PQS performance specification

WHO/PQS/E06/TR04.1
Original: English
Distribution: General

TITLE: Wall-mounted pen recording thermometer

Specification reference:	E06/TR04.1
Product verification protocol:	E06/TR04.VP.1
Date of origin:	30 November 2006
Date of last revision:	Replaces PIS specification E6/TR1 rev. 01.01.1998

Contents:

1. Scope:

This specification describes the performance requirements for *wall-mounted pen recording thermometers* to be used to record the storage temperature in primary and intermediate cold rooms and freezer rooms containing vaccine stocks in situations where electronic logger systems are inappropriate[1].

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.
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:* Wall-mounted pen recording thermometers to be used to record the storage temperature in primary and intermediate cold rooms and freezer rooms

[1] Inappropriate locations for electronic systems includes store sites where technical support is weak and/or the electricity supply is unreliable.

containing vaccine stocks in situations where electronic logger systems are inappropriate.

4.2 *Performance:*

4.2.1 *Operating temperature range:*
Upper limit: +50°C.
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 *Temperature sensors:*

- **Temperature sensor(s):** One or two remote electronic, or gas/vapour pressure temperature sensors to be located in the refrigerated chamber.
- **Lead length:** up to 15 metres.

4.2.5 *Alarm contacts and 'door-open' sensor:*

- **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 cold rooms and above -15°C for freezer rooms. A minimum contact for freezers and freezer rooms is not essential.
- **'Door open' sensor:** A 'door open' sensor will be required in some applications.

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

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

4.2.9 *IP rating:* Protection of the product not less than IEC 60529: IP54.

4.2.10 *Chart type:* Replaceable paper disc or replaceable fanfold paper strip.

4.2.11 *Pen type:* Refillable or inkless pen. Fibre pens are not acceptable. Thermal trace models are acceptable provided the requirements of clause 4.2.12 are satisfied.

4.2.12 *Longevity of temperature trace:* The chart and pen combination is to be capable of retaining a legible trace for a period of not less than three years when the used chart is stored in the dark at ambient temperatures up to 43°C.

4.2.13 *Recording period:* The minimum acceptable recording period between chart changes is to be seven days.

4.2.14 *Power source:* 110/240 volt 50/60 Hz mains operated with rechargeable battery backup with a minimum 48 hr charge capacity. The battery is to be replaceable.

4.2.15 *Power lead:* The device is to be supplied with a power lead for wiring directly into an electrical outlet. Plugs are unacceptable as they can be removed by the user.

4.2.16 *Digital display:* Products may include a digital temperature displaying the current temperature at the sensor head(s). The display must be in degrees Centigrade.

4.2.17 *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:* -30°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 *Resistance to electrical storms:* The functionality of the device must not be affected by intense electrical storm activity.

4.4 *Physical characteristics:*

4.4.1 *Overall dimensions:* Not critical provided chart trace is fully legible.

4.4.2 *Weight:* Not critical.

4.5 *Interface requirements:* Alarm contacts as clause 4.2.4 to interface to a battery or mains operated alarm sounder as specified in PQS specification **E06/AL.01**.

4.6 *Human factors:*

4.6.1 *Temperature charts:* Temperature charts are to be pre-printed with a 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:

- 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 (depending upon application) to be printed on the chart in the form of clearly identified lines or applied tone.
- Numeral size: 2 mm high minimum.
- 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 *Digital display:* Digital readout, where included, must be 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.

4.6.3 *Mounting device:* The product is to be mounted on a vertical surface. Fixings suitable for attachment to a sectional cold room/freezer room or to a masonry wall are to be supplied.

4.7 *Materials:*

4.7.1 *Ozone depleting chemicals:* During manufacture and assembly of the 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 three year replacement warranty in the event of any component failure.

4.9 *Servicing provision:* The product is to be maintenance-free apart from routine re-calibration and the replacement of charts, pens and rechargeable batteries.

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:* Detailed fixing, commissioning and end user instructions are to be supplied with every instrument, in Arabic, English, French, Mandarin Chinese, Russian and Spanish.

4.12 *Training:* No requirement.

4.13 *Spare parts:* Blank charts and ink refills (where relevant) are to be supplied with every instrument, sufficient for 5 years normal operation.

4.14 *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.
- 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 sensor lead(s), paper chart and pen(s). [The sample will be returned following evaluation provided the manufacturer pays the return carriage charge.]
- Indicative cost of the product per unit, per 10 units and per 100 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	Footnote 1 amended. 4.2.15: changed to fixed wiring. 4.2.17: clause added. 4.3.1: Lower limit changed to -30°C, upper limit changed to +55°C, 'storage' and 'with device inactivated' added. 4.3.2: 'storage' added. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 5: 'CFC' changed to 'ozone-depleting'.	Corrections. Consistency with other specifications during final review. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 - PQS secretariat)