**Temperature Monitoring Devices Vaccine Storage and Distribution**

This document contains the following guidance related to Temperature Monitoring Devices Vaccine Storage and Distribution

- [Procurement Reference Guide](#)
- [Technical Reference Guide](#)

**Procurement Reference Guide**

This document offers specific commercial guidance and references to UNICEF Country Offices (COs) for ordering of Temperature Monitoring Devices. It can also be used as guidance for external partners as well. Technical details in this context are provided in the Technical Reference Guide for Temperature Monitoring Devices.

**Preparing the procurement of Temperature Monitoring Devices**

**a. Assessing the purpose of use**

Guidance on technical considerations in the context of Temperature Monitoring Devices can be found in the Technical Reference Guide for Temperature Monitoring Devices.

**b. Identifying available standard Temperature Monitoring Devices**

In general, the range of products available on international markets is large. It is recommended that COs consult with Supply Division (SD) to ensure that reliable temperature monitoring devices are chosen that are fit for purpose and that, wherever possible and available, are World Health Organization (WHO) Performance, Quality and Safety (PQS) pre-qualified. A number of Temperature Monitoring Devices are PQS pre-qualified, representing UNICEF's primary source of choice.

Each Temperature Monitoring Device possesses specific properties and UNICEF has a number of Long Term Arrangements (LTAs) for these to address individual country’s user preferences. Temperature Monitoring Devices for categories for which no LTA is in place are being procured through ad hoc tendering processes on the basis of individual country requests. While the range of PQS-listed devices should cover the user requirements from the central storage level down to single health facilities, SD is also able to procure other devices which have features of interest to countries in order to respond to their individual temperature monitoring and reporting requirements.

**c. Calculating timelines for receiving Temperature Monitoring Devices**

SD offers tools to assist COs to assess timelines for planning. The [TAD estimation tool](#) is helpful to identify a realistic arrival at point of unloading prior to COs raising a Sales Order with SD.

Standard supplier lead times for Temperature Monitoring Devices available on established LTAs are 1 to 4 weeks. This is calculated from the supplier’s receipt of the Purchase Order to delivery to the port of shipment ((INCOTERMS FCA), i.e. time for international transport has to be added. If the project is time critical you may [contact the Supply Division Cold Chain Unit](#) to obtain more specific information on estimated supplier lead times at a given point of time.

The [Freight Estimate Tools](#) will assist you in identifying the sea transit time and approximate shipping cost. Estimated Weight and Volume for standard Temperature Monitoring Devices are stated in the item specifications in the [UNICEF Supply Division Supply Catalogue](#).

---

E-mail: supply@unicef.org
www.unicef.org/supply
Considerations for Country Offices:
- Temperature Monitoring Devices are relatively low in weight and volume and hence the standard mode of shipment even for larger quantities is by air. If in doubt, COs can contact SD for detailed information on the weight and volume of the different devices.
- Requests for Central Monitoring Systems for Cold and Freezer Rooms should consider the need for installation and the potential necessity to customise the system according to the circumstances at the installation site. Ample time for site assessment and installation should be calculated in the overall timing of the procurement process.
- Requests for non-standard devices can add up to an additional 2-3 months in the procurement process due to necessary tender processing. Supplier lead times may be longer than for LTA standard devices.
- Based on technical review of incoming country requests for non-standard Temperature Monitoring Devices, SD may suggest alternative standard devices to be procured instead, unless specific reasons prevent the use of a standard device.

Please contact the Supply Division Cold Chain Unit for any related queries.

Technical Reference Guide

This document provides specific technical guidance and references to UNICEF Country Offices for Temperature monitoring devices in a procurement context. Procurement related guidelines are provided in the Procurement Reference Guide for Temperature monitoring devices.

Contents
Temperature Monitoring Devices Vaccine Storage and Distribution
Procurement Reference Guide
Technical Reference Guide
1. General / Introduction
2. Classification of the different types of cold chain temperature monitoring device
3. Application of the different types of cold chain monitoring device
   3.1. Central temperature monitoring system (TR03)
   3.1.1 Description
   3.1.2 Smart view
   3.1.3 Beyond wireless
   3.1. Multilog with 8, 12,16, and 24 sensors (Non PQS)
   3.2. Pen chart recorder with charts for 7 days (Non PQS)
   3.3. User programmable temperature data logger (TR05)

E-mail: supply@unicef.org
www.unicef.org/supply
1. **General / Introduction**

Vaccines are biological products that could lose their potency if exposed to excessive heat and/or freezing. Different vaccines have different sensitivity to freezing and heat; it is because of this that monitoring the temperature of vaccines during storage and transportation remains vital.

