



BSI Standards Publication

**Temperature recorders for the transport, storage
and distribution of temperature sensitive
goods - Tests, performance, suitability**

National foreword

This British Standard is the UK implementation of EN 12830:2018. It supersedes BS EN 12830:1999, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee RHE/19, Commercial refrigerated food cabinets (cold room and display cases).

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Temperature recorders for the transport, storage and distribution of temperature sensitive goods - Tests, performance, suitability

Enregistreurs de température pour le transport, le stockage et la distribution des marchandises thermosensibles - Essais, performance, aptitude à l'emploi

Temperaturregistriergeräte für den Transport, die Lagerung und die Verteilung von temperaturempfindlichen Produkten - Prüfungen, Leistung, Gebrauchstauglichkeit

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European foreword

This document (EN 12830:2018) has been prepared by Technical Committee CEN/TC 423 "Means of measuring and/or recording temperature in the cold chain", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2019 and conflicting national standards shall be withdrawn at the latest by February 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12830:1999.

The standard has been completely revised and updated to the state of the art as follows:

- Scope was enlarged, i.e. location of sensors of the recorder with respect to types of usage are included now;
- Update of Clause 2 "Normative references";
- Update of Clause 3 "Terms and definitions";
- Clause 4 "Concepts" was added;
- Clause 5 "Requirements" was enlarged, i.e. subclause 5.3 "Protection of the data from manipulation" and 5.12 "Software verification levels" were added and furthermore Clause 5 has been updated, e.g. values for maximum relative timing error and response time ;
- New subclause 6.7 "Software test" and the related Annex A "Software testing" and Annex B "Manufacturer software test form" were added;
- New Annex D "Expected operation time and storage capacity" and Annex E "Required access to recorded data or functions" were added.

This European Standard is a document meeting the objectives of Directives:

- 92/1/EEC of January 13, 1992 of the Commission on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption;
- 93/43/EEC of June 14, 1993 of the Council of the hygiene of foodstuffs and in particular on "temperature control criteria".

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This document specifies the technical and functional characteristics of temperature recorders for the transport, storage and distribution of temperature sensitive goods between $-80\text{ }^{\circ}\text{C}$ and $+85\text{ }^{\circ}\text{C}$.

It specifies the test methods which allow the determination of the equipment's conformity, suitability and performance requirements.

It applies to the whole temperature recording system. The temperature sensor(s) may be integrated into the recorder or be remote from it [external sensor(s)].

It gives some requirements with regards to the location of sensors of the recorder with respect to types of usage such as transport, storage and distribution.

NOTE Examples for the transport, storage and distribution of temperature sensitive goods between $-80\text{ }^{\circ}\text{C}$ and $+85\text{ }^{\circ}\text{C}$ are chilled, frozen and deep frozen, quick frozen food, ice cream, fresh and hot food, pharmaceuticals, blood, organs, chemicals, biologicals, electronic and mechanical devices, flowers, plants, bulbs, raw materials and liquids, animals, art and furnishing.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13486, *Temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream - Periodic verification*

EN 60529, *Degrees of protection provided by enclosures (IP Code) (IEC 60529)*

EN 61000-6-2, *Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity for industrial environments (IEC 61000-6-2)*

EN 61000-6-3, *Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments (IEC 61000-6-3)*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements (IEC 61010-1)*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC 27001, *Information technology - Security techniques - Information security management systems - Requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

quantity

property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference

3.2

unit of measurement

particular quantity, defined and adopted by convention, with which other quantities of the same kind are compared in order to express their magnitudes relative to that quantity

EXAMPLE The unit of temperature used in this standard is “degree Celsius”.

3.3

value of a quantity

number and reference together expressing magnitude of a quantity

EXAMPLE 15 °C.

3.4

measurement

set of operations having the object of determining a value of a quantity

3.5

measurand

particular quantity subject to a measurement

EXAMPLE Temperature.

