

PQS Independent type-testing protocol

TITLE: Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options

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1. Scope:

This document describes the procedure for verifying the performance of *programmable electronic temperature and event logger systems with integral alarm and auto-dialler options* for monitoring storage conditions 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/TH01.1: WHO Performance Specification for programmable electronic temperature and event logger systems with integral alarm and autodialler options.

WHO/PQS/E06/TH01.VP2.1: WHO Quality Assurance Protocol for Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.

3. Terms and definitions:

EPROM: Electrically erasable, programmable, read-only memory. In writing: means communication by letter, fax or email. Intermediate vaccine store: stores which receive vaccine from a primary vaccine store where it is stored and distributed to health facilities. Such stores are typically located in a regional or district centre.

LCD: Liquid Crystal Display.

LED: Light-Emitting Diode.

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.

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

NIST: United States National Institute of Standards and Technology. Primary vaccine store: stores which receive vaccine directly from the vaccine manufacturer where it is stored and distributed to intermediate vaccine stores. Such stores are typically located in a national or regional centre. 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.

SMS: Short Message Service.

4. Applicability:

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

5. Sample-examination checklist:

- 5.1 <u>Evidence of conformity assessment:</u> Products must carry the CE mark and/or equivalent internationally accepted evidence of conformity assessment.
- 5.2 <u>Samples and supporting material:</u> 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 complete sample system is required for evaluation purposes, as described in specification clause 7.
- 5.3 <u>Test 1: Type examination:</u>
 - Step 1: Check all sample system components for similarities between different models¹, dissimilarities between samples of one model, and any defects or damage.
 - Step 2: Record any differences between the sample components ordered and those received.

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

• Step 3: Tabulate the following information for all sample system components submitted for examination. Obtain any additional supporting information required in writing from the Legal Manufacturer or Reseller and attach this information to the report:

System characteristics:

- Generic description of system including minimum system setup and details of expansion options;
- List of submitted system components, including software.

Identification of system components:

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

Performance characteristics of system components: <u>Sensors (specification clause 4.2.1)</u>:

- Temperature sensor operating range conforms/does not conform;
- Temperature sensor accuracy conforms/does not conform;
- Temperature sensor resolution conforms/does not conform;
- Temperature sensor response time conforms/does not conform;
- Temperature sensor type conforms/does not conform;
- 'Door-open' event sensor conforms/does not conform;
- Voltage sensor conforms/does not conform;
- Sensor lead length restrictions (if any) are acceptable;
- Sensor fixings conform/do not conform;
- Sensor IP rating conforms/does not conform.

Logger units (specification clause 4.2.2 – where applicable):

- Logger unit operating parameters conform/do not conform;
- Logger unit power source conforms/does not conform;
- Logger unit memory conforms/does not conform;
- Logging interval conforms/does not conform;
- Logger unit casing conforms/does not conform;
- Logger unit fixings conform/do not conform;
- Logger unit IP rating conforms/does not conform;
- Connection to base station conforms/does not conform.

Base station (specification clause 4.2.3):

- Base station channels conforms/does not conform;
- 'Active' base station (where applicable) conforms/does not conform;
- 'Passive' base station (where applicable) conforms/does not conform;
- Base station power source conforms/does not conform;
- Base station data connection leads conform/do not conform;
- Base station IP rating conforms/does not conform.

Central alarm sounder (specification clause 4.2.4):

- Alarm power source conforms/does not conform;
- Alarm sound intensity conforms/does not conform;
- Alarm operation mode conforms/does not conform;
- Alarm IP rating conforms/does not conform.

Auto-dialler (specification clause 4.2.5):

- Auto-dialler power source conforms/does not conform;

- Auto-dialler functionality conforms/does not conform.

Software (specification clause 4.2.6):

- Software format conforms/does not conform;
- Software functionality conforms/does not conform;
- Security functionality conforms/does not conform;
- Optional remote monitoring available/not available;
- Output documentation conforms/does not conform.
- Unit of measurement (specification clause 4.2.8):
- Unit of measurement conforms/does not conform.

Calibration (specification clause 4.2.9):

- System component calibration certificate(s) conforms/does not conform. Power leads (specification clause 4.2.10):

- Power leads conform/do not conform.

Circuit design for electromagnetic compatibility (specification clause 4.2.11)

- Circuit design conforms/does not conform.
- Tolerance of ambient temperature range (specification clause 4.3.1)

- Design conforms/does not conform.

