PQS performance specification

TITLE: Acoustic and/or visual alarm units

Specification reference:	E06/AL01.1
Product verification protocol:	E06/AL01.VP.1
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Contents:

1. Scope:

This specification describes the performance requirements for acoustic and/or visual alarm units to be used as a connected component part of a temperature monitoring system in primary and intermediate vaccine stores.

The alarms specified in this document are intended to be used in conjunction with fixed gas or vapour pressure dial thermometers (with alarm contact option) as described in WHO Performance Specification E06/TH02 and with wall-mounted pen recording thermometers as described in WHO Performance Specification E06/TR04.

Alarms forming a component part of a programmable electronic temperature and event logger system with integral alarm and auto-dialler options are described in WHO Performance Specification E06/TR03.

2. Normative references:

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

3. Terms and definitions:

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.
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.
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.

4. Requirements:

4.1 *General:* Acoustic and/or visual alarm units to be used as a component part of a temperature monitoring system in primary and intermediate vaccine stores. The following types may be offered:

- **Type Ext-1:** Acoustic alarm in weatherproof housing for mounting externally.
- **Type Ext-2:** Visual alarm in weatherproof housing for mounting externally.
- **Type Ext-3:** Acoustic and visual alarm in weatherproof housing for mounting externally.
- **Type Int-1:** Acoustic alarm for mounting internally.
- **Type Int-2:** Visual alarm for mounting internally.
- **Type Int-3:** Acoustic and visual alarm for mounting internally.

4.2 *Performance:*

4.2.1 *Acoustic alarm – Types Ext-1, Ext-3, Int-1 and Int-3:* Sound intensity to be 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 standard for fire alarm sounders 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.

4.2.2 *Visual alarm – Types Ext-2, Ext-3, Int-2 and Int-3:* Flashing coloured light, clearly visible in full sunlight at an intensity of 100,000 lux when viewed against a white background.

4.2.3 *Ancillary components:* Key-operated switch or keypad used to cancel the alarm signal.

4.2.4 *Power source:* 110/240 volt 50/60 Hz mains-operated wall-mounted audio alarm with rechargeable battery backup with a minimum 48 hr charge. The device is to be supplied with a power lead for wiring directly into an electrical outlet. Plugs are unacceptable as they can be removed by the user.

4.2.5 *Mode of operation:* The alarm is to be triggered by a signal received from either of the following temperature monitoring devices:

- Fixed gas or vapour pressure dial thermometer (with alarm contact option) as described in WHO Performance Specification **E06/TH02**.
- Wall-mounted pen recording thermometer as described in WHO Performance Specification **E06/TR04**.

After an alarm event has been signaled, the alarm is to continue until cancelled by the key operated switch or by means of a code entered on the keypad.

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

4.2.7 *IP rating:*

- **Types Ext-1, Ext-2 and Ext-3:** Protection of the product not less than IEC 60529: IP65.
- **Types Int-1, Int-2 and Int-3:** Protection of the product not less than IEC 60529: IP50.

4.2.8 *Battery:* Rechargeable back-up battery with a minimum 48 hr charge capacity with the acoustic and/or visual alarm operating. The battery is to be replaceable.

4.2.9 *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.

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport, storage and use:* -50°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.

4.4 *Physical characteristics:*

4.4.1 *Component dimensions:* Not critical.

4.4.2 *Component weight:* Not critical.

4.5 *Interface requirements:* As clause 4.2.4.

4.6 *Human factors:* As clauses 4.3.2 to 4.2.4.

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 1 year replacement warranty in the event of any component failure.

4.9 *Servicing provision:* The system is to be maintenance-free, apart from routine battery replacement.

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:* Installation and user instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish.

4.12 *Training:* No requirement.

4.13 *Verification:* In accordance with PQS Verification Protocol **E06/AL01.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.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- 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. If the product is available in more than one of the versions described in clause 4.1, provide one sample of each version. The sample(s) will be returned following evaluation provided the manufacturer pays the return carriage charge.
- Indicative cost of the product per unit, per 10 units and per 100 units EXW (Incoterms 2000).

8. On-site maintenance:

Not required.

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.

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep 06	4.2.1: adjustable sound profile option added. Clause 4.2.9 added. 5. 'CFC' changed to 'ozone-depleting'. New clause 4.7.2. 4.7.3 and 4.7.4 deleted.	In response to final review comments. EU RoHS Directive material restrictions incorporated.	Yes (UK - 30 November 2006 = PQS secretariat)