Temperature and humidity monitoring systems for transport operations

Technical supplement to

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

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Abbreviations

AWB  Air Way Bill
CI    Chemical Indicator
CRT   Controlled Room Temperature
ETI   Electronic Temperature Integrator
EDLM  Electronic Data Logging Monitor
IATA  International Air Transport Association
NIST  National Institute of Standards and Technology (USA)
NOTOC Notice to Captain
PDA   Parenteral Drug Association
SOP   Standard Operating Procedure
TTI   Time-Temperature Integrator
TTSPPP Time- and Temperature-Sensitive Pharmaceutical Product
ULD   Unit Load Device
URS   User Requirements Specification
**Glossary**

**3PL:** Third party logistics provider: a firm that provides service to its customers of outsourced (or "third party") logistics services for part, or all of their supply chain management functions.

**4PL:** Fourth party logistics provider: a general contractor who manages other 3PLs, truckers, forwarders, custom house agents, and others, essentially taking responsibility for a complete logistics process for the customer.

**Ancillary packaging components:** Articles of packaging used to protect the TTSP and support or enhance performance of the completed package. This may include retainers, dunnage, secondary protective packaging, and temperature data logging devices.

**Chemical indicators:** (also called markers or phase-change indicators), are generally impregnated onto a paperboard substrate. These indicators, sometimes referred to as critical temperature indicators, are based on a phase change or chemical reaction that occurs as a function of temperature. Examples include liquid crystals, waxes, polymers, and lacquers that change phase, and thereby their appearance, as a function of temperature. Chemical temperature threshold indicators may be reversible or irreversible and are suitable for high or low temperatures. Temperature threshold indicators show a response and typically are single-use devices. These indicators provide a signal only when exposed to temperatures higher than (ascending indicator) or lower than (descending indicator) a predetermined threshold temperature.

**Critical Control Point:** A step, process or procedure at which an action can be applied to prevent or reduce risk or hazard to an acceptable (critical) level.

**Electronic Data Integrator (EDI):** A hybrid electronic instrument intelligently programmed like an Electronic Temperature Indicator (ETI) with the report/data producing capabilities of an Electronic Data Logging Monitor (EDLM) that combines the features and functions of a Go/No-go device with the record retention and data tracking of an EDLM but with greater granularity and data management flexibility. It uses pre-programmed temperature threshold intelligence to integrate post-analytic functional steps that are typically performed by trained personnel.

**Electronic Data Logging Monitor (EDLM):** A small portable device that measures and stores temperature at a pre-determined time intervals by means of an electronic sensor. They have programmable alarm capabilities, integrated displays, and can create reports and graphs which may be permanently stored, shared and analysed via proprietary hardware, software, desktop application or through hosted databases.

**Electronic temperature monitoring and event logger system:** System for recording and reporting air and/or product temperatures, with optional facilities for recording and reporting specific events such as door-opening or defrost cycles, and for issuing alarms. Such systems may be user-programmable and may also be remotely monitored via a satellite link.

**Electronic Temperature Indicator (ETI):** A compact, portable device that measures, temperature over time by means of a built-in sensor. They come in a wide range of forms, features, configurations, cost and levels of performance. Their composition consists of four...
basic components: a thermistor sensor, a microprocessor, a memory chip, and power source (lithium battery). They provide either a single temperature threshold or multiple alarm thresholds. These devices are employed for simple accept / reject decision making, and their time and temperature accuracy is quite precise.

**External distribution:** Transport of TTSPPs through various steps in the customer’s supply chain (i.e. transport from a pharmaceutical manufacturer’s distribution centre, to commercial customers (including wholesalers, retailers and buying groups), to clinical facilities or direct to the patient). Contrast with *internal distribution*.

**Humidity (Relative Humidity):** The partial pressure of water vapour in air to the vapour pressure of saturated air at a given temperature. In other words, the relative humidity is the amount of water vapour present, divided by the theoretical amount of moisture that could be held by that volume of air at a given temperature.

**Internal distribution:** Transport of a TTSPP within a pharmaceutical manufacturer’s internal supply chain (i.e. all internal transports from manufacturing facility to packaging facility to warehouse to distribution centre). Contrast with *external distribution*.

**Passive systems:** Systems which maintain a temperature-controlled environment inside an insulated enclosure, with or without thermostatic regulation, using a finite amount of pre-conditioned coolant in the form of chilled or frozen gel packs, phase change materials, dry ice or others.