Tolerance of ambient humidity range (specification clause 4.3.2)

- Design conforms/does not conform.

Circuit design for resistance to electrical storms (specification clause 4.3.3):

- Design conforms/does not conform.

Software compatibility (specification clause 4.5.1):

- Software compatibility conforms/does not conform.

De-activation (specification clause 4.6.1):

- De-activation requirements conform/do not conform.

User interface (specification clauses 4.6.2 and 4.6.3):

- Logger interface conforms/does not conform;
- Base station interface conforms/does not conform.

Materials and construction:

- Materials of all major visible components;
- Materials used conform/do not conform to specification section 4.7;
- Major rectangular dimensions $(\pm 1 \text{ mm})$;
- Weight $(\pm l g)$;
- Special features;
- Presence of dust and moisture-proofing seals;

Instructions:

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

- Warranty conforms/does not conform to specification clause 4.8.
- **Step 4:** Take a three quarter view digital photograph of each system component.
- Acceptance criteria: Inspection indicates full conformity with specification requirements.

5.4 <u>Test 2: System setup:</u>

- **Number of samples:** One complete set of system components as offered for verification.
- **Step 1:** Provide three test chambers with the following characteristics:

- Test chamber 'A' is to be controlled between +5°C and +50°C with an accuracy of ±1°C. This chamber will house the system components designed to be installed at ambient temperature.
- Test chamber 'B' is to be controlled between -5°C and +10°C with an accuracy of ±0.5°C. This will house the logger/sensor unit # 1.
- Test chamber 'C' is to be controlled between -30°C and 0°C with an accuracy of ±0.5°C. This will house logger/sensor unit # 2.
- Step 2: Using the system manufacturer's installation instructions only, set up the system components. Install all components, designed to operate at ambient temperature, inside test chamber 'A'. Place temperature logger/sensor #1 in test chamber 'B' and temperature logger/sensor #2 in test chamber 'C'. Position a calibrated temperature logger adjacent to each sensor programmed to log at exactly the same intervals as the system sensors.
- **Step 3:** Install the optional 'door-open' sensor (where provided) on a hinged panel to simulate a cold room door.
- **Step 4:** Install the optional voltage sensor (where provided). Provide a calibrated voltage recorder to monitor the power source to which the sensor is connected.
- **Step 5:** Link the system components to a PC running the oldest versions of Microsoft Windows and Excel supported by the system. Install the software provided. Attach an A4 monochrome printer.
- **Step 6:** Program the system as follows:
 - Both sensors to log once every 60 seconds;
 - Sensor # 1 high alarm: +8°C;
 - Sensor # 1 high alarm lag: 20 minutes;
 - Sensor # 1 sensor low alarm: $+ 0^{\circ}$ C;
 - Sensor # 1 low alarm lag: 20 minutes;
 - Sensor # 2 high alarm: -15°C;
 - Sensor # 2 high alarm lag: 20 minutes;
 - Sensor # 2 low alarm: -25°C;
 - Sensor # 2 low alarm lag: 20 minutes;
 - 'Door-open' sensor alarm lag: 5 minutes;
 - Voltage sensor to monitor power source.
 - Auto-dialler to trigger after any one or multiple combination of alarm events and to dial three numbers in rotation and/or send an SMS text message (depending on system functionality);
 - Alarm sounder to trigger after any one or multiple combination of alarm events;
 - Printer to produce a separate 24 hour temperature graph for each sensor, labelled to indicate the sensor location and to show upper and lower alarm limits.
- **Step 7:** Comment on the hardware setup procedure. Comment on the software setup and programming procedure. Identify any problems encountered.
- Acceptance criteria: The system setup must be straightforward and trouble-free.
- 5.5 <u>*Test 3: System operation temperature test:*</u>
 - Number of samples: One complete system as set up during Test 2.

• Test conditions:

Condition 1: +43°C in test chamber 'A'. +5°C in test chamber 'B'. -20°C in test chamber 'C'. 'Door-open' sensor in 'closed' position. *Condition 2:* +5°C in test chamber 'A'. +5°C in test chamber 'B'. -20°C in test chamber 'C'. 'Door-open' sensor in 'closed' position.

