



TITLE: Irreversible freeze indicator

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1. Scope:

This specification describes the performance requirements for *irreversible freeze indicators* used for detecting exposure of freeze-sensitive vaccines to temperatures below -0.5°C during transport or storage. Both electronic and passive (phase change) products are covered by this specification.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*

European Union Directive 2002/96/EC: *Waste Electrical and Electronic Equipment.*

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: 2005: *General requirements for the competence of testing and calibration laboratories.*

3. Terms and definitions:

In writing: means communication by letter, fax or email.

LCD: Liquid Crystal Display.

LED: Light-emitting diode.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling 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.

NIST: United States National Institute of Standards and Technology.

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.

4. Requirements:

- 4.1 *General:* The product will be packed with freeze-sensitive vaccines during transport, or during storage in fixed locations, and will be used to warn of exposure to temperatures below -0.5°C.

4.2 Performance:

4.2.1 *Operating temperature range:*

Upper limit: +43°C.

Lower limit (without triggering alarm): -0.5°C.

Lower limit (without device failure): -20°C.

4.2.2 *Accuracy:* ±0.5°C or better at 0°C

4.2.3 *Power source:* None, or non-replaceable battery.

4.2.4 *Sensor:* Electronic sensor or irreversible phase change indicator.

4.2.5 *Mode of operation:* The product is to be triggered by exposure to a temperature of -0.5°C, ±0.5°C, for 60 minutes ± 5 minutes maximum. It must not be possible for the end user to re-set the device after a freezing event.

4.2.6 *Calibration:* Electronic products are to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an [ISO/IEC 17025](#) accredited testing laboratory, to [NIST](#), or to another internationally recognized standards agency.

4.2.7 *Casing:*

- **Electronic devices:** The sensor and any other working parts are to be housed in a non-corrodible water-resistant casing.
- **Passive devices:** The device must be unaffected by overall wetting.

4.2.8 *IP rating:*

- **Electronic devices:** Protection of the product not less than [IEC 60529](#): IP64.
- **Passive devices:** Not applicable.

4.2.9 *Battery life:* Minimum acceptable battery life for electronic products, with the product switched on, measured at any point in the *operating temperature range*, is to be 3 years.

4.2.10 *Shelf life:* Minimum 3 years from date of manufacture, inclusive of operational life.

4.2.11 *Electromagnetic compatibility:* Operation of the device must be unaffected in the normal electromagnetic compatibility environment in which it is intended to work, taking into account disturbance generated by adjacent apparatus which is compliant with relevant ISO, EN, or other internationally recognized standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions.

4.3 Environmental requirements:

4.3.1 *Ambient temperature range during transport and storage:* 5°C to +55°C with device inactivated.

4.3.2 *Ambient humidity range during transport, storage and use:* 0 to 95% RH.

4.3.3 *Electrical storm activity:* Operation of an electronic device must be unaffected by intense electrical storm activity.

4.3.4 *Impact resistance:* Product to withstand 5 drops from 1 metre onto a concrete floor, when cooled to a temperature of +3°C, without physical damage or loss of calibration.

4.3.5 *Vibration:* Product to withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.

4.4 Physical characteristics:

4.4.1 Overall dimensions: Not exceeding 100 x 50 x 25mm.

4.4.2 Weight: Not critical.

4.5 Interface requirements: None.

4.6 Human factors:

4.6.1 Activation: The product may be supplied already activated. Alternatively the user may be required to activate the device. Manual activation, however achieved, must be irreversible.

4.6.2 User interface for phase change products: When the product is triggered this must be indicated by an irreversible colour change from a light to a dark colour. The colour change must take the form of a rapid and complete transformation from light to dark – products that retain an intermediate state will not be acceptable. The colour change must be readily distinguishable by users with all forms of colour blindness.

