaccines in these cartons.

Vaccine storage capacity: The **vaccine storage compartment** is loaded with boxes measuring 100x100x100 mm or 100x100x50 mm, packed so that there is minimal air space between each column of packets or between the packets and the ice-pack lining. The total volume of the boxes, in litres, represents the net volume available for the storage of vaccines.

Vaccine storage compartment: The zone within an insulated container which can be used for storing vaccine when the container is loaded with the full number of **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 **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.

4. Requirements:

4.1 *General:*

Short range or long range insulated cold box, with hinged and insulated lid, designed for transporting vaccines.

4.2 *Performance:*

4.2.1 *Vaccine storage capacity:*

- **Short range:** 5.0 to 25.0 litres.
- **Long range:** 5.0 to 25.0 litres.

4.2.2 *Cold life:*

- **Short range:** minimum 48 hours.
- **Long range:** minimum 96 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:*

Containers must be substantially square or rectangular in plan and section. Rounded corners are permitted.

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.

4.2.7 *Lid seal:*

The lid of the container must be fitted with a captive labyrinth seal which engages with the container walls when the lid is closed so as to minimize cold bridging and maximize structural strength.

4.2.8 *Hinges:*

The lid of the container must be fitted with a robustly constructed hinge mechanism. The lid must open beyond 90° to give full access to the interior of the cold box. 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 *Lid stay:*

The container must be fitted with a stay device designed to prevent damage caused by over-stressing the lid when open. The stay device must be designed to prevent it becoming trapped between the lid seal and the body of the container when the lid is closed **and it must be secured to the container in a manner which prevents loosening due to vibration.**

4.2.10 *Catches:*

The lid of the container must be secured in the closed position by a catch or catches and it must not be possible for a catch to open accidentally once engaged. 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.

4.2.11 *Carrying handles:*

The body of the container must be fitted with at least two hinged handles designed so that they can be used to lift and carry the container comfortably when it is fully loaded. The hinge mechanism must restrain the handle in a near-horizontal position when the container is lifted and the handles must automatically drop back into the vertical position when they are released. Preferably the handles should be recessed so that they are fully protected against damage during transport and storage. Handles must be maintenance-free, without need for lubrication and must be secured to the container in a manner which prevents loosening due to vibration.

4.2.12 *Vaccine storage advice:*

Cold boxes 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 cold box:** As Annex 1.
- **On the inside of the lid:** As Annex 2.

4.2.13 *Stacking:*

The design of the container should allow multiple units of the same model to be stacked on top of one another in a safe and stable manner.

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: IP56.

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.

4.3.2 *Ambient humidity range during transport, storage and use:*

5% to 95% RH.

4.4 Physical characteristics:

4.4.1 Overall dimensions:

In conformity with clauses 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 empty weight: 12.5 kg. Maximum loaded weight, inclusive of the recommended number of water filled packs: 35.0 kg
- **Long range:** Maximum empty weight: 25.0 kg. Maximum loaded weight, inclusive of the recommended number of water filled packs 50.0 kg.

4.5 Interface requirements:

4.5.1 Dimensional compatibility with ice-packs:

The internal dimensions of the container must be compatible with any of the three standard types of pack specified in **E05/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:

Cold boxes are generally used to transport vaccine in secondary packaging. The net dimensions of the storage compartment (length, breadth and height, with packs in place) should accommodate the widest possible range of standard immunization vaccines in this form of packaging, with the vials arranged upright in the container¹.

4.5.3 Dimensional compatibility with transport mode:

Short range cold boxes must be designed so that they can safely be carried upright inside cars, light vans or 4WD vehicles, strapped to the luggage rack of a small motorcycle or moped or carried by a single porter or a pack animal.

Long range cold boxes must be designed so that they can safely be carried upright inside cars, light vans, 4WD vehicles or boats, or carried by two porters or a pack animal.

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.

¹ Definitive guidance on secondary packaging is not available and there are no fixed standards. However, a survey of a sample of 20 vaccines from 16 manufacturers in 74 presentations gives the following statistics:

	Length	Width	Height
Maximum:	25.3 cm	16.4 cm	14.5 cm
Minimum:	6.1 cm	2.9 cm	1.7 cm
95 th percentile:	19.5 cm	14.8 cm	11.0 cm

4.7 Materials:

4.7.1 Casing material selection:

Internal and external casing materials 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 Other restricted materials:

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

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 must 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 **E04/CB01-VP**.

