PQS Type-examination protocol

TITLE: User-programmable temperature data loggers

Product verification protocol:	E06/TR05.VP.1
Applies to specification ref(s):	E06/TR05.1
Date of origin:	30 November 2006
Date of last revision:	No previous protocol.

Contents:

1. Scope:

This document describes the procedure for verifying the performance of *user-programmable electronic temperature data loggers* to be used for study and commissioning purposes throughout the vaccine cold chain.

2. Normative references:

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/TR05.1: *WHO Performance Specification for user-programmable temperature data loggers.*

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 complete with battery and all accessories.

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;
- Type: (e.g. remote sensor/replaceable battery, internal sensor/non-replaceable battery).
- Legal Manufacturer or Reseller;
- Mode of operation;
- Country of origin;
- Conformity assessment markings (e.g. CE mark).

Performance characteristics:

- 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;
- Memory conforms/does not conform to specification clause 4.2.6;
- Response time conforms/does not conform to specification clause 4.2.7;
- Unit of measurement conforms/does not conform to specification clause 4.2.8;
- Calibration certification conforms/does not conform to specification clause 4.2.9;

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

- Logging interval conforms/does not conform to specification clause 4.2.10;
- Logging start delay conforms/does not conform to specification clause 4.2.11;
- Alarm settings conform/do not conform to specification clause 4.2.12;
- Casing conforms/does not conform to specification clause 4.2.13;
- IP rating conforms/does not conform to specification clause 4.2.14;
- Battery life conforms/does not conform to specification clause 4.2.15 and is supported by written evidence from the device manufacturer;
- Circuit design for electromagnetic compatibility conforms/does not conform to specification clause 4.2.16;
- Data connection leads conform/do not conform to specification clause 4.2.17;
- Software conforms/does not conform to specification clause 4.2.18;
- Over- and under-range protection conforms/does not conform to specification clause 4.3.1;
- Humidity resistance conforms/does not conform to specification clause 4.3.2;
- Circuit design for resistance to electrical storms conforms/does not conform to specification clause 4.3.3.
- Impact resistance conforms/does not conform to specification clause 4.3.4;
- Vibration resistance conforms/does not conform to specification clause 4.3.5;
- Physical dimensions conform/do not conform to specification clause 4.4.1;
- Software compatibility conforms/does not conform to specification clause 4.5.1;
- Activation mechanism conforms/does not conform to specification clause 4.6.1;
- De-activation mechanism conforms/does not conform to specification clause 4.6.2;
- User interface conforms/does not conform to specification clause 4.6.3;
- Mounting device conforms/does not conform to specification clause 4.6.4;

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;

Warranty

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

Instructions:

- Instructions conform/do not conform to specification clause 4.11.

- **Step 4:** Take a three quarter view digital photograph of each sample.
- **Acceptance criteria:** Inspection indicates full conformity with all major 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 user-programmable temperature data loggers in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E06/TR05.1**.

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
21 Sep 06	5.3: Reference to specification clauses 4.2.16 and 4.3.2 added.	Correction. Consistency with other VPs during final review.	UK (30 November 2006 - PQS secretariat)