



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

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1. Scope:

This specification describes the performance requirements for *programmable electronic temperature and event logger systems with integral alarm and auto-dialler options* for monitoring storage conditions in primary and intermediate vaccine stores.

Two verification protocols are associated with this specification.

E06/TR03.VP1.1 is a laboratory-based system integration test protocol which will be used for pre-qualification evaluations. **E06/TR03.VP2.1** is a quality assurance protocol to be used for system commissioning in the field.

Guidance note: The equipment described in this specification will be purchased to suit the individual requirements of a specific vaccine store. Consequently this document characterizes the required performance of typical components of a temperature monitoring system; it does not specify particular configurations of these components.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme*.

EN 12830:1999: *Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream. Tests, performance and suitability*.

European Union Directive 2002/96/EC: *Waste Electrical and Electronic Equipment*.

ETSI EN 300-220: *Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Technical characteristics and test methods for radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW*.

IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code)*.

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

ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use*.

ISO/IEC 17025: 2000: *General requirements for the competence of testing and calibration laboratories*.

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.

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 labeling 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.

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

4. Requirements:

4.1 ***General:*** Programmable temperature and event logger systems with integral alarm and auto-dialler options, principally used for monitoring storage conditions in **primary** and **intermediate** vaccine stores. Systems must be configurable to suit specific applications and scaleable to allow for the later installation of additional storage facilities. A typical system will include some or all of the following elements.

1. **Temperature sensor:** A device that reads the temperature at a specific location within a cold room, freezer room, refrigerator or freezer unit. Sensors may be connected individually or collectively to a logger unit or directly to a base station. Temperature sensors may also be integrated into a logger unit (internal sensor device).
2. **'Door open' sensor:** A device that detects whether a door is open or closed.
3. **Voltage sensor:** A device that records the incoming mains voltage supplying the vaccine store.
4. **Logger unit:** A device that records data received from individual sensor(s) to which it is connected and transmits this data by wire or by radio signal to a base station or to a PC. Such devices may also include a visual display and/or an audible alarm sounder.

5. **Base station:** A device that receives data from individual logger units, or directly from an array of sensors. The base station may have its own on-board memory and power supply ('active' base station) or it may act as a router directly connected to a PC ('passive' base station).
 6. **PC:** Typically the base station is connected to a personal computer. The PC and its peripherals are used to store, display and print temperature and event records.
 7. **Alarm:** A central alarm sounder and/or flashing light signal which is triggered whenever a sensor records a temperature or event excursion outside programmed norms.
 8. **Auto-dialler:** A device which automatically dials a pre-programmed telephone number or numbers when an alarm is triggered and issues an alert to the recipient. The alert may take the form of a recorded voice message or an [SMS](#) text message.
 9. **Application software:** System-specific software which is designed to drive the system elements described above.
 10. **Mode of operation:** Always on.
- Annex 1 illustrates three possible system configurations.

4.2 *Performance:*

4.2.1 *Sensors:*

1. **Temperature sensor operating temperature range:**
Upper limit: +50°C.
Lower limit: -30°C.
2. **Temperature sensor accuracy:** $\pm 0.5^{\circ}\text{C}$ or better within the range -30°C to +20°C.
3. **Temperature sensor resolution:** $\pm 0.2^{\circ}\text{C}$ or better within the range -30°C to +20°C.
4. **Temperature sensor response time:** T90 20 minutes maximum in accordance with [EN12830:1999](#).
5. **Temperature sensor type:** Electronic.
6. **'Door-open' event sensor operating parameters:** Door open or door closed with a user-programmable delay function. A 'door-open' event must be identified whenever the door panel is not fully seated in the closed position.
7. **Voltage sensor operating parameters:** To monitor all national standard combinations of single phase or three phase AC voltage and frequency, including the range of fluctuations encountered in the country where the equipment is installed.
8. **Sensor lead length:** Supplied as required to suit site conditions.
9. **Sensor fixings:** Remote sensors are to be supplied with fixings suitable for permanent attachment to the inside skin of a sectional cold room or freezer room or to the inside skin of a vaccine refrigerator or freezer.
10. **IP rating for all sensors and connection leads:** Protection of the product not less than [IEC 60529](#): IP64.