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 cold boxes will be conducted by purchasing agencies. This inspection will be based upon **E04/CB01-VP** clause 5.3.1 (Test 1: Type examination).

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 **packs** in place.
- 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 2000 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 **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.

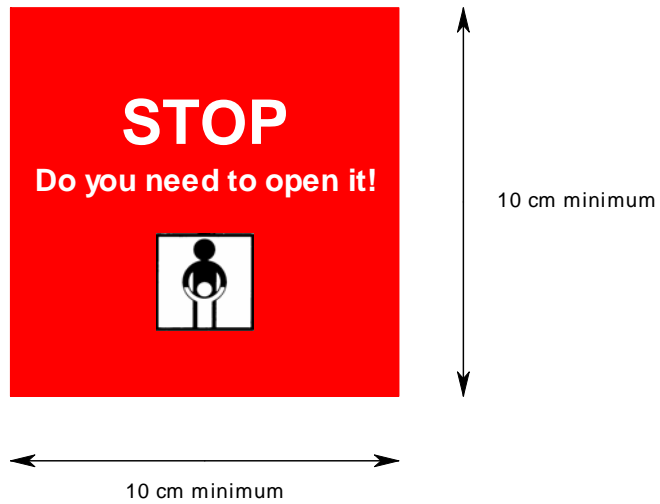
10. Defect reporting:

The [legal manufacturer](#) or [reseller](#) must 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 cold box

White lettering on red ground.

Black and white EPI logo



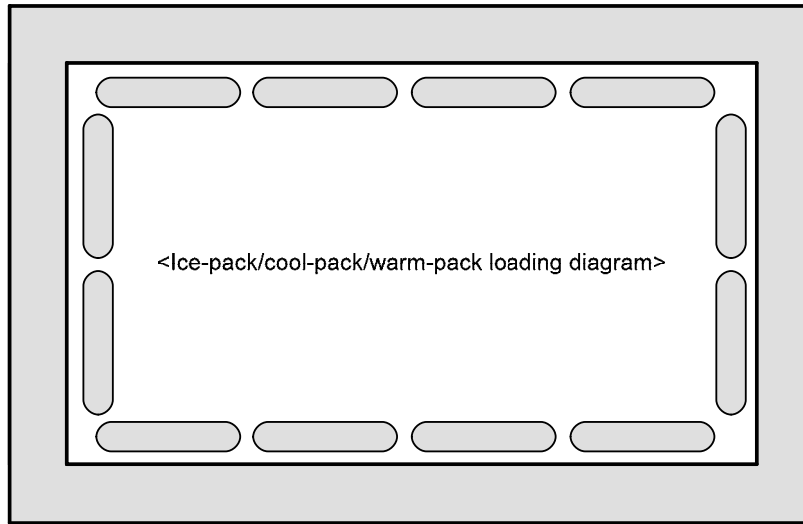
Annex 2 – Label on inside of lid

Performance data:

- Rated cold life: <xx> hours at +43°C with <xx> number <xx> litre frozen ice-packs
- Tested cool life: <xx> hours at +43°C with <xx> number <xx> litre cool-packs at +5°C.

OPTIONAL DATA, IF REQUESTED BY PURCHASER:

- Tested warm life: <xx> hours at -20°C with <xx> number <xx> litre warm-packs at +18°C.



Vaccine transport advice:

- **OPV** : Only use frozen ice-packs. NEVER transport freeze-sensitive vaccines in the same cold box as OPV.
- **BCG, Measles, MMR, MR and Yellow Fever** : Refrigerated cool-packs at +2°C to +8°C are recommended, but frozen ice-packs will not harm these vaccines. If you use ice-packs, NEVER transport freeze-sensitive vaccines in the same cold box.
- **Other vaccines, including combination vaccines** : Only use refrigerated cool-packs at +2°C to +8°C. NEVER transport these vaccines using frozen ice-packs.

OPTIONAL DATA, IF REQUESTED BY PURCHASER:

- Use warm-packs for transporting freeze-sensitive vaccines in cold weather.

Manufacturer: <name> Model no: <ref> Date of manufacture/serial no: <xxxxx>

Note: The layout of the label must suit the shape of lid in order to ensure maximum legibility.

Revision history:			
Date	Change summary	Reason for change	Approved
20.08.2007	General revisions.	Compatibility with PQS requirements.	
02.11.2007	Minor changes	Version for review.	
04.01.2008	Minor changes	Version for review.	
09.01.2008	Minor changes	Version for external review.	
28.01.2008	Changes in response to comments from K O'D, JV, SS	Version for industry review	