Temperature monitoring devices are needed to keep track of the temperature to which the vaccines and diluents are exposed. Based on the data from these devices important decisions may be made. This includes using the vaccine if the temperature is within the recommended range, conducting a shake test if freezing is suspected or discarding the vaccine. Link to Shake Test

Temperature monitoring devices are used from point of dispatch of vaccines to the point of use, this means that they are used when shipping the vaccine from manufacturer to primary vaccine stores, during storage at the primary vaccine stores, transportation from primary store to point of use and at district levels and primary health care centres (PHCs) where vaccines are to be stored.
The tables below show the sensitivity of different vaccines to heat and freezing:

<table>
<thead>
<tr>
<th>Heat</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>most sensitive</td>
<td>Oral poliovirus</td>
</tr>
<tr>
<td></td>
<td>Varicella-zoster virus</td>
</tr>
<tr>
<td></td>
<td>Influenza (inactivated, split)</td>
</tr>
<tr>
<td></td>
<td>Inactivated poliovirus</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (live)</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps, rubella</td>
</tr>
<tr>
<td></td>
<td>Cholera (inactivated)</td>
</tr>
<tr>
<td></td>
<td>DTaP</td>
</tr>
<tr>
<td></td>
<td>DTwP</td>
</tr>
<tr>
<td></td>
<td>DTaP-hepatitis B-Hib-IPV (hexavalent)</td>
</tr>
<tr>
<td></td>
<td>DTwP-hepatitis B-Hib (pentavalent)</td>
</tr>
<tr>
<td></td>
<td>Hib (liquid)</td>
</tr>
<tr>
<td></td>
<td>Measles</td>
</tr>
<tr>
<td></td>
<td>Rotavirus (liquid and freeze dried)</td>
</tr>
<tr>
<td></td>
<td>Rubella</td>
</tr>
<tr>
<td></td>
<td>Yellow fever</td>
</tr>
<tr>
<td>least sensitive</td>
<td>Bacillus Calmette-Guérin</td>
</tr>
<tr>
<td></td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td></td>
<td>Japanese encephalitis (inactivated)</td>
</tr>
<tr>
<td></td>
<td>T, DT, dT</td>
</tr>
<tr>
<td></td>
<td>Hepatitis A</td>
</tr>
<tr>
<td></td>
<td>Hepatitis B</td>
</tr>
<tr>
<td></td>
<td>Hib (freeze dried)</td>
</tr>
<tr>
<td></td>
<td>Meningitis A (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Meningitis C (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal (polysaccharide-protein conjugate)</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
</tr>
<tr>
<td></td>
<td>Typhoid PS</td>
</tr>
<tr>
<td>Freezing</td>
<td>Vaccine</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>most sensitive</td>
<td>DTaP&lt;br&gt;DTaP-hepatitis B-Hib-IPV (hexavalent)&lt;br&gt;DTwP&lt;br&gt;DTwP-hepatitis B-Hib (pentavalent)&lt;br&gt;Hepatitis A&lt;br&gt;Hepatitis B&lt;br&gt;Human papillomavirus&lt;br&gt;Meningitis C (polysaccharide-protein conjugate)&lt;br&gt;Pneumococcal (polysaccharide-protein conjugate)&lt;br&gt;T, DT, dT&lt;br&gt;Cholera (inactivated)&lt;br&gt;Influenza (inactivated, split)&lt;br&gt;Hib (liquid)&lt;br&gt;Inactivated poliovirus&lt;br&gt;Typhoid PS&lt;br&gt;Meningitis A (polysaccharide-protein conjugate)*&lt;br&gt;Rotavirus (liquid and freeze dried)&lt;br&gt;Yellow fever&lt;br&gt;Bacillus Calmette-Guérin&lt;br&gt;Hib (freeze dried)&lt;br&gt;Japanese encephalitis (live and inactivated)&lt;br&gt;Measles&lt;br&gt;Measles, mumps, rubella&lt;br&gt;Oral poliovirus&lt;br&gt;Rabies&lt;br&gt;Rubella&lt;br&gt;Varicella-zoster virus</td>
</tr>
<tr>
<td>least sensitive</td>
<td></td>
</tr>
</tbody>
</table>
2. Classification of the different types of cold chain temperature monitoring device

There are several types of cold chain monitoring device which can be classified based on the supply chain level they are used and the purposes they serve.