4.2.2 *Logger units:*

1. **Logger unit operating parameters:** Where logger units form part of the system they may incorporate integrated temperature sensors or they may be connected to one or more remote sensors.

2. **Logger unit power source:**
 - EITHER: 110/240 volt 50/60 Hz mains operated with rechargeable battery backup with a minimum 48 hr charge capacity. The battery is to be replaceable.
 - OR: Replaceable battery with a minimum two year operational life.
3. **Logger unit memory:** EPROM or equivalent non-volatile solid-state memory device capable of storing a minimum of 1920 temperature readings per sensor.
4. **Logging interval:** The system administrator must be able to program the logging interval at discrete periods between one minute and 60 minutes. Products with a wider range of logging intervals will be acceptable.
5. **Casing:** Non-corrodible plastics or metal case.
6. **Logger fixings:** Loggers are to be supplied with fixings suitable for permanent attachment to the inside or outside skin of a sectional cold room or freezer room or to the inside or outside skin of a vaccine refrigerator or freezer. Fixings are to be designed to prevent unauthorized removal.
7. **IP rating for logger units:** Protection of the product not less than IEC 60529: IP64.
8. **Connection to base station:** Data transmission to the base station may be via a cable connection or via a radio frequency (RF) link. RF links must be in accordance with ETSI EN 300-220 or the ZigBee standard¹ operating at 2.4GHz .

4.2.3 Base station:

1. **Base station channels:** The base station must be capable of receiving and processing data from at least eight separate sensors.
2. **'Active' base station:** Active base stations must incorporate EPROM or equivalent non-volatile solid-state memory capable of storing data from a minimum of eight channels. The memory capacity must be sufficient to store 72 hours worth of sensor data from all connected channels, logged at one minute intervals. The system is to be configured to overwrite data cyclically on a first-in-first-out basis when the memory is full.
3. **'Passive' base stations:** Passive base stations must be capable of receiving data from a minimum of eight channels.
4. **Base station power source:**
 - Active base stations must have a 110/240 volt 50/60 Hz mains operated with rechargeable battery backup with a minimum 72 hr charge capacity. The battery is to be replaceable without need for tools.
 - Passive base stations may have their own power supply or may draw power from an 'always on' PC.
5. **Data connection leads:** The product must include an RS232 or USB connection lead for downloading data to a PC.
6. **IP rating for base unit:** Protection of the product not less than IEC 60529: IP50.

4.2.4 Central alarm sounder:

1. **Alarm power source:** 110/240 volt 50/60 Hz mains-operated wall-mounted audio alarm with rechargeable battery backup with a minimum 48 hr charge

¹ <http://www.zigbee.org/en/index.asp>

2. **Sound intensity for acoustic alarms:** 100dB(A) at a distance of one metre from the sounder. The pattern of the signal is to be an intermittent pulse. The timing and/or pattern of the pulse should be set to ensure that it cannot be confused with the fire alarm sounder standard applicable in the country of installation. Devices with an adjustable sound profile will be acceptable provided the means for adjustment is not accessible once the device is mounted in its final position.
3. **Light intensity for visual alarms:** Flashing coloured light capable of being seen in full sunlight at an intensity of 100,000 lux when viewed against a white background.
4. **Mode of operation:** The sounder is to be triggered whenever an alarm event occurs and is to be cancelled by software command.
5. **IP rating for sounder:** Protection of the product not less than IEC 60529: IP65 for sounders mounted outdoors and IP50 for sounders mounted indoors.

4.2.5 *Auto-dialler:*

1. **Auto-dialler power source:** 110/240 volt 50/60 Hz mains operated auto-dialler unit with rechargeable battery backup with a minimum 72 hr charge. The unit must be capable of:
2. **Auto-dialler functionality:** Dial a minimum of three landline numbers on a cyclical basis until an answer is received AND/OR: transmit an SMS text message to a minimum of three cell phone numbers. The dialing configuration is to be specified through the PC software.