3.6

influence quantity

quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result

3.7

indication (of a measuring instrument)

value of a quantity provided by a measuring instrument

3.8

accuracy class

class of measuring instruments of measuring systems that meet stated metrological requirements that are intended to keep measurement errors or instrumental measurement uncertainties within specified limits under specified operating conditions

3.9

maximum permissible measurement error

maximum permissible error

extreme value of **measurement error**, with respect to a known **reference quantity value**, permitted by specifications or regulations for a given **measurement, measuring instrument, or measuring system**

3.10

measurement uncertainty

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

3.11

error of measurement

measured quantity value minus a reference quantity value

3.12

measuring instrument

device intended to be used to make measurements, alone or in conjunction with supplementary device(s)

3.13

displaying device

indicating device

part of a measuring instrument that displays an indication

3.14

recording device

part of a measuring instrument that provides a record of an indication

3.15

temperature sensor

element of a measuring instrument or measuring chain that is directly affected by the temperature

3.16

scale

scale of a measuring instrument

ordered set of marks, together with any numbering, forming part of a displaying device of a measuring instrument

3.17

adjustment

adjustment of a measuring instrument

operation of bringing a measuring instrument into a state of performance suitable for its use

3.18

span

modulus of the difference between the two limits of a nominal range

EXAMPLE For a nominal range of - 35 °C to + 25 °C, the span is 60 K.

3.19**measuring range**

working range

set of values for which the error of a measuring instrument is intended to lie within specified limits

3.20**rated operating conditions**

operating condition that has to be fulfilled during **measurement** in order that a **measuring instrument** or **measuring system** perform as designed

3.21**limiting conditions**

extreme conditions that a measuring instrument is required to withstand without damage, and without degradation of specified metrological characteristics when it is subsequently operated under its rated operating conditions

3.22**reference conditions**

operating condition prescribed for evaluating the performance of a measuring instrument or measuring system or for comparison of measurement results

3.23**resolution (of a displaying device)**

smallest difference between indications of a displaying device that can be meaningfully distinguished

3.24**response time**

time needed for the recorded value to reach and remain with specified limits around actual temperature to which it is measuring

3.25**storage and transport conditions**

extreme conditions which a non-operational measuring instrument can withstand without damage and without degradation of specified metrological characteristics when it is subsequently operated under its rated operating conditions

3.26**chilled application**

application which has been subjected to cooling (without freezing) and is intended to be maintained at low temperature

3.27**frozen food**

food which has been subjected to a freezing process specially designed to preserve the wholesomeness and quality of the product

3.28**deep-frozen or quick-frozen food**

food which has been subjected to a quick freezing process

3.29**recording interval**

time interval that has elapsed between two successively stored measurements

3.30

recording duration

time interval between the beginning and the end of the recording

3.31

chart

tape, disk, form or other structure upon which is recorded the measurand

3.32

duration of transport

time interval between loading and unloading

3.33

subunit

distinct part or component of the temperature recorder that generates, encodes, transports, prints, indicates and/or stores relevant data

Note 1 to entry: It is housed in its own enclosure.

3.34

audit trail

chronological record that reconstructs and examines the sequence of activities surrounding or leading to a specific operation, procedure, or event in a security relevant transaction from inception to final result

Note 1 to entry: See National Information Assurance (IA) Glossary. Committee on National Security Systems. 7 August 1996. p. 4). It documents who did what and when.

3.35

service provider

organization or business which offers service to others in exchange for payment

3.36

relevant measurement data

set of temperature—time—location tuples recorded during the traceability time span

Note 1 to entry: Once data age exceeds this time span it loses its “relevant” status.

3.37

relevant parameters

parameters that affect relevant measurement data

EXAMPLE Calibration parameters, time-date settings and installation location (such as truck ID or warehouse room ID).

3.38

relevant software

software that produces, stores, process or transmits relevant data

Note 1 to entry: Relevant software can cohabit with non-relevant software.