Temperature monitoring devices can be classified based on their purpose as follows:

A. Condition indicators; these are indicators like the Vaccine Vial Monitor (VVM) and Irreversible Freeze Indicator.

B. Temperature readers; this includes bimetallic and stem thermometers which shows the instantaneous measurement (no longer recommended).

C. Temperature recorders; this includes data loggers which measure and record the data over a longer period of time.

Temperature monitoring devices can also be classified based on the level in which they can be used.

Cold room and freezer room:

- Pen chart recorder (TR04)
- Programmable electronic temperature data logger (TR05)
- Event logger systems with integral alarm and auto-dialer options (TR03)

Refrigerators and freezers:

- 30 day electronic refrigerator data logger (TR06)

Transportation in cold boxes and vaccine carrier:

- Irreversible freeze indicators (INO3),
- Electronic shipping indicators (TR07),
- Cold chain monitors (IN02)

3. Application of the different types of cold chain monitoring device

3.1. Central temperature monitoring system (TR03)

3.1.1 Description

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.
**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).

**Door open sensor:**
A device that detects whether a door is open or closed.

**Voltage sensor:**
A device that records the incoming mains voltage supplying the vaccine store.

**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 personal computer (PC). Such devices may also include a visual display and/or an audible alarm sounder.

**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 onboard memory and power supply (‘active’ base station) or it may act as a router directly connected to a PC (‘passive’ base station).

**PC:**
Typically the base station is connected to a PC. The PC and its peripherals are used to store, display and print temperature and event records.

**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.

**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.

**Application software:**
System-specific software which is designed to drive the system elements described above.

**Mode of operation:**
Always on.

**3.1.2 Smart view**
Radio frequency (RF) receiver and General Packet Radio Service (GPRS) internet gateway for real time temperature monitoring of cold/freezer rooms or facility temperature monitoring.

RF. This is a monitoring network that uses wireless communication for continuous monitoring. The receiver/gateway communicates with battery operated wireless temperature sensors that are placed in storage facilities. These sensors contain a temperature and/or humidity sensor, but also function as wireless data loggers. The measured data is uploaded to and analysed by a secured central database. In case of a temperature excursion or a door left open in a cold or freezer room or facility, a flashing light turns on and automated emails and or SMS alerts are sent to user configurable addresses.

E-mail: supply@unicef.org
www.unicef.org/supply
GPRS: This is a flexible web-based software platform that collects data from various locations into an integrated real-time view. The software platform creates real-time visibility, alerts, history reports, analysis and is accessible via Login and Password through any web browser without installation of any software.

Berlinger E006/019

3.1.3 Beyond wireless
Beyond wireless is a device to constantly monitor the temperature of cold/freezer rooms. All sensors (analogue and digital) are cable connected to this unit. This is also referred to as the BeyondCom Unit. The unit stores data in the erasable programmable read only memory (EPROM) and sends it through a Global System for Mobile Communications (GSM) connection to a Beyond Wireless database portal through the Internet. The server is referred to as the Intelliswitch. The analogue and digital sensor capability makes it possible to monitor various parameters such as temperature, humidity, door access, power supply, generator function, fuel levels, etc. The Intelliswitch server is capable of alarm and resolution notifications via GSM based SMS and email. The alarm notification can be set up to handle progressive levels for escalation when resolution is not affected within a set period of time by each level.

Beyondwireless E006/025

3.1. Multilog with 8, 12,16, and 24 sensors (Non PQS)
Multilog is a device used to constantly monitor the temperature of cold/freezer rooms via a computer. The device is equipped with a built in audio alarm and an optional automatic dial out facility, and can monitor the temperature in up to 16 locations simultaneously.

This device can be configured to suit user requirements by adjusting parameters such as logging interval, measurement unit (°C or °F), auto download, site location and data files location. It requires software for configuring and downloading the data to the computer.