4.2.6 *Software:*

1. **Software format:** The system must be supplied with software on CD – refer also to clauses 4.5 and 4.11. Downloadable software is not acceptable because of poor or absent internet connections in many user settings.
2. **Software functionality:** As a minimum, the software must allow the user to program the system to:
 - identify the location of individual sensors;
 - set a logging interval for all sensors;
 - set upper and lower temperature alarm conditions for individual sensors or groups of sensors (the two standard alarm settings for vaccine storage are +2°C/+8°C, or -25°C/-15°C).
 - Multilingual software, in the languages specified in clause 4.11, is desirable, but not mandatory.
3. **Security:** Authentication and access control of user and privileges standard not less stringent than US 21 CFR Part 11.
4. **Optional remote monitoring for PC-based systems:** Internet-linked remote monitoring of the system via a web-enabled secured monitoring system with authentication and access control in accordance with 4.2.6.3 and Annex 1.
5. **Output documentation:** As a minimum the software must be able to display and print data received from individual sensors in the form of temperature graphs. Graphs must:
 - identify the location of the individual sensor to which the graph refers;
 - display time periods in seconds, minutes, hours or days to suit the programmed logging interval;
 - display temperatures in degrees Centigrade;
 - clearly show the programmed alarm settings;

- print legibly in A4 format.
- 4.2.7 *PC*: The PC and printer to which the temperature monitoring system is connected will generally be supplied by others.
- 4.2.8 *Unit of measurement*: Temperatures throughout the system must be recorded in degrees Centigrade.
- 4.2.9 *Calibration*: System components are to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the components are traceable to an [ISO/IEC 17025](#) accredited testing laboratory, to [NIST](#), or to another internationally recognized standards agency. The certificate must be accompanied by a copy of the reference instrument calibration certificate.
- 4.2.10 *Power leads*: Each mains connected component is to be supplied with a factory sealed plug to suit the mains electrical socket standard in the country of intended use (to be specified by the relevant UN-purchasing agency at the time of ordering).
- 4.2.11 *Electromagnetic compatibility*: Operation of the system and of the individual system components must be unaffected in the normal electromagnetic compatibility environment in which the system is intended to work, taking into account disturbance generated by adjacent apparatus which is compliant with relevant ISO, EN, or other internationally recognized standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions.
- 4.3 *Environmental requirements:*
 - 4.3.1 *Ambient temperature range during transport and storage*: -30°C to +55°C with the system components inactivated.
 - 4.3.2 *Ambient humidity range during transport, storage and use*: 0 to 95% RH.
 - 4.3.3 *Resistance to electrical storms*: The functionality of the system and of the individual system components must not be affected by intense electrical storm activity.
- 4.4 *Physical characteristics:*
 - 4.4.1 *Component dimensions*: Not critical.
 - 4.4.2 *Component weight*: Not critical.
- 4.5 *Interface requirements:*
 - 4.5.1 *Software compatibility*:
 - If the software requires an interface with a proprietary spreadsheet program, the list of compatible programs must include all releases of Microsoft Excel currently supported by Microsoft.
 - The software must be compatible with all Microsoft PC operating systems currently supported by Microsoft.
- 4.6 *Human factors:*
 - 4.6.1 *System de-activation and changes to system configuration*: Only authenticated users should be able to de-activate the system or change the system configuration. De-activation and configuration changes should be password controlled.