**Pharmaceutical product:** Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices

**Refrigerated vehicles:** Road transport vehicles such as vans, trucks and semi-trailers whose isolated thermostatically controlled cargo compartment maintains the temperature at all times within the labelled range of the product being transported.

**Refrigeration equipment:** The term ‘refrigeration’ or ‘refrigeration equipment’ means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

**Service Level Agreement (SLA):** A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes

**Shipping container or shipping system:** All components constituting a completed package including: the outer shipping container, all internal ancillary packaging components and temperature stabilizing medium.

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2 Definition from IATA, Chapter 17, 9th Edition, June 2013.
**Standard Operating Procedure (SOP):** A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

**Storage temperature:** The temperature range listed on the TTSPP label, and within the regulatory filings, for long-term storage.

**Temperature excursion:** An event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

**Temperature stabilizing medium:** Ice or gel packs; gel bricks, bottles or pouches; cool water or warm water packs, phase change materials, dry ice, rapid evaporation media.

**Temperature-controlled vehicles:** Road transport vehicles such as trucks tractor-trailers and vans whose isolated thermostatically controlled cargo compartment is maintained within a specified temperature range through the use of a dedicated refrigeration and/or heating unit.

**Temperature-controlled:** Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise pre-defined limits.

They typically use liquid diffusion technology to signal when a single event time-temperature threshold has been exceeded by irreversibly changing colour, either instantaneously or with some time delay. The active colloidal substance in freeze indicators is typically composed of particles of material evenly distributed within a liquid. At a specific relative temperature the particles in the marker colloid become unstable, eliminating the repulsive forces that keep the particles separate. The chemicals coagulate, resulting in a change of colour. The accuracy and precision of these indicators depend to some extent on human interpretation.

**Time and temperature sensitive pharmaceutical product (TTSPP):** Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

**Time-Temperature Integrators (TTI's):** Are generally chemically impregnated onto a pulp or paperboard substrate. Their reaction rate or diffusion process is used to estimate a temperature equivalent integrated over time. Thus, TTIs provide a measure of accumulated heat rather than instantaneous temperature such as a spike or critical threshold (see Chemical Indicators). The reactions generally are irreversible—once a colour change, colour development, or diffusion process has taken place, exposure to low temperatures will not restore the indicator to its original state. The accuracy and precision of these indicators depend to some extent on human interpretation. They change colour, or are marked by a hue progression in intensity (generally from light to dark) in response to cumulative changes in temperature, such as heat, at a rate dependent on the Arrhenius Equation. A TTI accumulates all of the temperature conditions experienced by the product to which it is affixed. The colour development can be customized based on the known stability of the product, and in much the same way that most biologics and
pharmaceuticals degrade when exposed to heat - faster at higher temperatures, and slower at lower temperatures.

**Transport temperature profile:** Anticipated ambient temperature variation and duration to which a TTSPP may be exposed during transport.

**Unit Load Device (ULD):** A container used for consolidating and transporting cargo aboard aircraft. They are generally made of aluminium and or fibreglass and configured to fit the geometry of an aircraft and are considered part of the aircraft frame. Large Active Systems fall into the category of ULD.

**User Requirement Specification (URS):** The attributes assigned by the user in advance of a qualification test to establish minimum performance limits.

**Validation:** Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.³

1. Introduction

This technical supplement has been written to amplify the recommendations given in section 6.5 and Section 9 of WHO Technical Report Series No. 961, 2011, Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.

The strength, efficacy, and potency of a drug can be profoundly degraded by changes in temperature. Some products may also be affected by exposure to adverse humidity levels.

It is not always possible completely to prevent degradation during transport, but damage can be minimized through good handling and storage practices, by qualifying the mode and route of transport, and by using qualified packaging.

For quality assurance purposes, stakeholders in the supply chain must be able to supply documentary evidence that the drug product has not exceeded the acceptable limits of time, temperature and humidity exposure, as determined by the drug manufacturer’s stability data for the product. This evidence is supplied by recording devices and technologies that provide a history of exposure to temperatures and/or humidity during transport and external distribution.

Effective temperature and humidity monitoring is an important component of Good Distribution Practice (GDP) and can only be achieved if close attention is paid to the relevant Critical Control Points.

The following Technical Supplements are also relevant:

- Qualification of temperature-controlled road vehicles.
- Qualification of shipping containers.
- Transport route profiling qualification.
- Temperature-controlled transport operations.