The devices are used mostly in cold and freezer rooms where bulk vaccines are stored and temperature monitoring is crucial for vaccine security in country programmes.

This device is not yet pre qualified by WHO.

3.2. Pen chart recorder with charts for 7 days (Non PQS)
The pen chart recorder is an instrument used to record the temperature of cold/freezer rooms for a given period of time, usually 7 days. This instrument records the temperature on paper, the paper is passed under a pen and the pen is deflected in proportion to the temperature and the result is a graph or chart of the temperature.

The 7 day wall-mounted pen recording thermometer should be mounted on the outer side of the cold room to make reading easier. The device should be fitted with alarm contacts and a door open sensor linked to the alarm system.

The pen which is used in the chart recorder is usually of the inkless or refillable type. The devices operate on a 110/240 volts 60/50 Hz power source and has a replaceable backup battery with a 48hr charge capacity.

The paper from the chart recorder should be kept in a safe place for audit purposes.
This type of chart recorder can be used to measure the temperature of either cold or freezer rooms.

E-mail: supply@unicef.org
www.unicef.org/supply
This device is a secondary back up to the electronic devices but is no longer a part of the PQS listing.

3.3. User programmable temperature data logger (TR05)
The user programmable temperature data logger is a battery operated device which measures and stores data for a longer period of time. This device does not necessarily display the data instantly; instead the data is downloaded by USB or cable to a computer for later analysis. The data logger functions as a “reusable cold chain temperature monitor” for use mainly in cold chain studies, vaccine refrigerators and freezers.

Prior to using this device, it must be configured. The date, time, recording interval, unit of measure, etc., can be configured according to user preference. This information will facilitate better decision-making, especially when the device is used for cold chain study purposes; it shows the exact time the temperature falls outside the recommended range.

Cables and software will usually be included with the device. PQS E006 TR05

3.4. 30 day electronic temperature logger (TR06)
This device is used to measure and log the temperature inside the refrigerator cabinet for a period of 30 days. The device makes it possible for users to read the maximum and minimum logged temperatures for each day via a ‘history mode’ function. If, at any time during the 30 day cycle the temperature in the cabinet exceeds the high/low alarm setting for certain period, the device will display the relevant alarm condition(s). At the end of the 30 day cycle the device will continue the temperature and alarm monitoring process by incrementally overwriting data older than 30 days.

The temperature display unit will be physically attached to the outside of the cabinet and the sensor lead will pass through the door seal. The sensor head is to be physically attached to the inside of the refrigerator or freezer in a position which accurately measures the load temperature.

The device is operated from a non-replaceable battery with a minimum operating life of two years from the date of activation. The device must be activated within twelve months of receipt in storage.

This device is used as a means for monitoring storage conditions in vaccine refrigerators in intermediate stores and health facility levels. The device may also be used as a, secondary back-up temperature monitoring device in cold rooms. Berlinger Fridge Tag 2 E006/020  Log tag TRID30-7FW E006/013  Berlinger Fridge tag E006/003

3.5. Dial thermometer (TH02)
The vapour pressure dial thermometer is a mechanical device that uses a metal pointer on a circular scale to indicate temperature measurements. The device has two primary components; the metal pointer or needle, and a temperature sensor.

The sensor is liquid, gas filled or vapor-tension-based which works on the principle of expansion and contraction. As the liquid expands or contracts in response to the temperature changes, the resulting pressure moves the needle on the scale.

This device is used to monitor temperatures in fixed cold chain equipment and classified into Type A and Type B devices:

Type A devices are typically supplied as part of a cold room or freezer room installation.

E-mail: supply@unicef.org
www.unicef.org/supply
Type B devices are supplied as an integrated component in vaccine refrigerators and freezers
Rueger SA E006/012

3.6. Electronic freeze indicator (IN03)
The irreversible freeze indicator is a single alarm electronic temperature indicator providing an
irreversible display of temperature exposure relative to the alarm setting of < -0.5 °C for a
continuous period of 60 minutes. If the indicator is exposed to conditions exceeding the alarm
setting, the display changes from a “√” to an “X”, informing the user of the triggered alarm state.
The device contains an integrated push-button switch for field activation and a dynamic “dot” icon
which affirms active monitoring. The recorded data cannot be manipulated by anyone as it is
irreversible.

