

COLD CHAIN

SUPPORT PACKAGE

PROCUREMENT GUIDELINES

TEMPERATURE MONITORING DEVICES

Procurement Guidelines

Temperature Monitoring Devices

Key information for UNICEF staff and partners, ensuring the effective and efficient procurement of Cold Chain equipment.

This module gives guidance to the procurement of temperature monitoring devices for vaccine storage and distribution.

Always make sure that you have the latest version of this document by checking the [CCSP website](#).

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Suggestions and feedback: sd.coldchain@unicef.org

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Acronyms

CCSP	Cold Chain Support Package
CO	Country Office
DOA	Direct Order Arrangement
LTA	Long Term Arrangement
PHC	Primary Health Care
PQS	Performance Quality and Safety
PQT	Prequalification Team
PS	Procurement Services
SD	Supply Division (UNICEF)
VC	Vaccine Carrier
VVM	Vaccine Vial Monitor
WHO	World Health Organization
WIC	Walk-In Cold Room
WIF	Walk-In Freezer Room

1 Introduction to Temperature Monitoring

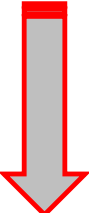
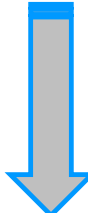
Vaccines are biological products that can lose their potency if exposed to excessive heat and/or freezing. Different vaccines have different sensitivity to freezing and heat; it is because of this phenomenon that monitoring the temperature of vaccines during storage and transportation is vital.

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 excursion 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. They are used when shipping the vaccine from the manufacturer to primary vaccine stores, during storage at the primary vaccine stores, during transportation from primary store to intermediate/district level stores and at Health Facilities (HFs) and out-reach services where vaccines are stored/transported and administered to the recipient.

The Figures below gives an indication of the level of sensitivity of different vaccines to heat and freezing.

Fig 1. Sensitivity of Vaccines to Heat and Freezing¹

Heat	Vaccine	Freezing	Vaccine
Most Sensitive	Oral poliovirus Varicella-zoster virus	Most Sensitive	DTaP DTaP-hepatitis B-Hib-IPV (hexavalent) DTwP
	Influenza (inactivated, split) Inactivated poliovirus Japanese encephalitis (live) Measles, mumps, rubella		DTwP-hepatitis B-Hib (pentavalent) Hepatitis A Hepatitis B Human papillomavirus Meningitis C (polysaccharide-protein conjugate) Pneumococcal (polysaccharide-protein conjugate) T, DT, dT
Least Sensitive	Cholera (inactivated) DTaP DTwP DTaP-hepatitis B-Hib-IPV (hexavalent) DTwP-hepatitis B-Hib (pentavalent) Hib (liquid) Measles Rotavirus (liquid and freeze dried) Rubella Yellow fever Bacillus Calmette-Guérin Human papillomavirus Japanese encephalitis (inactivated) T, DT, dT Hepatitis A Hepatitis B Hib (freeze dried) Meningitis A (polysaccharide-protein conjugate) Meningitis C (polysaccharide-protein conjugate) Pneumococcal (polysaccharide-protein conjugate) Rabies Typhoid PS	Least Sensitive	Cholera (inactivated) Influenza (inactivated, split) Hib (liquid) Inactivated poliovirus Typhoid PS Meningitis A (polysaccharide-protein conjugate)* Rotavirus (liquid and freeze dried) Yellow fever Bacillus Calmette-Guérin Hib (freeze dried) Japanese encephalitis (live and inactivated) Measles Measles, mumps, rubella Oral poliovirus Rabies Rubella Varicella-zoster virus

¹ Source: Sensibilité des vaccins à la température, Les Températures Recommandés par l'OMS pour le stockage des vaccins (PATH/WHO, 2014)

