



**TITLE: Portable alcohol stem thermometer**

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<i>Product verification protocol:</i>	E06/TH03.VP.1
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**Contents:**

<b>1. Scope:</b> .....	<b>2</b>
<b>2. Normative references:</b> .....	<b>2</b>
<b>3. Terms and definitions:</b> .....	<b>2</b>
<b>4. Requirements:</b> .....	<b>2</b>
4.1 General:.....	2
4.2. Performance: .....	2
4.2.1 <i>Operating temperature range:</i> .....	2
4.2.2 <i>Accuracy:</i> .....	2
4.2.3 <i>Resolution:</i> .....	2
4.2.4 <i>Sensor:</i> .....	2
4.2.5 <i>Unit of measurement:</i> .....	2
4.2.6 <i>Calibration:</i> .....	2
4.2.7 <i>Casing:</i> .....	3
4.2.8 <i>IP rating:</i> .....	3
4.3 Environmental requirements:.....	3
4.3.1 <i>Ambient temperature range during transport:</i> .....	3
4.3.2 <i>Ambient humidity range during transport and use:</i> .....	3
4.3.3 <i>Impact resistance:</i> .....	3
4.3.4 <i>Vibration:</i> .....	3
4.4 Physical characteristics: .....	3
4.4.1 <i>Overall dimensions:</i> .....	3
4.4.2 <i>Weight:</i> .....	3
4.5 Interface requirements: .....	3
4.6 Human factors:.....	3
4.6.1 <i>Temperature display:</i> .....	3
4.6.2 <i>Mounting device:</i> .....	3
4.7 Materials: .....	3
4.8 Warranty: .....	3
4.9 Servicing provisions: .....	3
4.10 Disposal and recycling:.....	3
4.11 Instructions:.....	4
4.12 Training:.....	4
4.13 Verification: .....	4
<b>6. On-site installation:</b> .....	<b>4</b>
<b>7. Product dossier:</b> .....	<b>4</b>
<b>8. On-site maintenance:</b> .....	<b>4</b>
<b>9. Change notification:</b> .....	<b>4</b>
<b>10. Defect reporting:</b> .....	<b>5</b>

1. **Scope:**

This specification describes the performance requirements for *alcohol stem thermometers*, principally for use in vaccine refrigerators and freezers.
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 2859-1: 1999: *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*.
3. **Terms and definitions:**

**AQL:** Acceptance Quality Limit (ISO 2859-1).  
**In writing:** means communication by letter, fax or email.  
**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.  
**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:** Portable alcohol stem thermometer suitable for monitoring storage temperatures in vaccine refrigerators and freezers. These devices may also be used for supplementary temperature measurement in freezer rooms, cold rooms, and air-conditioned rooms used for storing vaccine in the vaccine cold chain.
  - 4.2. **Performance:**
    - 4.2.1 **Operating temperature range:**

Upper limit: +50°C with over-range protection as clause 4.3.1.  
Lower limit: -30°C with under-range protection as clause 4.3.1.
    - 4.2.2 **Accuracy:** ±1.0°C or better within the range -30°C to +20°C
    - 4.2.3 **Resolution:** ±0.5°C or better within the range -30°C to +20°C
    - 4.2.4 **Sensor:** Coloured alcohol in glass column.
    - 4.2.5 **Unit of measurement:** Temperatures must be displayed in degrees Centigrade only.
    - 4.2.6 **Calibration:** Lot inspection in accordance with AQL procedures as defined in ISO 2859-1: 1999.

- 4.2.7 *Casing*: Non-corrodible plastics or metal case. The glass column must be protected against breakage and strongly supported so that the column cannot be displaced more than 0.5 mm vertically with respect to the scale
- 4.2.8 *IP rating*: Protection of the product not less than [IEC 60529](#): IP67.
- 4.3 *Environmental requirements*:
- 4.3.1 *Ambient temperature range during transport*: -50°C to +55°C.
- 4.3.2 *Ambient humidity range during transport and use*: 0 to 95% RH.
- 4.3.3 *Impact resistance*: Product to withstand 5 drops from 1 metre onto a concrete floor without physical damage or loss of calibration.
- 4.3.4 *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*: Maximum 200 x 25 x 25mm.
- 4.4.2 *Weight*: Not critical, provided the product is fully portable.
- 4.5 *Interface requirements*: None.
- 4.6 *Human factors*:
- 4.6.1 *Temperature display*:
- Easily readable centigrade scale with a minimum space of 1 mm between each line:
  - Long lines with numbers: for each 10 degrees.
  - Short lines: for even numbered degrees.
  - Shorter lines: for odd numbered degrees.
  - Below zero temperature range indicated with a minus sign.
  - Above zero temperature range indicated with a plus sign.
  - Safe zones for ranges of 2°C to +8°C and -15°C to -25°C to be marked with a solid bar.
  - Numeral size: 2 mm high minimum.
  - Font: high-legibility font.
  - Reading angle: between 80 and 100° to the plane of the support plate.
  - Colour of markings: dark blue or black on a white background.
- 4.6.2 *Mounting device*: The following options are acceptable:
- Hanging hook with minimum 8.0mm throat to hook over the rim of a refrigerator/freezer basket.
  - Rubber sucker.
- The position of the mounting device must not prevent the temperature scale from being clearly visible in a suitable reading plane.
- 4.7 *Materials*: No specific requirements subject to achieving adequate robustness.
- 4.8 *Warranty*: The product is to be covered by a one year replacement warranty in the event of any failure not caused by mechanical damage.
- 4.9 *Servicing provisions*: The product is to be maintenance-free.
- 4.10 *Disposal and recycling*: No requirement.

4.11 Instructions: None required

4.12 Training: No requirement.

4.13 Verification: In accordance with PQS Verification Protocol **E06/TH03.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.
- Details of the [legal manufacturer's](#) internal [AQL](#) sampling procedures in respect of ISO 2859-1: 1999.
- 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 complete with accessories and carrying case.
- 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 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 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. Normative references, definitions and additional clauses added.	To achieve conformity with PQS documentation standards	UK
21 Sep 06	4.2.1: 'over-range protection' added. 4.3.1: Upper limit changed to 55°C. 5: 'CFC@ changed to 'ozone-depleting.	Corrections. Consistency with other specifications during final review.	UK (30 November 2006 - PQS secretariat)