



TITLE: Fixed gas or vapour pressure dial thermometer

<i>Specification reference:</i>	E06/TH02.1
<i>Product verification protocol:</i>	E06/TH02.VP.1
<i>Date of origin:</i>	30 November 2006
<i>Date of last revision:</i>	Replaces PIS specification E6/TH2 rev. 01.01.1998

Contents:

1. Scope:	2
2. Normative references:	2
3. Terms and definitions:	2
4. Requirements:	2
4.1 General:	2
4.2 Performance:	2
4.2.1 Operating temperature range:	2
4.2.2 Accuracy:	2
4.2.3 Resolution:	2
4.2.4 Sensors:	3
4.2.5 Additional features:	3
4.2.6 Unit of measurement:	3
4.2.7 Calibration:	3
4.2.8 Power source:	3
4.2.9 Casing:	3
4.2.10 IP rating:	3
4.3 Environmental requirements:	3
4.3.1 Ambient temperature range during transport and storage:	3
4.3.2 Ambient humidity range during transport, storage and use:	3
4.4 Physical characteristics:	3
4.4.1 Overall dimensions:	3
4.4.2 Weight:	3
4.5 Interface requirements:	3
4.6 Human factors:	3
4.6.1 Temperature display:	3
4.7 Mounting device:	4
4.8 Materials:	4
4.9 Warranty:	4
4.10 Servicing provision:	4
4.11 Disposal and recycling:	4
4.12 Instructions:	4
4.13 Training:	4
4.14 Verification:	4
5. Packaging:	4
6. On-site installation:	4
7. Product dossier:	4
8. On-site maintenance:	5
9. Change notification:	5
10. Defect reporting:	5

1. Scope:

This specification describes the performance requirements for *fixed gas or vapour pressure dial thermometers* used to monitor temperatures in fixed cold chain equipment, principally in [primary](#) and [intermediate](#) vaccine stores.

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

3. Terms and definitions:

[Intermediate vaccine store](#): stores which receive vaccine from a [primary vaccine store](#) where it is stored and distributed to health facilities. Such stores are typically located in a regional or district centre.

[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.

[NIST](#): United States National Institute of Standards and Technology.

[Primary vaccine store](#): stores which receive vaccine directly from the vaccine manufacturer where it is stored and distributed to [intermediate vaccine stores](#). Such stores are typically located in a national or regional centre.

[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: Gas or vapour pressure dial thermometers used to monitor temperatures in fixed cold chain equipment principally in [primary](#) and [intermediate](#) vaccine stores.

4.2 Performance:

4.2.1 Operating temperature range:

Upper limit for dial unit and sensor: +50°C with over-range protection as clause 4.3.1.

Lower limit for dial unit: -30°C with under-range protection as clause 4.3.1.

Lower limit for sensor: -30°C.

4.2.2 Accuracy: ±1°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 *Sensors:* Single external gas or vapour pressure sensor with minimum 1.5 metre long lead. Sensor leads are to be of a size and shape which does not damage the door seal or cause an air leak when used with refrigerators and freezers. The lead is to be positively located and protected against mechanical damage where it passes through the seal.

4.2.5 *Additional features:*

EITHER:

- **Alarm contacts:** Adjustable, break on rise and fall, with 2 contacts. It must be possible to set contacts to trigger below +2°C and above +8°C for refrigerators and cold rooms and above 0°C for freezers and freezer rooms. A minimum contact for freezers and freezer rooms is not essential.

OR:

- **Maximum and minimum needle:** 'Lazy pointer' needles to record maximum and minimum temperatures. Re-settable without tools.

4.2.6 *Unit of measurement:* Temperatures must be displayed in degrees Centigrade.

4.2.7 *Calibration:* Each instrument is to be supplied with a calibration certificate issued by an [ISO/IEC 17025](#) accredited testing laboratory or by [NIST](#). The certificate must be accompanied by a copy of the reference instrument calibration certificate.

4.2.8 *Power source:* None.

4.2.9 *Casing:* Non-corrodible plastics or metal case.

4.2.10 *IP rating:* Protection of the product case not less than [IEC 60529](#): IP54.

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport and storage:* -30°C to +55°C.

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

4.4 *Physical characteristics:*

4.4.1 *Overall dimensions:* Not critical.

4.4.2 *Weight:* Not critical.

4.5 *Interface requirements:* Optional alarm contacts as clause 4.2.5 to interface either to a battery or to a mains operated alarm sounder as specification **E06/AL01**.

4.6 *Human factors:*

4.6.1 *Temperature display:*

- High legibility circular Centigrade scale capable of being read by a person with normal vision (with or without glasses) both in bright sunlight and in tungsten/fluorescent lighting at 100 lux on the working plane:
 - Long lines or wide lines, with numbers: for each 10 degrees.
 - Short lines or narrower lines: for each 5 degrees.
 - Shorter lines: for intermediate 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.
- Colour of markings: dark blue or black on a white background.
- Colour of pointer: high visibility colour.
- Reading angle: between 80 and 100° to the plane of the dial.

- 4.7 Mounting device: The product is to be mounted on a vertical surface. Fixings suitable for non mechanical attachment to a refrigerator or freezer cabinet and mechanical attachment to a masonry wall are to be supplied.
- 4.8 Materials: No specific requirements subject to achieving adequate robustness.
- 4.9 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.
- 4.10 Servicing provision: The product is to be maintenance-free.
- 4.11 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.
- 4.12 Instructions: User, installation and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish.
- 4.13 Training: No requirement.
- 4.14 Verification: In accordance with PQS Verification Protocol **E06/TH02.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.
 - Certified photocopy of calibration certificate issued by an [ISO/IEC 17025](#) accredited testing laboratory or by [NIST](#).
 - 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 unit, 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: lower limit corrected to -30°C. 4.2.4 'when used with refrigerators and freezers' added. 4.2.6: Fahrenheit option omitted. 4.3.1: upper limit changed to 55°C. 4.6.1: '75' changed to '100'. 5: 'CFC' changed to 'ozone-depleting.	Corrections and consistency with other specifications during final review.	UK (30 November 2006 - PQS secretariat)