- Step 1: Stabilize the temperatures in the test chambers as *test condition 1*. Activate the calibrated temperature loggers and activate the test system. Run the system for 48 hours. After each 24 hour period, print off a temperature graph for both sensors. At the end of the test period, print off a 48 hour temperature log for the two sensors and a time-matched 48 hour temperature log for the two calibrated temperature loggers.
- Step 2: Stabilize the temperatures in the test chambers as *test condition 2*. Activate the calibrated temperature loggers and activate the test system. Run the system for 48 hours. After each 24 hour period, print off a temperature graph for both sensors. At the end of the test period, print off a 48 hour temperature log for the two sensors and a time-matched 48 hour temperature log for the two calibrated temperature loggers.
- Acceptance criterion: The temperatures recorded by the system sensors and the calibrated temperature loggers are to vary by no more than ±0.5°C.

5.6 *Test 4: System operation – alarm and auto-dialler test:*

- Number of samples: One complete system as set up during Test 2.
- **Test conditions:** +43°C in test chamber 'A'. +5°C in test chamber 'B'. 20°C in test chamber 'C'. 'Door-open' sensor in 'closed' position.
- Step 1: Stabilize the temperatures in the test chambers.
- Step 2: Activate the 'door-open' sensor (where present). Record whether an alarm is triggered after the expiry of the programmed alarm lag period. Record whether the auto-dialler activates as programmed. Close the 'door-open' sensor. Re-set the alarm.
- Step 3: Lower the temperature of test chamber 'B' to -0.5°C. Record whether the sensor # 1 low alarm is triggered after the expiry of the low alarm lag period. Record whether the auto-dialler activates as programmed. Re-set the alarm.
- Step 4: Raise the temperature of test chamber 'B' to +8.5°C. Record whether the sensor # 1 high alarm is triggered after the expiry of the high alarm lag period². Record whether the auto-dialler activates as programmed. Re-set the alarm.
- Step 5: Lower the temperature of test chamber 'C' to -25.5°C. Record whether the sensor # 2 low alarm is triggered after the expiry of the low alarm lag period³. Record whether the auto-dialler activates as programmed. Re-set the alarm.
- **Step 6:** Raise the temperature of test chamber 'B' to -14.5°C. Record whether the sensor # 2 high alarm is triggered after the expiry of the high

 $^{^{2}}$ A maximum of five minutes may be added to the nominal exposure period to take account of the thermal time constant of the device. Products that do not trigger within this additional time period must be rejected.

³ Ibid.

alarm lag period⁴. Record whether the auto-dialler activates as programmed. Re-set the alarm.

- **Step 7:** At the end of the test, print off the system log together with timematched temperature logs for the two calibrated temperature loggers.
- Acceptance criteria:
 - The system log is to indicate clearly the start and duration of all alarm events, including the 'door-open' alarm event (where present).
 - The temperature recorded by the relevant system sensor at the start and end of each alarm event is to match the temperature recorded by the associated calibrated temperature logger, $\pm 0.5^{\circ}$ C.
 - The alarm sounder is to activate correctly after each of the alarm events.
 - The auto-dialler is to activate correctly after each of the alarm events.
 - The voltage record from the system log (where present) matches the voltage record from the calibrated voltage recorder.

5.7 <u>Test 5: IP rating test to IEC 60529:</u>

- **Step 1:** Obtain independent test reports from the manufacturer showing that, where an IP rating is specified, system components are in full conformity with the relevant IP rating in accordance with IEC 60529.
- Acceptance criterion: Evidence of satisfactory IP- test received from manufacturer.
- 5.8 <u>Criteria for qualification:</u> A final report must be issued after all testing is complete. The report of the tests must contain the following data and analyses:
 - Summary: Conclusions and recommendations.
 - **Test 1:** Comments on samples received, tabulated data and photographs of samples.
 - **Test 2:** Results of system setup test.
 - **Test 3:** Results of system operation temperature test.
 - Test 4: Results of system operation alarm and auto-dialler test.
 - Test 5: Results of IP rating test.
 - Annexes: Test chamber temperature records. Copy of reference thermometer calibration certificate(s). Additional supporting documentation requested and received from the Legal Manufacturer or Reseller during the course of the type-testing.

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 system will qualify for inclusion on the register of PQS pre-qualified programmable electronic temperature and event logger systems with integral alarm and auto-dialler options in accordance with WHO procedures provided

⁴ Ibid.

the final report indicates full conformity with the requirements of specification **E06/TR03.1.**

8. Modified systems:

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

Revision history:					
Date	Change summary	Reason for change	Approved		
21 Sep 06	5.3: Reference to specification clause 4.2.11, 4.3.1 and 4.3.2 added. 5.4 step 6: '2' changed to '0'.	Consistency with other VPs during final review.	UK (30 November 2006 - PQS secretariat)		