- 4.6.2 *User interface for loggers/base stations with LED indicator(s) only:* The indicator or indicators must provide the user with the following information by means of combinations of steady or flashing lights:
- that the component is activated;
 - battery charge level indicator OR battery replacement warning indicator activated when no less than 10% or 90 days of battery life remains (whichever is the longer);
 - whether or not the component is in an alarm condition.
- 4.6.3 *User interface for loggers/base stations with LCD displays:* An LCD display, with or without LEDs, must provide the user with the following information:
- that the component is activated;
 - battery charge level indicator OR battery replacement warning indicator activated when no less than 20% of battery life remains;
 - the most recently read load temperature (loggers only);
 - whether or not the component is in an alarm condition.
 - The LCD may show all this information together on the display or the user may be required to access the information by means of a button mounted on the device. Loggers with more than one attached sensor must be able to show temperature and alarm data from all connected sensors.
- 4.7 *Materials:*
- 4.7.1 *Ozone depleting chemicals:* During manufacture and assembly of the printed circuit boards and final assembly of the product do not use any substance included in Annex A, B or C of the Montreal Protocol.
- 4.7.2 *Other restricted materials:* The product and its constituent components, including batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).
- 4.8 *Warranty:* All system components are to be covered by a three year on-site maintenance or replacement warranty in the event of any component failure. All warranty rights are to pass from the Approved Installer to the Employer² after the system has been commissioned and has been formally accepted by the Employer. Where the Employer is a UN agency, the warranty rights are to pass to the host government³.
- 4.9 *Servicing provision:* The system is to be maintenance-free, apart from routine battery replacement and re-calibration.
- 4.10 *Disposal and recycling:* The manufacturer is to provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union WEEE compliance in accordance with European Union Directive 2002/96/EC is mandatory.

² Typically the system will be installed by an Approved Installer as a component part of a cold room or freezer room installation. .

³ Some installations will initially be purchased by one of the UN procurement agencies. In this situation, warranty rights must pass to the host government.

- 4.11 **Instructions:** Installation, commissioning and end-user instructions, including software manual, in Arabic, English, French, Mandarin Chinese, Russian and Spanish. The manual may be in hard copy format or supplied with the software on CD.
- 4.12 **Training:** Training in the use of the equipment will generally be given by the cold room/freezer room installer. The equipment supplier should provide the necessary training materials.
- 4.13 **Verification:** Pre-qualification evaluation of sample systems will be carried out in accordance with PQS Verification Protocol **E06/TR03.VP1.1**. Post-tender assessment and field commissioning of systems incorporating pre-qualified system components will be carried out in accordance with PQS Verification Protocol **E06/TR03.VP2.1**.

5. Packaging:

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

6. On-site installation:

System components are to be installed on site, and the software loaded and commissioned by personnel who have been trained to carry out these tasks.

7. Product dossier:

The [legal manufacturer](#) or [reseller](#) is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the [legal manufacturer](#), including name and address.
- List of countries where the [legal manufacture](#) has a service network capable of installing and maintaining the offered system.
- Unique identification reference for each of the system components.
- Full specifications of the system being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopy of Certificate of Traceability and Calibration traceable to an [ISO/IEC 17025](#) accredited testing laboratory, to [NIST](#), or to another internationally recognized standards agency for all system components intended for temperature measurement.
- Certified photocopies of all type-approvals obtained for the system components, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 2000 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.

- Where available, laboratory test report(s) proving conformity with the product specifications.
- One complete sample of the system comprising a minimum of:
 - two temperature sensors;
 - one 'door-open' sensor (where offered);
 - one voltage sensor (where offered);
 - two loggers (where part of system);
 - one base station (where part of system);
 - alarm sounder;
 - auto-dialler;
 - software;
 - installation, commissioning and user instructions for the system in English language.

The sample will be returned following evaluation provided the manufacturer pays the return carriage charge.
- Indicative cost of each system component EXW (Incoterms 2000).

8. On-site maintenance:

On-site maintenance of the system and the system components will be required and the [legal manufacturer](#) or [reseller](#) must provide evidence of the ability to provide this service.