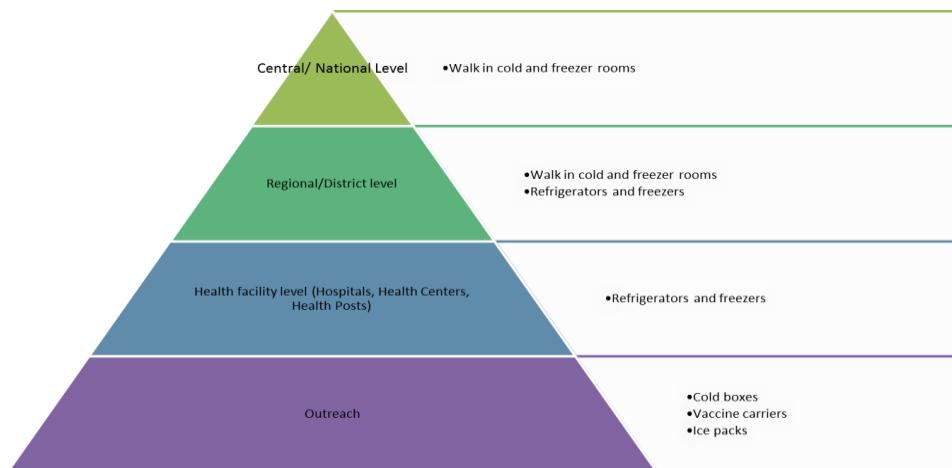
Cold Chain temperature monitoring devices can be classified based on the supply chain level at which they are used and also on the purpose they serve. For the purpose of this manual, we classify devices based on the category level of product where they are used.

2 Classification of Temperature Monitoring Devices

2.1 Categories of Application

Cold Chain equipment is used at various levels, as shown in the figure below.

Fig 2. Cold Chain Equipment by Level of Use



For the purpose of this guideline, Temperature Monitoring Devices are categorized by level of application, as follows:

- Devices for Cold Rooms and Freezer Rooms
- Devices for Refrigerators and Freezers
- Devices for Transportation in Cold Boxes and Vaccine Carriers

2.2 Devices for Cold Rooms and Freezer Rooms

2.2.1 Central Temperature Monitoring System

These are 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 where WICs and/or WIFs are installed. Systems must be configurable to suit specific applications, and scalable 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 on-board 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.



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At the Ministry of Health national vaccine store in Vientiane, Lao People's Democratic Republic, boxes of vaccine are stored in sub-zero conditions. This worker checks the temperature of the cold rooms.

Central TMS, Example 1: Smart View

The Smart View is a 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. The network 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.

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.

Central TMS, Example 2: 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 also 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.

2.2.2 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.

2.2.3 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 safe place for auditing purposes. This type of chart recorder can be used to measure the temperature of either Cold or Freezer rooms.

This device is a secondary back up to the electronic devices but is no longer a part of the PQS listing.

2.3 Devices for Refrigerators and Freezers

2.3.1 User Programmable Temperature Data Logger

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.

2.3.2 30 Day Electronic Temperature Logger

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.

2.3.3 Dial Thermometer

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 vapour-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. Type A devices are typically supplied as part of a Cold Room or Freezer Room installation. Type B devices are supplied as an integrated component in vaccine refrigerators and freezers.

2.4 Devices for Transportation in Cold Boxes and Vaccine Carriers

Monitoring of temperature during transport, mainly in Cold Boxes and Vaccine Carriers, but also in refrigerated trucks and other means of transport.

2.4.1 Electronic Freeze Indicator

This device is used to monitor temperature during storage and in-country distribution. The irreversible freeze indicator is a single alarm electronic temperature indicator providing an irreversible display of temperature exposure relative to the alarm setting of $< -0.5^{\circ}\text{C}$ for a continuous period of 60 minutes. If the indicator is exposed to conditions exceeding the alarm setting, the display changes from a “V” 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.



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A worker rides a donkey, who is hauling an insulated carrier filled with polio vaccines, in the remote mountain village of Gartail in Pakistan. Other workers walk behind them, vaccine carriers in hand

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.

2.4.2 Cold Chain Monitor

The Cold Chain Monitor (CCM) is a paper-based temperature monitoring device using time-temperature sensitive indicators which change colour 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 colour 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 colour change process.
- +34°C indicator: 3 hours to full scale colour change at 37°C.

2.4.3 Vaccine Vial Monitor (VVM)

The VVM is a round 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 1. VVM times to end point

VVM Category	Time to end point		
	at +37 °C	at +25 °C	at +5 °C
VVM 30 (High stability)	30 days	193 days	> 4 years
VVM 14 (Medium stability)	14 days	90 days	> 4 years
VVM 7 (Moderate stability)	7 days	45 days	> 4 years
VVM 2 (Least stable)	2 days	n/a	225 days

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.

