PQS performance specification

WHO/PQS/E06/IN02.1
Original: English
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TITLE: Cold Chain Monitor

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Product verification protocol:	E06/IN02.VP.1
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Contents:

1. Scope:

This specification describes the performance requirements for *cold chain monitors* (CCM). CCMs provide a warning when excessive heat exposure occurs during transport. They are used primarily to monitor the international shipment of freeze-dried vaccine consignments where dry ice is used as the

cooling medium. CCMs may also be appropriate for national vaccine shipments where the delivery takes several days.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
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.
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.
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:* Cold chain monitor used to monitor the temperature of vaccine consignments and to warn of excessive heat exposure during international or national transport under the conditions described in clause 1.

4.2 *Performance:*

4.2.1 *Mode of operation:* Progressive colour spread or colour change above threshold temperatures. Indicator strip attached to a card on which instructions for use are printed, in accordance with the format prescribed below.

4.2.2 *Threshold temperatures:* The monitor is to have two time-temperature sensitive indicators which change colour irreversibly and at a constant rate at the following ambient temperatures:

- +10°C.
- +34°C.

4.2.3 *Time temperature function:* The indicators are to respond to temperature exposure as follows:

- **+10°C indicator:** 14 days to full scale colour change at +12°C. The +10°C indicator strip is to be mounted behind three equal sized windows marked ‘A’, ‘B’ and ‘C’ so that users can clearly identify three distinct stages in the colour change process.
- **+34°C indicator:** 3 hours to full scale colour change at 37°C.

No colour change must occur unless the indicator is activated. The +34°C indicator is to be mounted behind a window marked ‘D’ so that users can clearly identify full colour change.

4.2.4 *Activation:* The indicator is to be activated by the shipper by means of the physical removal of a trigger strip or other positive user intervention.

4.2.5 *Front face of card:* The front face of the card is to carry the time-temperature indicator and is to be printed in the chosen language, in black, with the following information:

- **Record keeping table for completion by vaccine manufacturer and recipient:**

Vaccine Cold Chain Monitor shipment record				
Date in	Index	Location	Date out	Index

There are to be a minimum of six blank rows not less than 7mm high.

- **Interpretation guide and supplier information:**

	If A all <end colour>	If B all <end colour>	If C all <end colour>	If A & B & C & D all <end colour>
Oral polio vaccine	Use within 3 months	TEST VACCINE BEFORE USE		
Measles, MR, MMR, yellow fever		Use within 3 months		
BCG, Hib freeze dried, meningitis			Use within 3 months	
SUPPLIER	Name: _____ Date of dispatch: _____ Vaccine: _____			

All text, other than the supplier information, is to be printed in the language option requested in the customer's order.

4.2.6 *Reverse face of card:* The reverse face of the card on which the indicator is mounted is to carry user instructions, printed in black. These instructions are to state clearly, in the general format set out below, how to use the card and how the indicator is to be interpreted. The manufacturer is to print the appropriate <start colour> and <end colour> on the card.

When a vaccine shipment arrives from the vaccine manufacturer, use the Cold Chain Monitor index reading to complete the Vaccine Arrival Report (VAR).

On the vaccine shipment record:
- fill in the date
- fill in the index (--,A,B,C and/or D)
- enter the name of the receiving store

Then transfer the index information to the Vaccine Arrival Report

If windows A, B, C & D are all <start colour>, use the vaccines normally.

If the windows A to C are completely <end colour>, but window D is still <start colour> this means that the vaccine has been exposed to a temperature above 10°C but below 34°C during shipment for the following number of days:

	INDEX		
	A	AB	ABC
At a temperature of 12°C	3 days	8 days	14 days
At a temperature of 21°C	2 days	6 days	11 days

If window D is <end colour> this means that the vaccine has been exposed during shipment to a temperature higher than 34°C for a period of at least two hours.

The instruction on the interpretation table <<use within three months>> is a general guide. The guidance should only be followed if:
- the vaccine expiry date will not be reached during the 3 month period.
- VVMs on the vaccine show that the vaccine is still good.
- use of heat-exposed vaccine is allowed by local cold chain policy.

Instructions are to be printed in the language option requested in the customer's order.

4.3 *Physical characteristics:*

4.3.1 *Overall dimensions:* Maximum 150 x 200mm, including mounting card.

4.3.2 *Weight:* Not critical.

4.4 *Interface requirements:* None.

4.5 *Human factors:*

4.5.1 *Indicator strip:* The colour change to be clearly visible to users with normal vision (with or without glasses).

4.5.2 *Mounting card:* The mounting card is to take writing in pencil, ball point pen, water-soluble and spirit-soluble marker pen.

4.6 *Materials:* The product is to be constructed of materials that are adequately robust and durable for the intended use. Materials used must be non-toxic and non-irritant to the end user and harmless to the environment.

4.7 *Reliability:* All batches of the product must be warranted to conform to the requirements of this specification.

4.8 *Servicing provision:* The product is to be maintenance-free.

4.9 *Disposal and recycling:* No requirement.

4.10 *Instructions:* An illustrated instruction insert describing the indicator activation procedure is to be supplied with every carton. Both the cards and the insert are to be made available in Arabic, English, French, Mandarin Chinese, Russian and Spanish versions.

Cards and inserts printed in other languages are to be supplied to special order, by arrangement.

4.11 *Training:* No requirement.

4.12 *Verification:* In accordance with PQS Verification Protocol **E06/IN02.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 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.
- Laboratory test report(s) proving conformity with the product specifications.
- One sample of the product together with activation instruction insert – both in English language .
- Indicative cost of the product per 100 units, per 1,000 units and per 10,000 units EXW (Incoterms 2000).

8. On-site maintenance:
Not applicable.

9. Change notification:

The legal manufacturer or reseller is 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 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
14 Mar 06	Specification redrafted. Normative references, definitions and additional clauses added.	To achieve conformity with PQS documentation standards	Yes (UK)
22 Sep 06	4.10: minor change. 5: 'CFC' changed to 'ozone-depleting'.	In response to final review comments.	Yes (UK)
29 Nov 06	4.2.5: Interpretation guide and supplier information has been changed	New assignments for vaccines were done based on the new temperature sensitivity information	Yes (30 Nov 2006 UK - PQS secretariat)