PQS performance specification

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TITLE: User-programmable temperature data loggers

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Product verification protocol:	E06/TR05.VP.1
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Contents:

1. Scope:

This specification describes the performance requirements for *user-programmable electronic temperature data loggers* to be used for study and commissioning purposes throughout the vaccine cold chain.

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.*
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: 2005: *General requirements for the competence of testing and calibration laboratories.*

3. Terms and definitions:

EPROM: Electrically erasable, programmable, read-only memory.
In writing: means communication by letter, fax or email.
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.

Operating life: In relation to replaceable batteries is the period following initial activation of the device. In the case of devices with non-replaceable batteries the period is measured from the date of delivery to the purchaser, regardless of whether the device is activated on that date.
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. Requirements:

4.1 *General:* User-programmable electronic temperature data loggers to be used for study and commissioning purposes throughout the vaccine cold chain. Devices with replaceable and non-replaceable batteries, with or without external sensor leads are included.

4.2 *Performance:*

4.2.1 *Operating temperature range:*
Upper limit: +55°C.
Lower limit: -30°C.
The logger electronics must function over the entire operating temperature range, with or without optional probes.

4.2.2 *Accuracy:* Accuracy: ±0.5°C or better within the range -20°C to +20°C for a minimum of 12 months following initial calibration or subsequent re-calibration. ±1.0°C or better after 12 months if re-calibration is not carried out.

4.2.3 *Resolution:* ±0.2°C or better within the range -30°C to +20°C.

4.2.4 *Power source:* Replaceable or non-replaceable battery.

4.2.5 *Sensor:* Devices with internal and/or external sensors will be considered[1].

- **Internal sensor:** Electronic.
- **External sensor:** Electronic exposed junction device with lead(s) up to 10 metres long. Devices offering more than one external sensor connection will not be excluded.

4.2.6 *Memory:* EPROM or equivalent non-volatile solid-state memory device capable of storing a minimum of 1920 temperature readings per sensor. Some applications will require devices with a larger memory.

4.2.7 *Product response time:* T90 20 minutes maximum in accordance with EN12830:1999.

4.2.8 *Unit of measurement:* Temperatures must be recorded in degrees Centigrade. A Fahrenheit scale is not required; however products with an optional Fahrenheit scale are acceptable.

4.2.9 *Calibration:* Each product is 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 product 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.

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[1] Devices with external sensors may be required for monitoring temperatures at more than one point at a time and for monitoring temperatures in vaccine freezer rooms and freezers where battery and/or LCD performance may be adversely affected.

4.2.10 *Logging interval:* The user must be able to program the logging interval at equal intervals between one minute and one hour. Products with a wider range of logging intervals will be acceptable.

4.2.11 *Logging start delay:* The user must be able to program a logging start delay between 0 seconds and 30 days. Products allowing a programmable delay greater than 30 days will be acceptable.

4.2.12 *Alarm settings:*

- User programmable upper and lower alarm temperatures and alarm time delays at any temperature in the operating temperature range.
- User programmable cumulative exposure facility for at least one upper temperature setting and one lower temperature setting.

4.2.13 *Casing:* Non-corrodible plastics or metal case.

4.2.14 *IP rating:* Protection of the product not less than IEC 60529: IP54 for devices with replaceable batteries and IP65 for devices with non-replaceable batteries.

4.2.15 *Battery:*

- **EITHER:** Replaceable battery with a minimum operating life of one year.
- **OR:** Non-replaceable battery with a minimum operating life of one year.

4.2.16 *Electromagnetic compatibility:* Operation of the device must be unaffected in the normal electromagnetic compatibility environment in which it 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.

4.2.17 *Data connection leads:* The product must include an RS232 or USB connection lead for linking the device to a PC OR the link between the product and the lead may be via a product-specific reader, provided the reader is an integral part of the cable assembly.

4.2.18 *Software:* The data link must be supplied with software on CD or USB stick – 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.

