



TITLE: Portable electronic thermometer

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1. Scope:

This specification describes the performance requirements for *electronic thermometers* to be used by supervisors and technicians to make on-site checks of air temperature in cold chain equipment.

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:* Hand-held electronic thermometer with internal sensor and/or one or two detachable probes suitable for monitoring air temperature in freezer rooms, cold rooms, vaccine freezers, vaccine refrigerators air-conditioned rooms and cold boxes as used in the vaccine cold chain.

4.2 *Performance:*

4.2.1 *Operating temperature range:*

Upper limit: +50°C minimum.

Lower limit: -30°C minimum.

The temperature display on the product must be legible to the user throughout the operating temperature range.

4.2.2 *Accuracy:* ±0.5°C or better within the range -30°C to +20°C

4.2.3 *Resolution:* ±0.2°C or better within the range -30°C to +20°C

4.2.4 *Power source:* Either rechargeable or replaceable battery, or solar cells capable of operating the product both in full daylight and under tungsten or fluorescent lighting. Minimum lighting level for full operational capability: 75 lux.

4.2.5 *Sensors and optional features:*

Internal sensor: Electronic.

External sensor(s): Single or two channel external sensor connection(s) with electronic sensor(s) on lead(s) up to ten metres long (minimum one metre).

4.2.6 *Instrument response time:* Instrument reading to stabilize between 30 and 60 seconds after exposure to an instantaneous still air temperature change of 20°C.

4.2.7 *Unit of measurement:* Temperatures must be displayed in degrees Centigrade. A Fahrenheit scale is not required; however products with an optional Fahrenheit scale are acceptable.

4.2.8 *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.

4.2.9 *Other features:*

Mandatory:

- Low battery indicator.

Optional:

- Automatic shut-off.
- Self-calibration.
- Maximum and minimum temperature recording.
- Data-logging.

4.2.10 *Casing:* Non-corrodible plastics or metal case in resilient belt-mounted holster.

4.2.11 *IP rating:* Protection of the product and accessories outside its carrying case not less than [IEC 60529](#): IP54.

4.2.12 *Battery charger (where applicable):* Worldwide dual voltage charger AC 100-240 volts 50/60 Hz.

4.2.13 *Power lead (where applicable):* Factory sealed plug to suit mains electrical socket standard in country of intended primary use (to be specified by the relevant UN-purchasing agency at the time of ordering).

4.2.14 *Battery life:* Minimum acceptable battery life with the device switched on is to be 100 hours.

4.2.15 *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.

4.2.16 *Carrying case*: Protective carrying case capable of containing the product, the sensor lead(s) and (where applicable) one spare set of batteries or the battery charger and power lead.

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 *Impact resistance*: Product to withstand 5 drops from 1 metre onto a concrete floor, with battery in place and when outside the holster, 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*: Not critical, provided the product is fully portable.

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*: Digital readout 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.

4.7 *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 not caused by mechanical damage.

4.9 *Servicing provision*: The product is to be maintenance-free, apart from routine re-calibration, battery replacement and/or recharging.

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*: User and maintenance instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish.

4.12 Training: No requirement.

4.13 Verification: In accordance with PQS Verification Protocol **E06/TH01.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	Redrafted with general amendments. Normative references, definitions and additional clauses added.	To achieve conformity with PQS documentation standards	UK
21 Sep 06	2: ISO 17025 date. 4.2.1: clarification. 4.2.10: holster description. 4.3.3: 'carrying case' changed to 'holster'. 4.3.1: Upper limit changed to 55°C. 4.3.2: 'storage' added. Clause 4.2.15 added. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 5: 'CFC' changed to 'ozone-depleting'.	Final corrections. Consistency with other specifications during final review. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 - PQS secretariat)