1.1 Requirements

Generally speaking, the shipper is responsible for ensuring product temperature compliance during transport. Shippers should operate under the terms of a formal Service Level Agreement with their carrier(s) or logistics service provider(s) i.e. freight-forwarder, 3PL, 4PL or integrator. If shipping operations are carried out in-house, they should be controlled by a comprehensive set of SOPs.

SLAs and SOPs must clearly specify the types of temperature and humidity monitoring device that are to be used, when and where they are to be employed, and how the data they generate should be collected, reported and stored.

1.2 Objectives

The objective of the Technical Supplement is to provide:

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5 Note that it is generally considered that humidity exposure data has a minimal effect on drug products that are in their original manufacturer’s packaging and further enclosed in an active or passive shipping container. However, there may be some products for which this is an important consideration. Card packaging and primary container labels can also be degraded by high levels of humidity.
• A technical understanding of the device technologies used to record temperature and humidity exposure during the transport life-cycle of a drug product.

• A description of the documentary evidence that should be supplied to regulatory authorities and other interested parties so that quality assurance and regulatory compliance can be demonstrated and maintained.

1.3 Target readership

This supplement is intended for all those responsible for the transport of TTSPPs from one fixed storage point to another in the supply chain. The target readership also includes those responsible for providing evidence of temperature and humidity exposure during this process. Monitoring temperatures in fixed storage locations is covered by the companion Technical Supplement: Temperature monitoring of storage areas.

Staff responsible for transport operations need to have a good knowledge of the various types of temperature and humidity monitoring device used in the transport environment, together with their strengths, weaknesses and appropriate uses. They must also be capable of operating, reading and interpreting data from these devices and must be familiar with, and follow, good documentation practice.
2. **Guidance**

Temperature control during air, ocean or ground transport can be maintained using either active or passive shipping systems. These systems are fully described in the companion Technical Supplement: *Temperature-controlled transport operations*; this supplement covers product packing, distribution and product off-loading for the following system types:

- Refrigerated and temperature-controlled vehicles;
- Passive shipping systems;
- Active shipping systems for air transport, and:
- Active shipping systems for ocean transport.

The guidance below focuses on the selection and use of suitable temperature monitoring devices for road, air and ocean transport.

2.1 **Associated materials and equipment**

The key physical components of a quality-assured temperature-controlled transport system are the active and passive packaging systems in which products are placed during transport and the monitoring devices used to record temperature and humidity exposure within these packaging systems. The specific characteristics of the operational environments where these monitoring devices are used are described in the companion Technical Supplement: *Temperature-controlled transport operations*.

2.2 **Temperature and humidity monitoring devices**

The main reason for choosing a temperature or humidity-monitoring device is to determine whether or not the quality of a drug product has potentially been compromised as a result of exposure to harmful or unwanted conditions. The type of technology and the device selected should be based on a user requirement specification (URS).

Depending on the purpose defined in the URS, the selected device may serve as a post-use analytical tool for determining weakness in a system, for carrying out a trend analysis, or to collect performance data. The level of detail possible varies widely and is dependent on the specific application and the technology used.

All monitoring systems must meet regulatory expectations and requirements and must provide the evidence needed to demonstrate that the TTSP has not been exposed to adverse temperatures during storage or transport. When specified to do so, the system must also be able to provide the temperature records needed for documentation purposes.

Multiple use devices should be calibrated against a certified, traceable reference standard at least once a year, unless otherwise justified. Calibration should demonstrate the accuracy of the unit across the entire temperature range over which the device is designed to be used. Single-use devices that are supplied with a manufacturer's calibration certificate do not need to be re-calibrated.

Whenever devices are selected it is essential to consider the needs of the specific application, including ease of use and ease of integration across the supply chain. Some
devices require additional software or hardware; this may not be acceptable in certain use-cases. Whatever system is chosen, it should be accurate, stable, reliable, validated and affordable.

Ideally, the system should reduce manpower by keeping the analysis of data to a minimum. For example, some devices are able automatically to integrate time-temperature exposure and compare this with a drug product’s stability data.

2.2.1 Device types and their strengths and weaknesses

The glossary gives a full definition of each of the temperature monitoring devices listed below. Some of the more sophisticated electronic devices include humidity data collection. However, as previously noted, it is generally considered that humidity exposure data has minimal adverse effect on drug products when they are in their original packaging and further enclosed in an active or passive shipping container.