This device is used to monitor temperature during storage and in-country distribution.

Before the advent of these devices, data recorded manually on temperature record sheets had the
potential for manipulation to give false-safe storage temperature compromising health and safety
of the children administered with vaccines.
Berlinger Freeze tag E006/007 Sensitech Freeze alert E006/009 Berlinger Q tag Quad E006/015

3.7. Cold chain monitor (IN02)
The cold chain monitor (CCM) is a paper-based temperature monitoring device using time-
temperature sensitive indicators which change color irreversibly and at a constant rate. Indicator
strips are attached to a card on which instructions for use are printed.

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

Time temperature function: The indicators respond to temperature exposure as follows:
+10°C indicator: 14 days to full scale color change at +12°C. The +10°C indicator strip is
mounted behind three equal sized windows marked ‘A’, ‘B’ and ‘C’ so that users can clearly
identify three distinct stages in the color change process.
+34°C indicator: 3 hours to full scale color change at 37°C.
Berlinger E006/004

3.8. Vaccine vial monitor (IN05)
The VVM is a circular indicator, printed directly on the vaccine vial label or affixed to the top of the
vial or ampoule. The inner square of the VVM is made of heat-sensitive material that is initially
light in colour and becomes darker when exposed to heat over time. By comparing the colour of
the square to the reference ring, health workers can determine the extent to which the vaccine
has been exposed to heat. The vaccine can be used as long as the colour of the inner square is
lighter than that of the reference ring.

The principal purpose of this product is to warn health workers when the cumulative heat
exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be
used. This is defined as the end point.

<table>
<thead>
<tr>
<th>VVM Category</th>
<th># days to end point at +37°C</th>
<th># days to end point at +25°C</th>
<th>Time to end point at +5°C</th>
</tr>
</thead>
</table>

E-mail: supply@unicef.org
www.unicef.org/supply
<table>
<thead>
<tr>
<th>VVM 30: (High stability)</th>
<th>30</th>
<th>193</th>
<th>&gt; 4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>VVM 14: (Medium stability)</td>
<td>14</td>
<td>90</td>
<td>&gt; 4 years</td>
</tr>
<tr>
<td>VVM 7: (Moderate Stability)</td>
<td>7</td>
<td>45</td>
<td>&gt; 4 years</td>
</tr>
<tr>
<td>VVM 2: (Least stable)</td>
<td>2</td>
<td>N/A</td>
<td>225 days</td>
</tr>
</tbody>
</table>

There are four different types of VVMs designed for different types of vaccines depending on their heat stability; VVM2, VVM7, VVM14 and VVM30. The numbers indicate the number of days the VVM reaches the end point at a temperature of 37°C.

For liquid vaccines, the VVM is permanently attached to the vaccine vial, even after the vial has been opened and remains readily observable before, during and after use.

For freeze-dried vaccines: The VVM is attached to the vaccine vial or ampoule and remains readily observable until the vial or ampoule is opened but not observable after opening.

### 3.9. Electronic Shipping Indicator (TR07)

These are irreversible electronic temperature indicators that show if a product, such as a vaccine, has been exposed to temperatures beyond the assigned alarm settings.

They consist of an electronic temperature measuring circuit with associated LCD display. As long as the temperature is within the allowed range, the “OK” sign is shown on the display. If the indicator is exposed to an out-of-range temperature the “ALARM” sign appears on the display.

Other information that can be displayed on these devices includes;
1. Actual elapsed transport time with “ALARM” sign and violated alarm condition.
2. Actual elapsed transport time since start with “OK” sign.
3. Extreme temperatures can be read out by every time segment.
4. Exact time since START until the alarm occurrence.

The electronic shipping indicators are attached onto a card which provides instructions for senders and receivers.

This electronic temperature indicator is used to monitor all kinds of shipments of vaccines and other perishable goods. This device is not re-usable once alarm conditions are triggered or the programmed time elapses.

Berlinger Q tag 2 E006/002  Sensitech Vax Alert E006/010  Berlinger Q tag CLM E006/014  Berlinger Q tag CLM Doc E006/016

[Link to Temperature monitoring devices PQS](https://www.unicef.org/supply)

Please contact the [Supply Division Cold Chain Unit](https://www.unicef.org/supply) for any related queries.