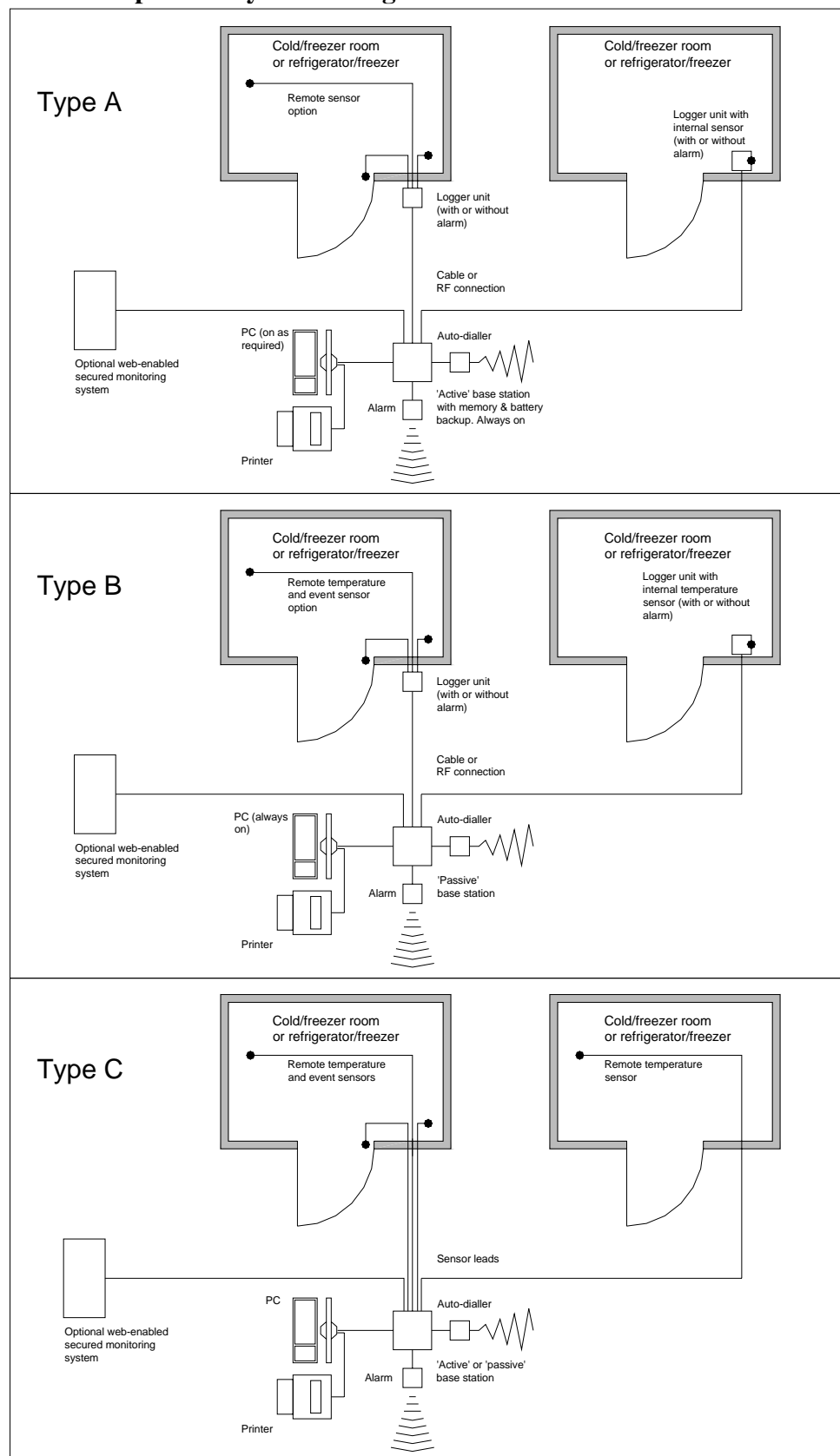
9. Change notification:

The [legal manufacturer](#) or [reseller](#) is required to advise WHO [in writing](#) of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

The [legal manufacturer](#) or [reseller](#) is required to advise WHO and the UN purchasing agencies [in writing](#) in the event of safety-related product recalls, component defects and other similar events.

Annex 1: Some possible system configurations



Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep 06	4.2.5: '48' changed to '72'. 4.2.8: Fahrenheit option removed. 4.2.11: clause added. 4.3.1: Upper limit changed to 55°C; 'storage' added.. 4.3.2: 'storage' added. New clause 4.7.2. 4.7.3 and 4.7.4 deleted.5: 'CFC' changed to 'ozone-depleting'.	Corrections. Consistency with other specifications during final review. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 - PQS Secretariat)