The tables below itemize the strengths and weaknesses of the following device types:

- Table 1: Chemical Indicators (CI).
- Table 2: Chemical Time-Temperature Integrators (CTTI).
- Table 3: Electronic Temperature Indicator (ETI).
- Table 4: Electronic Data Logging Monitors (EDLM).
- Table 5: Electronic Data Integrators (EDI).
- Table 6: Electronic temperature monitoring and event logger systems for refrigerated and temperature-controlled vehicles.

The tables include photographs of some typical devices.
### Table 1 – Chemical Indicators (CI), Chemical Time-Temperature Integrators (CTTI)

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provides Go/No-go information at a glance.</td>
<td>Properly identifying colour change is subjective and not exact.</td>
</tr>
<tr>
<td>Little or no training required.</td>
<td>Not an analytical tool.</td>
</tr>
<tr>
<td>Typically used for last mile applications.</td>
<td>Temperature accuracy $+/- 1.0^\circ \text{C}$.</td>
</tr>
<tr>
<td>Long operating life (12-14 months).</td>
<td>Must be stored and transported at specific temperatures to avoid activation before use.</td>
</tr>
<tr>
<td>Inexpensive.</td>
<td>Monitoring upper and lower limits requires use of two indicators (or a dual indicator).</td>
</tr>
<tr>
<td></td>
<td>Standard time and temperature limits (some customization available for high volume applications).</td>
</tr>
</tbody>
</table>

**CI: 3M FreezeWatch™ device**

**CTTI: Vaccine Vial Monitor**

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**Technical Supplement: Temperature and humidity monitoring systems for transport**
## Table 2 – Electronic Temperature Indicators (ETI)

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provides Go/No-go information at a glance – no separate reading software needed.</td>
<td>Not an analytical tool.</td>
</tr>
<tr>
<td>Temperature accuracy generally ±0.5°C.</td>
<td>No post calibration capabilities. Accuracy cannot be verified after use.</td>
</tr>
<tr>
<td>Little or no training required.</td>
<td>Not reusable.</td>
</tr>
<tr>
<td>Typically used for last mile applications.</td>
<td>Level of performance varies between manufacturers.</td>
</tr>
<tr>
<td>Long operating life (12 months or more).</td>
<td>Accuracy varies with range and by manufacturer.</td>
</tr>
<tr>
<td>Moderate cost.</td>
<td>Limited event and time traceability.</td>
</tr>
<tr>
<td>Multiple alarm thresholds.</td>
<td>Standard time and temperature limits (some customization available for high volume applications).</td>
</tr>
</tbody>
</table>

Sensitech TagAlert™ Berlinger Q-tag® Quad
### Table 3 – Electronic Data Logging Monitors (EDLM)

<table>
<thead>
<tr>
<th><strong>Strengths</strong></th>
<th><strong>Weaknesses</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Generally meets regulatory requirements for accuracy of ±0.5ºC.</td>
<td>Temperature accuracy varies among manufacturers and over operating range.</td>
</tr>
<tr>
<td>Can be validated in accordance with USP General Chapters &lt;1079&gt; and &lt;1118&gt;.</td>
<td>Typical settings only take temperature readings 1-4 times per hour.</td>
</tr>
<tr>
<td>Often used as an analytical tool. Time-stamped temperature data is easily exported and manipulated through statistical programs such as Excel®.</td>
<td>Proprietary additional hardware, software application or licensing may be required for downloading data.</td>
</tr>
<tr>
<td>Wide variety of device choices and manufacturers.</td>
<td>Device complexity varies. End users without hardware/software may not be able to extract data.</td>
</tr>
<tr>
<td>Graphs, numerical summaries and data are easily produced, together with standard reports.</td>
<td>Limited operating time – Total memory available and frequency of readings impacts the length of use of the device.</td>
</tr>
<tr>
<td>Analysis of multiple data sets capabilities.</td>
<td>Managing large or multiple data sets may be cumbersome.</td>
</tr>
<tr>
<td>Single use devices are often calibrated and serialized for traceability.</td>
<td>Typically much more expensive than chemical or electronic indicators.</td>
</tr>
<tr>
<td>Data retrieval achievable, 3&lt;sup&gt;rd&lt;/sup&gt; party data management options available.</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; party data management is often an additional cost.</td>
</tr>
<tr>
<td>Most devices have two pre-programmed alarm settings (high/low).</td>
<td>High incidence of false alarms causing additional data analysis, and non-value added labour costs.</td>
</tr>
</tbody>
</table>

