PQS Type-examination protocol

TITLE: Portable electronic thermometer

Product verification protocol:	E06/TH01.VP.1
Applies to specification ref(s):	E06/TH01.1
Date of origin:	30 November 2006
Date of last revision:	Replaces PIS test procedure E6/PROC/1 dated 01.01.1998

Contents:

1. Scope: 1
2. Normative references: 1
3. Terms and definitions: 1
4. Applicability: 2
5. Sample-examination checklist: 2
5.1 Evidence of conformity assessment: 2
5.2 Samples and supporting material: 2
5.3 Type-examination procedure: 2
5.4 Criteria for qualification: 3
6. Quality control checklist: 4
6.1 Quality control standards: 4
6.2 Quality control checklist: 4
7. Pre-qualification evaluation: 4
8. Modified products: 4

1. Scope:

This document describes the procedure for verifying the performance of *portable electronic thermometers* to be used by supervisors and technicians to make on-site temperature checks.

2. Normative references:

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/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*
WHO/PQS/E06/TH01.1: *WHO Performance Specification for portable electronic thermometers.*

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 labelling 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.

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. Applicability:

Type-examination will be carried out by an independent ISO/IEC 17025 testing laboratory, accredited by WHO.

5. Sample-examination checklist:

5.1 *Evidence of conformity assessment:* Products must carry the CE mark and/or equivalent internationally accepted evidence of conformity assessment.

5.2 *Samples and supporting material:* The Legal Manufacturer or Reseller must supply the testing laboratory with a full duplicate set of the Product Dossier already supplied to WHO in accordance with the requirements of specification clause 7. One sample of the product is required.

5.3 *Type-examination procedure:*

- **Step 1:** Check all samples for similarities between different models[1], dissimilarities between samples of one model, and any defects or damage.
- **Step 2:** Record any differences between the samples ordered and those received.
- **Step 3:** Tabulate the following information for each model submitted for examination. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the report:

Identification:

- Code (a unique identifier to be assigned by the testing laboratory);
- Model;
- Legal Manufacturer or Reseller;
- Mode of operation: (e.g. thermistor);
- Country of origin;
- Conformity assessment markings (e.g. CE mark).

Performance characteristics:

- Device is/is not capable of operating at -30°C without an external sensor;
- Operating temperature range conforms/does not conform to specification clause 4.2.1;
- Accuracy conforms/does not conform to specification clause 4.2.2;
- Resolution conforms/does not conform to specification clause 4.2.3;
- Power source conforms/does not conform to specification clause 4.2.4;
- Internal and external sensors conform/do not conform to specification clause 4.2.5;
- Response time conforms/does not conform to specification clause 4.2.6;
- Temperature display conforms/does not conform to specification clause 4.2.7;

[1] The purpose of this inspection is to establish whether products offered by competing companies are re-badged versions of an otherwise identical device.

- Calibration certificate conforms/does not conform to specification clause 4.2.8;
- Low battery indicator conforms/does not conform to specification clause 4.2.9. Review and list optional features.
- Casing construction conforms/does not conform to specification clause 4.2.10;
- IP rating conforms/does not conform to specification clause 4.2.11;
- Battery charger (where applicable) conforms/does not conform to specification clause 4.2.12;
- Power lead (where applicable) conforms/does not conform to specification clause 4.2.13;
- Battery life conforms/does not conform to specification clause 4.2.14 and is supported by written evidence from the device manufacturer;
- Circuit design for electromagnetic compatibility conforms/does not conform to specification clause 4.2.15;
- Carrying case conforms/does not conform to specification clause 4.2.16;
- Over-range protection conforms/does not conform to specification clause 4.3.1;
- Humidity resistance conforms/does not conform to specification clause 4.3.2;
- Legibility of temperature display conforms/does not conform to specification clause 4.6.1.

Materials and construction:

- Materials of all major visible components;
- Materials used conform/do not conform to specification section 4.7;
- Major rectangular dimensions (± l mm);
- Weight (± l g);
- Special features;
- Presence of dust and moisture-proofing seals;

Instructions:

- Record the presence of any written instructions together with the languages in which they are printed.

Warranty

- Warranty conforms/does not conform to specification clause 4.8.

- **Step 4:** Take a three quarter view digital photograph of each sample.
- **Acceptance criteria:** Inspection indicates full conformity with all major mandatory specification requirements.

5.4 *Criteria for qualification:* A final report must be issued after the type-examination is complete. The report must contain the following data and analyses:

- **Summary:** Conclusions and recommendations.
- **Type-examination:** Comments on samples received, tabulated data and photographs of samples.
- **Annexes:** Additional supporting documentation requested and received from the Legal Manufacturer or Reseller during the course of the type-examination.

6. Quality control checklist:

6.1 *Quality control standards:* All testing and reporting must be carried out in accordance with the requirements of ISO 17025:2005 or later edition.

6.2 *Quality control checklist:* An on-site inspection of the manufacturing plant is not required.

7. Pre-qualification evaluation:

A product will qualify for inclusion on the register of PQS pre-qualified portable electronic thermometers, in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E06/TH01.1.**

8. Modified products:

The legal manufacturer or reseller must notify WHO in writing of any changes which affect the performance of the product. WHO will carry out a desk evaluation of the reported change(s). If any change is deemed adversely to affect the performance of the product, WHO may request full or partial re-verification based on the type-examination procedures described in this document.

Revision history:			
Date	Change summary	Reason for change	Approved
14 Mar 06	Type examination procedure redrafted with general amendments. Normative references, definitions and additional clauses added.	To achieve conformity with PQS documentation standards	UK
21 Sep 06	5.3: Reference to specification clauses 4.2.15 and 4.3.2 added.	Consistency with other VPs during final review.	UK (30 November 2006 - PQS secretariat)