



TITLE: Programmable electronic temperature and event logger systems with integral alarm and auto-dialler options	
Location of installation: < insert details >	
Name of Employer: < insert details >	
<i>Product verification protocol:</i>	E006/TR03.VP2.1
<i>Applies to specification ref(s):</i>	E006/TR03.1
<i>Date of origin:</i>	30 November 2006
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1. Scope:

This document sets out a quality assurance protocol for the installation of a *programmable electronic temperature and event logger system with integral alarm and auto-dialler options*. In conjunction with specification **E006/TR03** and verification protocol **E006/TR03-VP1** it may be used to specify the system performance requirements and commissioning activities for a vaccine store temperature monitoring installation. The document is intended to cover the stage in the procurement process commencing when an [Approved Installer](#) is invited by the [Employer](#) to submit a tender offer for the [System](#) and ending when the [System](#) has been satisfactorily installed and commissioned on site.

Guidance note for specifiers: When preparing the tender documents the system specifier must complete all the entries in this specification enclosed in arrow brackets, e.g. <insert details>.

2. Normative references:

ISO 9001: 2000: *Quality Management Systems – Requirements.*

WHO Performance Specification for vaccine cold rooms and freezer rooms

WHO/PQS/E001/CRFR01.1.

WHO/PQS/E006/TR03.1: *WHO Performance Specification for programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.*

WHO/PQS /E006/TR03.VP1.1: *WHO Independent type-testing protocol for programmable electronic temperature and event logger systems with integral alarm and auto-dialler options.*

3. Terms and definitions:

Approved Installer: A person or organization approved by the **Legal Manufacturer** or **Reseller** as a competent installer of the system components and who has been appointed by the **Employer** to carry out the installation of the **System**.

Employer: The organization that contracts with the **Approved Installer** to carry out the system installation and commissioning.

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.

QA: Quality Assurance.

QA Assessor: the person or organization appointed by the **Employer** to assess the suitability of candidate **Approved Installers**, to evaluate their proposals and to monitor the installation and commissioning of the **system** on site.

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.

System: The programmable electronic temperature and event logger system referred to in this document.

4. Applicability:

The **QA** assessment will be conducted, for and on behalf of the **Employer**, by a **QA Assessor**.

5. Specification checklist:

- 5.1 *Specification requirements:* The programmable electronic temperature and event logger system is to be designed and installed by the [Approved Installer](#) using component elements already pre-qualified by WHO in accordance with PQS specification **E006/TR03** and PQS verification protocol **E006/TR03-VP1**. The [System](#) must provide a secure and effective monitoring system for the cold chain equipment listed below, in accordance with the parameters specified in this document:

Guidance note for specifiers: The following sections are to be completed by the specifier. In the case of freezer rooms and cold rooms, enter a separate section for each size of room as some system design parameters (e.g. number of sensors) will vary with room size.

5.1.1 Central equipment:

- **PC:**
 - To be supplied by: [Employer/Approved Installer](#).
 - System parameters to be specified by the [Approved Installer](#).
 - Location: [specify](#).
- **Application software:**
 - To be supplied by the [Approved Installer](#).
 - Software setup: [specify required format of daily/weekly/monthly reports](#).
- **Base station:**
 - Number of channels: The base station must include sufficient channels to cover all the sensors specified below.
 - Expansion: [specify an allowance for expansion if required](#).
 - Location: [specify](#).
- **Voltage sensor:**
 - A voltage sensor connected to the incoming power supply to the vaccine store [is/is not](#) required.
 - Location: Downstream of the standby generator and voltage regulation equipment.
 - Alarm time lag: [specify](#).
- **Alarm:**
 - Type: [sounder/flashing light](#).
 - Location(s): [internal/external](#).
 - Number required: [specify](#).
- **Auto-dialler:**
 - Landline dialler option: [required/not required](#).
 - **SMS** text message dialler option: [required/not required](#).
 - Location: [specify](#).

5.1.2 Freezer rooms:

- **Temperature range:** -15°C to -25°C.
- **High alarm setting:** [specify temperature and lag interval](#).
- **Low alarm setting:** [specify temperature and lag interval](#).
- **Logging interval:** [specify](#).
- **'Door-open' sensor:** [required/not required/specify time lag](#).
- **Room size:** [state dimensions or internal volume](#).

- **Number of temperature sensors:** <specify>.
- **Number of rooms of this size:** <specify>.

5.1.3 Cold rooms:

- **Temperature range:** +2°C to +8°C.
- **High alarm setting:** <specify temperature and lag interval>.
- **Low alarm setting:** <specify temperature and lag interval>.
- **Logging interval:** <specify>.
- **'Door-open' sensor:** <required/not required/specify time lag>.
- **Room size:** <state dimensions or internal volume>.
- **Number of temperature sensors:** <specify>.
- **Number of rooms of this size:** <specify>.

