TITLE: Acoustic and/or visual alarm units

Product verification protocol:	E06/AL01.VP.1
Applies to specification ref(s):	E06/AL01.1
Date of origin:	30 November 2006
Date of last revision:	New protocol

Contents:

1. Scope:

This document describes the procedure for verifying the performance of *acoustic and/or visual alarm units* to be used as a component part of a temperature monitoring system in primary and intermediate vaccine stores.

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/AL01.1: *WHO Performance Specification for acoustic and/or visual alarm units.*

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. If the product is available in more than one of the versions described in specification clause 4.1, provide one sample of each version.

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:** Install the device in an acoustic enclosure. Connect the device and its ancillary component(s) to a power supply and connect the alarm leads to a switch capable of triggering an alarm event. Allow the backup battery to charge fully.
- **Step 4:** 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;
  - Specification type classification: (e.g. Ext-1, Int-1);
  - Country of origin;
  - Conformity assessment markings (e.g. CE mark).

  Performance characteristics:
  - Mode of operation conforms/does not conform to one of the categories described in specification clause 4.1;
  - Trigger an alarm event and measure whether the sound intensity and sound pattern (where applicable) conforms/does not conform to specification clause 4.2.1;
  - Trigger an alarm event and assess whether the visual alarm (where applicable) conforms/does not conform to specification clause 4.2.2;
  - Ancillary components conform/do not conform to specification clause 4.2.3;

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

- Power source conforms/does not conform to specification clause 4.2.4;
- Mode of operation conforms/does not conform to specification clause 4.2.5;
- Casing construction conforms/does not conform to specification clause 4.2.6;
- IP rating conforms/does not conform to specification clause 4.2.7;
- Trigger an alarm event followed by a mains power failure and assess whether the battery conforms/does not conform to specification clause 4.2.8;
- Circuit design for electromagnetic compatibility conforms/does not conform to specification clause 4.2.9.
- Operational temperature range 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.

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 portable electronic thermometers, in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E06/AL01.1.**

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 2006	Reference to specification clause 4.2.9 and 4.3.2 added.	Corrections. In response to final review comments.	UK (30 November 2006 - PQS secretariat)