2.4.4 Electronic Shipping Indicator

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:

- a) Actual elapsed transport time with “ALARM” sign and violated alarm condition.
- b) Actual elapsed transport time since start with “OK” sign.
- c) Extreme temperatures can be read out by every time segment.
- d) 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 kind of shipments of vaccines and other perishable goods. This device is not re-usable once alarm conditions are triggered or the programmed time elapses.

3 Devices Supplied by UNICEF SD

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-qualified². 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)³ for these to address individual country’s user preferences. UNICEF exclusively supplies devices that fulfil the quality requirements set by WHO. UNICEF SD procures the following Temperature Monitoring Devices via Long Term Arrangements (LTA):

Table 2. Temperature Monitoring Devices supplied by UNICEF SD (LTA, 2014)

Product Description
30-day Electronic Refrigerator Logger
Temperature indicator comprising a combination of a freeze-tag indicator and vaccine cold chain monitor card
Irreversible freeze indicators for detecting exposure of freeze-sensitive vaccines to temperatures below -0.5°C during transport or storage
Log Tag LTI/USB Interface Cradle and Log Tag Analyzer Operating Software on CD for Log Tag 30 Day Temperature Recorders
Thermometer for vaccine storage
Vaccine cold chain monitoring cards
Central temperature monitoring system - Programmable electronic temperature and event logger with integral alarm and auto dialler option

² UNICEF SD procures pre-qualified and listed equipment that conform to the WHO guidelines for developing countries and those in transition.

³ UNICEF SD establishes Long Term Arrangements (LTAs) with product suppliers, with terms and conditions, usually for a period of 24 months, on a non-exclusive basis for the repeated purchase of specified products and services (refer to General Procurement Guidelines for more details).

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, products for temperature monitoring which closely match compliance to PQS standards but are not listed in the PQS can be procured on special request with justification from the requesting country.

4 Devices in the WHO PQS

Click on [this link](#) to view Temperature Monitoring Devices in the WHO PQS Catalogue, with performance specifications and verification protocols.

5 How to Order

5.1 The Ordering Process

Refer to the [General Procurement Guidelines](#) document and the UNICEF SD [Procurement Services](#) website for general guidance on how to order products. Please contact the [Supply Division Cold Chain Unit](#) for specific queries related to ordering Temperature Monitoring Devices.

5.2 Considerations for Country Offices

- a) 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. Estimated Weight and Volume for standard Temperature Monitoring Devices are stated in the item specifications in the UNICEF Supply Division Supply Catalogue.
- b) Requests for Central Monitoring Systems for Cold and Freezer Rooms should consider the need for installation and the potential necessity to customize 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.
- c) Bear in mind that the cost of the hardware components of Central Monitoring Devices may be low, but additional system components and services may be costly. Consider the need for computer equipment, software requirements, installation of the system, cost of replacing sensors and telecommunication cost (e.g. GPRS).
- d) 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.
- e) 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.

5.3 Delivery lead time

For estimated supplier lead times, refer to the section 'When to Order' in the document '[General Procurement Guidelines](#)'.

Annex 1: Additional Resources

Links to additional resources on Temperature Monitoring Devices.

Description	Source
Introduction to electronic temperature monitoring devices for international vaccine shipments and refrigerators	WHO Website on Immunization Standards: WHO training videos for electronic temperature monitoring devices. Click here .
Videos on Shake Test: 'Shake and tell' & 'Step-by-step'.	Berlinger videos: Click here .
Handbook for Vaccine and Cold Chain Handlers	UNICEF Website (India)
LogTag Vaxtag setup guide	YouTube Link , Download Link
Fridge-Tag 2 Setup Guide and User Guide	YouTube Link , Download Link

Note: Users of this manual are invited to suggest additional resource materials, to add to this list.

Annex 2: Record of Revisions

Date	Description	By
April 1, 2012	First draft of this manual, by UNICEF SD\HTC\Cold Chain Unit	GK,DH,AS
June 26, 2014	Second draft of this manual	BR
August 9, 2014	Updated, minor corrections and additions	BR
October 28, 2014	YouTube Clips added in Annex 1	DH, BR