4.6.3 User interface for products with LED indicator(s) only: The product is to have a minimum of one indicator light. The indicator or indicators must provide the user with the following information by means of unambiguous combinations of steady or flashing lights:

- that the product is activated;
 - that the battery is functioning;
 - whether the temperature of the load has remained above 0°C
- OR;
- whether the temperature of the load has fallen below 0°C.

Clear instructions on interpreting the display must be printed on the product in a graphical form that is not language-dependent.

4.6.4 User interface for products with LCD displays: The product is to have an LCD display, with or without LEDs, capable of showing the following information:

- that the product is activated;
 - that the battery is functioning;
 - whether the temperature of the load has remained above 0°C
- OR;
- whether the temperature of the load has fallen below 0°C.

The status of the load must be clearly and permanently indicated on the LCD. Indicator symbols must not be language-dependent and must be easily understood by untrained users. Acceptable indicators include, but are not confined to, the following:

Tick' or 'OK' symbol for temperatures above 0°C as graphic below:



'Cross' or 'Crossed OK' symbol for exposure to 0°C or less as graphic below:





- 4.6.5 *Legibility:* It must be possible for a person with normal visual acuity (with or without glasses) to read the indicator both in bright sunlight and in tungsten/fluorescent lighting at 100 lux on the working plane, both before and after exposure to the trigger temperature.
- 4.6.6 *Mounting device:* The product should have a means for attaching it to the vaccine load – for example a self-adhesive strip or an eyelet.
- 4.7 *Materials:*
- 4.7.1 *Ozone depleting chemicals:* During manufacture and assembly of printed circuit boards and final assembly of the product do not use any substance included in Annex A, B or C of the [Montreal Protocol](#).
- 4.7.2 *Other restricted materials:* The product and its constituent components, including batteries, 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 one year replacement warranty in the event of any component failure not caused by mechanical damage.
- 4.9 *Servicing provision:* The product is to be maintenance-free.
- 4.10 *Disposal and recycling:* The manufacturer is to provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union [WEEE](#) compliance in accordance with European Union Directive 2002/96/EC is mandatory.
- 4.11 *Instructions:* One illustrated instruction sheet, in Arabic, English, French, Mandarin Chinese, Russian and Spanish, is to be supplied in the quantities requested by the end user at the time of ordering. The instructions are to be in large format on single sided ISO A4 or 8.5 inch x 11 inch poster format so that they can be used for staff training.
- 4.12 *Training:* No requirement.
- 4.13 *Verification:* In accordance with PQS Verification Protocol **E06/IN03.VP.1**
- 5. Packaging:**
Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the [Montreal Protocol](#).
- 6. On-site installation:**
Not applicable.
- 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.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability and documentary evidence of claimed battery life.
- Certified photocopy of Certificate of Traceability and Calibration traceable to an [ISO/IEC 17025](#) accredited testing laboratory, to [NIST](#), or to another internationally recognized standards agency.
- 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 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.
- One sample of the product and of the instruction leaflet in English language.
- Indicative cost of the product per 100 units, per 1,000 units and per 10,000 units EXW (Incoterms 2000).

8. On-site maintenance:

Not applicable.

9. Change notification:

The [legal manufacturer](#) or [reseller](#) is required to advise WHO **in writing** of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

The [legal manufacturer](#) or [reseller](#) is required 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
14 Mar 06	Specification redrafted with general amendments to cover electronic devices. Normative references, definitions and additional clauses added.	To achieve conformity with PQS documentation standards	UK
20 Sep 06	1 and 4.1: trigger threshold -0.5°C. 4.2.1: Additional lower limit added. 4.2.5: electronic and passive sensitivities harmonized. Re-settable devices omitted. 4.2.7: 'waterproof' changed to 'water-resisting', 'immersion' changed to 'overall wetting'. 4.2.10: clarification added; re-settable devices removed. 4.2.11: clause added. 4.3.1: upper limit changed to 55°C. 4.6.1: minor change. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 4.11 changed. 5: 'CFC' changed to 'ozone-depleting'. 7: instruction leaflet added.	In response to final review comments and consistency with other specifications. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 - PQS secretariat)