



TITLE: Water-packs for use as icepacks, cool-packs and warm-packs	
<i>Specification reference:</i>	E005/IP01.3
<i>Product verification protocol:</i>	E005/IP01-VP.3
<i>Issue date:</i>	21.05.2010
<i>Date of last revision:</i>	16.12.2019

Contents

1. Scope.....2

2. Terms and definitions2

3. Normative references.....2

4. Requirements.....3

4.1 General.....3

4.2 Performance.....3

4.2.1 *Sizes*.....3

4.2.2 *Water filling requirements*.....3

4.2.3 *Deformation*.....3

4.2.4 *Robustness*.....3

4.2.5 *Leakage*.....4

4.2.6 *Pack colour*.....4

4.3 Environmental requirements4

4.3.1 *Ambient temperature range during transport, storage and use*4

4.4 Physical characteristics4

4.4.1 *Overall dimensions and weights*4

4.5 Interface requirements5

4.5.1 *Compatibility with cold boxes and vaccine carriers*.....5

4.6 Human factors.....5

4.6.1 *Generally*.....5

4.7 Materials5

4.8 Warranty.....5

4.9 Servicing provision.....5

4.10 Disposal and recycling.....5

4.11 Instructions.....5

4.12 Training6

4.13 Verification.....6

5. Packaging.....6

6. On-site installation6

7. Product dossier6

8. On-site maintenance7

9. Change notification	7
10. Defect reporting	7
Revision history	8

1. Scope

This specification defines the requirements for [water-packs](#) that are designed to be used as [icepacks](#), [cool-packs](#) or [warm-packs](#) in order to maintain safe temperatures inside the cold boxes, vaccine carriers and specimen carriers specified in PQS category E004. Four types are covered: two 0.3 litre types, a 0.4 litre type and a 0.6 litre type.

2. Terms and definitions

[Cool-pack](#): a water-pack pre-cooled to a temperature between + 2°C to +8°C before use.

[Icepack](#): a water-pack frozen to a temperature between -5°C and -20°C before use. Icepacks are used for the transport of oral polio vaccine (OPV) or stool specimens.

[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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party.

[Montreal Protocol](#): Montreal Protocol on Substances that Deplete the Ozone Layer.

[Rated water content](#): the volume of water, in cubic centimetres measured at 21.0°C, which the water-pack is designed to hold. The volume is defined by a fill line that is permanently marked on the face of the water-pack.

[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.

[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 this specification.

3. Normative references

(Use most current version)

EMAS: European Union Eco-Management and Audit Scheme.

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.

4. Requirements

4.1 General

A water pack is a robust container designed to store water which, when frozen, cooled or warmed to an appropriate temperature, provides the thermal inertia needed to maintain safe storage conditions for vaccines and biological specimens when carried inside a cold box, vaccine carrier or specimen carrier.

4.2 Performance

4.2.1 *Sizes*

Four **water-pack** types may be offered in three nominal capacities:

- Types 1 and 2: 0.3 litre;
- Type 3: 0.4 litre,
- Type 4: 0.6 litre.

Refer to clause 4.4.1 for the overall dimensions and weights of each type.

4.2.2 *Water filling requirements*

Water-packs must be supplied with a removable filling cap and delivered empty.

Either: The recommended level for filling the **water-pack** must be clearly visible on the outside of the container and it must be possible to check the water level inside with the cap in place.

Or: The **water-pack** must be designed in such a way that it cannot be over-filled.

4.2.3 *Deformation*

The **water-pack** must have effective reinforcement to restrain the walls against swelling. When frozen solid and laid flat on a flat surface, the pack must not exceed the unfrozen thickness by more than 25%. Deformation caused by ice expansion must be reversible: when the **water-pack** thaws its thickness must return to the pre-frozen measurement.

4.2.4 *Robustness*

Water-packs must be able to withstand a two metre drop onto every face, edge and corner when frozen to -20°C. After thawing they must then pass a leakage test.

Water-packs must also be able to withstand a two metre drop onto every face, edge and corner with the contents in the liquid state, at +5°C. They must then pass a leakage test.

4.2.5 Leakage

Unfrozen [water-packs](#), including the cap, must be able to resist a lateral force of 80kg applied to either of the two main faces without leaking.

4.2.6 Pack colour

[Water-packs](#) must be constructed using uncoloured translucent material.

