



**TITLE: Cold Chain Monitor**

<i>Product verification protocol:</i>	E06/IN02.VP.1
<i>Applies to specification ref(s):</i>	E06/IN02.1
<i>Date of origin:</i>	30 November 2006
<i>Date of last revision:</i>	Replaces PIS test procedure E6/PROC/4 dated 01.01.1998

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**1. Scope:**

This document describes the procedure for verifying the performance of cold chain monitors.

**2. Normative references:**

ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories.*

*WHO Performance Specification for Cold Chain Monitors.* WHO/PQS/E06/IN02.1.

E6/PROC/4: 01.01.1998: *E6 Standard test procedures for temperature monitoring equipment: Indicators monitoring temperature and time.* In EPI Equipment performance specifications and test procedures: E6: Temperature Monitoring Devices: 25.03.2002.

**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 must be carried out by an independent **ISO/IEC 17025** accredited testing laboratory, pre-qualified by WHO.

**5. Sample-examination checklist:**

5.1 *Evidence of conformity assessment:* Samples must be accompanied by a laboratory test report showing that the indicator strip has been tested in accordance with PIS test procedure E6/PROC/4 dated 01.01.1998 and conforms to the requirements of that protocol. Provide written evidence that the design and formulation of the indicator strip has not changed since the date of the test report.

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. Twelve samples of the product are required; two in each of the languages listed in specification clause 4.10.

5.3 *Type-examination procedure:*

- **Step 1:** Check that the submitted test report shows conformity to the test procedure cited in clause 5.1. Record results.
- **Step 2:** Check that the written evidence requested in clause 5.1 shows that no change has been made to the design and formulation of the indicator strip since the date of the test report. Record results.
- **Step 3:** Check the dimensions of a random sample of five indicator backing cards against the limits set out in specification **E06/IN02.1**, clause 4.4.1. Record results.
- **Step 4:** Check the accuracy of the printed text in the six target languages against the requirements set out in specification **E06-IN02**, clauses 4.2.5 and 4.2.6. Record results.
- **Step 5:** Check the ability of the card surface to receive and to retain writing in pencil, ball point pen, water-soluble and spirit-soluble marker pen in accordance with **E06/IN02.1**, clauses 4.6.2. Record results.
- **Acceptance criteria:** Test report indicates conformity with the requirements of PIS E6/PROC/4 dated 01.01.1998. Written evidence indicates no changes to design and formulation of the indicator strip. Card dimensions within specified limits. Text and graphic design correct in all six language versions. Card capable of receiving and retaining markings using the four specified types of writing implement.

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. Copy of the original PIS E6/PROC/4 test report. Copy of the submitted written evidence that the design and formulation of the indicator strip has not changed since the date of the test report.
- **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 Cold Chain Monitors in accordance with WHO procedures provided the final report indicates full conformity with the requirements of specification **E06/IN02.1**.

**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 test procedures described in this document.

Revision history:			
Date	Change summary	Reason for change	Approved
29 Nov 2006	Re-drafted as a type-examination protocol	To achieve conformity with PQS documentation standards	UK (30 Nov 2006 - PQS secretariat)