3.39

command

any physical or logical system that enables the access to a function

3.40**relevant command**

command that impacts on relevant parameters and relevant measurement data

3.41**cloud**

cloud computing, also known as remote on-demand computing; it is a kind of internet-based computing, where shared resources and information are provided to computers and other devices on-demand

3.42**solution as a service (SaaS)**

solution where the monitoring system hardware (sensors, recorders and base stations) is installed at the organization site, but the software, server and database are hosted by a service provider; the data are collected, stored and managed by the service provider whilst the organization owner of the recorders has access to the data through a secure web interface

Note 1 to entry: In this scenario, the service provider ensures the cloud system maintenance, correct performance and qualification.

3.43**measuring system**

set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds

Note 1 to entry: A measuring system can consist of one measuring instrument.

4 Concepts**4.1 General**

The objective of the temperature recorder is to generate and to record at least the accurate temperature and time, and the accurate location if applicable.

An additional concept is the time span that the recorded data has to be traceable (for example, minimum one year for deep frozen food.)

The recorder can be a fully mechanical recorder, a mechanical and electronic recorder or a fully electronic recorder. This is why “relevant software” is not always present. Relevant measurement data can be exported for its exploitation by other systems, for example a fleet or warehouse management system. If the exporting mechanism cannot guarantee the traceability of the data, the exported data loses its “relevant” status.

The instrument will normally include a set of parameters that affect relevant characteristics of the temperature recorder. For example, calibration parameters, time-date settings and installation location (such as truck ID or warehouse room ID). We will call these parameters “relevant parameters”.

The combination of the relevant measurement data plus the relevant parameters forms the “relevant data”.

The software that produces, stores, process or transmits relevant data are called reporting software. Relevant software can cohabit with non-relevant software.

4.2 Temperature recorder elements

Figure 1 shows the main elements of a temperature recorder.

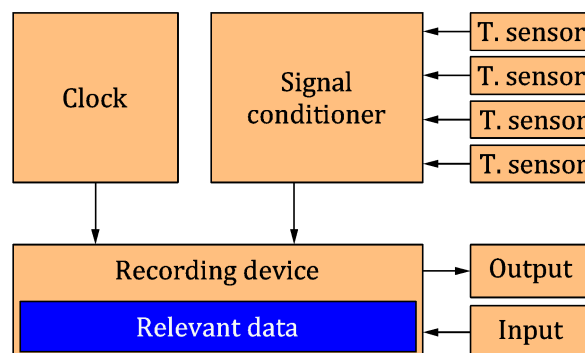


Figure 1 — Abstract view of the temperature recorder showing its main elements

Temperature sensor type can be PT100, PT1000, NTC, Thermocouple, etc. Sensor can be internal, when they are located within the unit enclosure, or external, when not. External sensors can be changeable or fixed to the unit. Sensor intended to measure the temperature of air or the core temperature of the product (insertion sensor).

External sensors can be packaged as digital probes when they include electronics to convert the temperature to a numeric value and to communicate with the recorder through a digital channel.

Power supply can be external or internal. Internal supply types can be rechargeable and non-rechargeable.

An output mechanism will provide output data. Common alternatives are display, printer, and communication port. Communication port can be wire connected or wireless, and can follow an approved standard or be of proprietary design.

An input mechanism is used to give commands to the temperature recorder. Common alternatives are keyboard, touchscreen and communication port.

The clock for electronic recorder is commonly based on a crystal oscillator that produces a very precise frequency. In order to maintain the correct time on power off, a backup power source is required to keep the clock running.

Temperature recorder memory can be volatile or non-volatile. The non-volatile memory can be erasable or permanent. When the temperature recorder program is stored in permanent memory the unit is non-reprogrammable. When the measurements are stored in volatile memory a backup power source is required to ensure that relevant data are not lost on power off.

4.3 Temperature recorder architecture (or configuration)

4.3.1 General

The temperature recorder can be built in a variety of architectures ranging from a monolithic instrument to a very complex distributed system. All the subunits of a distributed system that generates, encodes, transports, or stores relevant data will form part of the temperature recorder.