5.1.4 Vaccine freezers:

- **Temperature range:** -15°C to -25°C.
- **High alarm setting:** <specify temperature and lag interval>.
- **Low alarm setting:** <specify temperature and lag interval>.
- **Logging interval:** <specify>.
- **'Door-open' sensor:** <required/not required/specify time lag>.
- **Number of temperature sensors per freezer:** <specify>.
- **Number of freezers:** <specify>.

5.1.5 Vaccine refrigerators:

- **Temperature range:** +2°C to +8°C.
- **High alarm setting:** <specify temperature and lag interval>.
- **Low alarm setting:** <specify temperature and lag interval>.
- **Logging interval:** <specify>.
- **'Door-open' sensor:** <required/not required/specify time lag>.
- **Number of temperature sensors per freezer:** <specify>.
- **Number of refrigerators:** <specify>.

5.2 Criteria for qualification: A system offered by an [Approved Installer](#) will be considered for acceptance by the [Employer](#) provided:

- All the specification requirements listed in Section 5.1 are included in the offer.
- The [Approved Installer](#) is ISO 9001 certified.
- The [Approved Installer](#) provides documentary evidence with his tender offer showing that he has been approved by the [Legal Manufacturer](#) or [Reseller](#) as a competent installer of the system components.
- The [Approved Installer](#) provides a minimum of three recent customer references as specified in clause 7.1.

6. Quality control checklist:

- 6.1 *Quality control standards:* ISO 9001: 2000. Documentary evidence of certification is to be supplied by the [Approved Installer](#).
- 6.2 *Manufacturing quality control checklist:* On-site inspection of the production facility is not required.
- 6.3 *Site work quality control checklist:* The [QA Assessor](#) will carry out an inspection of the completed installation and will witness the commissioning tests specified below. The [Employer](#) will only accept the [System](#) after the [QA Assessor](#) has confirmed that the installation is satisfactory.
- 6.3.1 *Pre-completion inspection checklist:*
- Check all system components are in place.
 - Check all temperature sensors are correctly located.
 - Check all system components have been positioned so that they can be routinely and safely maintained.
 - Check that no system components are exposed to the weather or to other environmental conditions for which they are not designed¹.
 - Check all system wiring is satisfactory and properly protected against damage.
 - Check all system components are functioning.
 - Check all temperature sensor alarm settings and time lags are correct.
 - Check all 'door-open' sensor alarm time lags are correct.
 - Check that voltage sensor alarm time lag is correct.
 - Check that software reporting formats are correct.
 - **Acceptance criteria:** All checks 100% satisfactory.
- 6.3.2 *Commissioning tests:*
- **Run test:** Run the system for 24 hours. Print off a full set of reports and check that these are satisfactory.
 - **High alarm test:** Trigger a high alarm in 50% of the temperature sensors. Check that both the alarm and the auto-dialler are correctly activated in every instance.
 - **Low alarm test:** Trigger a low alarm in 50% of the temperature sensors. Check that both the alarm and the auto-dialler are correctly activated in every instance.
 - **'Door-open' sensor test:** Trigger an alarm in 50% of the 'door-open' sensors. Check that both the alarm and the auto-dialler are correctly activated in every instance.
 - **Voltage sensor test:** Trigger a power failure. Check that both the alarm and the auto-dialler are correctly activated in every instance.
 - **Auto-dialler test:** Fully test the auto-dialler to ensure that all programmed numbers are dialled and that messages are received.
 - **Acceptance criteria:** Zero failure rate on all tests.
- 6.3.3 *Training:* The [Approved Installer](#) must prepare and administer a training course for the users of the system. The training course material must be

¹ For example an internally rated alarm sounder mounted externally.

presented in Microsoft PowerPoint in a language understood by all those attending the course. The syllabus must cover the following topics:

- Introduction to the system and its component parts.
- Periodic maintenance requirements: including cleaning, battery changing, etc. With hands-on demonstrations.
- Hardware operation: including system activation, cancelling alarms, etc. With hands-on demonstrations.
- Report generation and printing. With hands-on demonstrations.
- System administrator software operations: including maintaining system security and setting passwords, setting logging intervals, setting alarm thresholds, setting alarm delays, changing 'phone numbers on the auto-dialler, etc.

6.4 *Handover dossier:* A handover dossier must be issued after all inspections, testing and training have satisfactorily been completed. The dossier must be presented in a lever arch folder with clearly marked subject dividers and must contain the following:

- Completed pre-completion checklist together with [QA Assessor's](#) observations.
- Results of commissioning tests together with [QA Assessor's](#) observations.
- Print-out of training course materials.
- CD of the training course materials.
- One set of as-installed drawings prepared by the [Approved Installer](#). The drawings must include a detailed wiring diagram which clearly identifies the connections to and the location of all system components.
- One complete set of user documentation and maintenance instructions, prepared by the [Approved Installer](#).

7. Customer reference checklist:

Not applicable.

8. Pre-qualification evaluation:

Refer to WHO/PQS /E006/TR03.VP1.1.

9. Modified products:

Not applicable.

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep 06	6.3.1: 'and safely' added. 6.4: additional text. 'Square brackets removed.	Final corrections.	UK (30 November 2006 - PQS secretariat)