As a minimum, the software must be capable of the following tasks:

- Allow the user to program the product to:
  - set the time zone at initialization either manually or automatically;
  - record user name and job description data;
  - set a logging start delay;
  - set a logging interval;
  - set upper and lower single exposure and cumulative exposure temperature alarm and delay conditions;
  - set the product to stop when the memory is full, or to overwrite data cyclically on a first-in-first-out basis;
  - batch program more than one logger with the same set-up data.
- Output downloaded data in the form of temperature graphs and data tables to:
  - show time periods in seconds, minutes, hours or days to suit the programmed logging interval;
  - show temperatures in degrees centigrade;
  - clearly show the programmed alarm settings;
  - show the time zone set by the user;
  - show the data logger serial number and/or user-set tracking number;

- show user description data;
- show statistics, including minimum and maximum temperatures, average temperatures, cumulative time out of range, etc.
- the ability to show a composite view of data recorded on multiple data loggers is desirable but not mandatory.
- print legibly in A4 format on a monochrome printer.

- Save logger data to a PC.
- Multilingual software, in the languages specified in clause 4.11, is desirable, but not mandatory.

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport, storage and use:* -30°C to +55°C

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 device must not be affected by intense electrical storm activity.

4.3.4 *Impact resistance:* Product to withstand 5 drops from 1 metre onto a concrete floor, with battery in place, without physical damage or loss of calibration.

4.3.5 *Vibration:* Product to withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.

4.4 *Physical characteristics:*

4.4.1 *Overall dimensions:* Not exceeding 100 x 75 x 50mm, excluding data connection lead and any external sensors.

4.4.2 *Weight:* Not critical, provided the product is fully portable.

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 *Activation:* The product may be activated, either by means of a button or switch mounted on the unit, or by software command.

4.6.2 *De-activation:* It should not be possible to de-activate the product inadvertently or deliberately at any time within the logging period, except by software command or by means of a pin-operated switch.

4.6.3 *User interface:*

Products with LED indicator(s) only: The product is to have a minimum of one indicator light. The indicator or indicators must provide the user with the following information by means of combinations of steady or flashing lights:

- that the product is activated;
- that the battery is functioning;
- whether the temperature of the load has remained within alarm limits since recording commenced,
  OR;
- whether the temperature of the load has strayed outside alarm limits since recording commenced.

Products with LCD displays: The product is to have an LCD display, with or without LEDs, capable of showing the following information:

- that the product is activated;
- that the battery is functioning;
- the most recently recorded load temperature;
- whether the temperature of the load has remained within alarm limits since recording commenced,
  OR;
- whether the temperature of the load has strayed outside alarm limits since recording commenced.
- 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 product. Products with more than one sensor must be able to show temperature and alarm data from all connected sensors.

4.6.4 *Mounting device:* Although this is not a mandatory requirement, a means to physically secure the device to the load is desirable. Acceptable options include, but are not confined to:

- Fixing eye for tie.
- Double-sided tape.
- Mounting cleat.

4.6.5 *Audible alarm:* Not required.

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:* The product is to be covered by a one year warranty in the event of any component failure not caused by mechanical damage.

4.9 *Servicing provision:* The product 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.

4.11 *Instructions:* 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:* No requirement.

4.13 *Verification:* In accordance with PQS Verification Protocol **E06/TR05.VP.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:

Not applicable.

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.
- Confirmation of the brand name of the product.
- Full specifications of the product 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.
- Certified photocopies of all type-approvals obtained for the product, 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 sample of the product complete with data connection lead, external sensor(s) (where offered) and software.
- Indicative cost of the product per unit, per 10 units and per 100 units EXW (Incoterms 2000).

8. On-site maintenance:

Not applicable.

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 to 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.

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep 06	4.2.1: upper limit changed to +55°C. 4.2.2: lower limit changed to -20°C. 4.2.6: clause added. 4.2.18: minor changes. 4.3.1: temperature range changed. 4.6.3: clarification. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 5. 'CFC' changed to 'ozone-depleting'.	Corrections. Response to final review comments. EU RoHS Directive material restrictions incorporated.	UK (30 November 2006 ' PQS secretariat)