Libero data logger
Table 4 – Electronic Data Integrators (EDI)

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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</thead>
<tbody>
<tr>
<td>Meets regulatory requirements for accuracy of ± 0.5°C.</td>
<td>Not an analytical tool.</td>
</tr>
<tr>
<td>Can be validated in accordance with USP General Chapters &lt;1079&gt; and &lt;1118&gt;.</td>
<td>Alarm parameters programmed by manufacturer may require multiple devices.</td>
</tr>
<tr>
<td>Continuously monitor temperatures every minute.</td>
<td>Requires users to decide on alarm limit parameters.</td>
</tr>
<tr>
<td>Calibrated and serialized for NIST traceability.</td>
<td></td>
</tr>
<tr>
<td>Eliminate false alarms – Allowable excursions pre-programmed into the alarm settings.</td>
<td></td>
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<tr>
<td>Up to five year operating life.</td>
<td></td>
</tr>
<tr>
<td>Device acquisition cost are typically well below EDLM + software costs.</td>
<td></td>
</tr>
<tr>
<td>Multi alarm settings possible.</td>
<td></td>
</tr>
<tr>
<td>Rapidly adapts to environmental temperature changes (low Tau – rating).</td>
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Berlinger Q-Tag® CLm Doc
Table 5 – Electronic temperature monitoring and event logger systems

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meets regulatory requirements for accuracy of ± 0.5°C.</td>
<td>Cannot monitor individual packages unless =&lt; number of available product probe sensors.</td>
</tr>
<tr>
<td>EN 12830 and/or USP &lt;1079&gt; and USP &lt;1118&gt; compliant.</td>
<td>Air temperature sensors may not reflect actual load temperature, especially with frequent door opening.</td>
</tr>
<tr>
<td>Factory calibrated against traceable standards.</td>
<td>Requires professional installation by vehicle vendor/system supplier.</td>
</tr>
<tr>
<td>Continuously monitors air temperature in the temperature controlled compartment and informs the driver about its status.</td>
<td></td>
</tr>
<tr>
<td>Product probes available to give more accurate representation of temperature if there is frequent door opening (multiple drop-offs).</td>
<td></td>
</tr>
<tr>
<td>Multiple interchangeable temperature sensors with temperature alarm, defrost, refrigeration failure and door-open sensor options.</td>
<td></td>
</tr>
<tr>
<td>User-selectable recording intervals – e.g. 5-30 minutes.</td>
<td></td>
</tr>
<tr>
<td>Cab mounting with on-board temperature display.</td>
<td></td>
</tr>
<tr>
<td>Historical temperature record and key performance indicator reporting.</td>
<td></td>
</tr>
<tr>
<td>Integrated thermal printer options for arrival reporting.</td>
<td></td>
</tr>
<tr>
<td>User-selectable, multi-language versions available.</td>
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</tr>
<tr>
<td>Can be integrated with web-based vehicle tracking and remote monitoring, including SMS event alerts and local wireless area data retrieval.</td>
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Transcan Sentinel with thermal printer
2.2.2 Data collection, storage and retrieval

Different devices generate different types and amounts of information. Devices, such as EDLMs, that record time and temperature data that can be downloaded must be used to produce this information in accordance with the relevant requirements for documented data storage.

In most instances, downloaded time and temperature data should be retained for at least three years in a non-volatile format that enables the data to be retrieved. Suitable formats include printed hard copies or a non-volatile and retrievable electronic medium such as a computer hard drive, tape drive, flash drive or DVD. Storage in a secure web-based data repository may also be acceptable.

Go/No go data of the type supplied by CIs, CTIs and ETIs should be recorded on the appropriate product arrival report and this information should be used to make decisions on whether to accept the TTSP consignment into active storage at the receiving store, or whether to quarantine it until an investigation has taken place and a final disposition has been made.
References


- IATA Chapter 17: *Perishable Cargo Regulations.* 2013.

  https://www.iata.org/publications/Pages/temperature-control-regulations.aspx


- WHO Technical Supplement. *Qualification of shipping containers.*

- WHO Technical Supplement. *Qualification of temperature-controlled road vehicles.*


## Revision history

<table>
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<tr>
<th>Date</th>
<th>Change summary</th>
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