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 and weights

The four [water-pack](#) types must conform to the dimensional and weight restrictions shown in the table below:

Type	Nominal size	Water content (litres) **	Length (mm) ***	Width (mm) ***	Thickness (mm) ***	Max empty weight (g) ****	Max weight filled with water (g) ****
1	0.3 L	0.25 to 0.35	173	120	26	70	420
2*	0.3 L	0.25 to 0.30	163	90	34	80	380
3	0.4 L	0.35 to 0.40	163	94	34	100	500
4	0.6 L	0.55 to 0.60	190	120	34	120	720

Tolerances

* "Type 2" 0.3 L pack is the preferred size.

** Water content: Within range.

*** Dimensions: ± 2.0 mm.

**** Weight: Not exceeding the defined maxima.

4.5 Interface requirements

4.5.1 *Compatibility with cold boxes and vaccine carriers*

Cold boxes, vaccine carriers and specimen carriers prequalified under PQS category E004 are required to be dimensionally compatible with [water-packs](#) covered by this specification. It is acceptable for these products to achieve their full designated performance using only one of the four [water-pack](#) types. The necessary type of [water-pack](#) and dimensions should always be confirmed prior to procurement to avoid any incompatibilities between [water-packs](#) and cold boxes, vaccine carriers or specimen carriers.

4.6 Human factors

4.6.1 *Generally*

When [water-packs](#) are stacked and frozen in bulk they must not bond together.

4.7 Materials

[Water-pack](#) and cap materials must resist UV degradation, must be easy to clean and must be selected with environmentally safe end-of-life disposal in mind. Manufacturers must use materials that are known to be non-toxic when incinerated at any temperature between 650°C and 1,200°C. Chlorinated plastics and composites containing epoxy resins are not permitted.

4.8 Warranty

The product is to be covered by a two-year replacement warranty in the event of any failure arising from defective design, materials or workmanship.

4.9 Servicing provision

The product is to be designed to achieve a maintenance-free life of not less than five years, apart from routine cleaning and the requirement to fill the packs with tap water.

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 must state the [rated water content](#) of the [water-pack](#), up to the fill line.

4.12 Training

No requirement.

Training on prevention of vaccine freeze damage and correct use of [water-packs](#) as [icepacks](#), [cool-packs](#) and [warm-packs](#) is the responsibility of the purchaser.

4.13 Verification

In accordance with PQS Verification Protocol **E005/IP01-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. **On-site installation**

[Water-packs](#) will be filled with tap water by the purchaser or end user.

7. **Product dossier**

The [legal manufacturer](#) or [reseller](#) is to provide WHO with a prequalification 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.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopies of all type-approvals obtained for the product, including CE marking etc.
- 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.
- Provide one sample for preliminary inspection.
- Indicative cost of the product per 100 units, per 1,000 units and per 10,000 units EXW (Incoterms 2000).

8. On-site maintenance

The product is to be designed to be maintenance-free apart from initial filling with tap water.

9. Change notification

The [legal manufacturer](#) or reseller is to advise WHO [in writing](#) of any changes in form, fit or function which may adversely affect the performance of the product after PQS prequalification 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.

Revision history			
Date	Change summary	Reason for change	Approved
24.04.2008	No changes following industry review.	Version for final approval.	UK
03.11.2008	4.2.2: Second option added 4.4.1: Dimensions and tolerances changed	Response to further industry comment.	UK
08.12.2008	4.4.1: Overall dimensions and weights: A new category for 0.3 L packs is added with a preference on the type 2.	Response to further industry comment.	UK
21.05.2010	Title changed and 'pack' changed to 'water-pack' throughout. 2: Normative reference dates updated. 4.2.4: one metre changed to two metres. 4.3.2: Clause deleted. 4.4.1 Type 1 water content range enlarged. 7. ISO 9001 wording amended.	Policy decision Conformity with VP Response to comments received Comments received.	DM
16.12.2019	1 Scope: edited to include four types, not three. 4.2.1: edited to include four types, not three. 4.2.4 changed final one metre value to two metres. 4.5.1: edited to include four types, not three.	Correcting inconsistencies due to previous changes	IG
16.12.2019	4.5.1: Added language for reference to encourage confirmation of water-pack sizing before procurement.	Comments received indicating concern about procurement misunderstandings between types of water-packs and cold chain equipment	IG