In order to clarify the boundaries of the temperature recorders, a description of the possible alternatives and major design challenges will be given in 4.3.2 to 4.3.5.

4.3.2 Monolithic instrument

A monolithic temperature recorder includes all of its components in a single package, excluding the temperature sensors that can be internal or external, as shown in Figure 2.

It has to be noted that in this solution all the relevant data are always maintained within the temperature recorder. This data could be exported to other devices but is nevertheless kept in the temperature recorder during the full duration of the traceability time span. Exported data loses its relevant status since traceability is not guaranteed.

Main challenges are:

- Instrument design to achieve the proposed accuracy within the measurement range and operational range.
- Memory design to allow for the storage of all the relevant data during the complete traceability span.
- Unit enclosure and sealing design to prevent electronic, memory and sensor tampering.

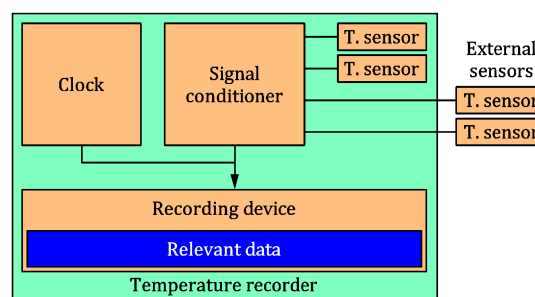


Figure 2 — Monolithic temperature recorder

4.3.3 Monolithic instrument with external relevant data

As shown in Figure 3, in this alternative the relevant data can be kept in an external medium. Relevant data are exported to an external device and can be erased from the temperature recorder. In many cases the external device will be a computer that will store in its disk the exported relevant data.

The exported relevant data are packaged in such a way as to prevent and/or detect its manipulation.

The packaging could be performed internally by the instrument or externally by a computer. In the first case, the downloading to the external storage can be done by an off the shelf application. In the second case, the data leaves the instrument in clear (that is without packaging) and is externally packaged. Therefore, the downloading and packaging application is instrumental to the traceability of the data, and is considered a subunit of the temperature recorder.

The connection between the instrument and the external storage can be by wired or wireless.

Note that the user of the temperature recorder has the responsibility of maintaining the exported relevant data, for example, implementing a sound backup policy.

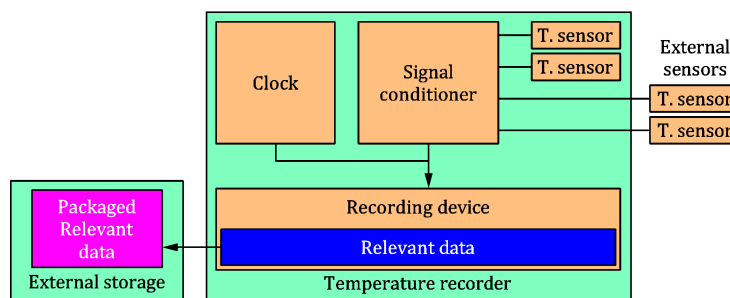


Figure 3 — Monolithic instrument with external storage of relevant data

In addition to the challenges defined for monolithic instruments, this architecture presents the following challenges:

- Design a data packaging that prevents and/or detects its manipulation;
- Design a packaging mechanism that guaranties authenticity;
- Design a communication mechanism that avoids data loss.

4.3.4 Temperature recorder with digital probes

A digital probe includes a temperature sensor as well as a signal conditioner which produces a numerical temperature value. As is depicted in Figure 4, the digital probes are connected to a base unit. The temperature recorder is a measurement system composed of the base station and the digital probes.

Digital probes can be simple, responding with the current temperature to a base command.

Alternatively, the digital probe could also include a clock and a memory to store relevant data, implementing a protocol to transmit the relevant data when appropriate.

In this architecture the temperature recorder is a measurement system composed of two subunits: the base station and the digital probe.

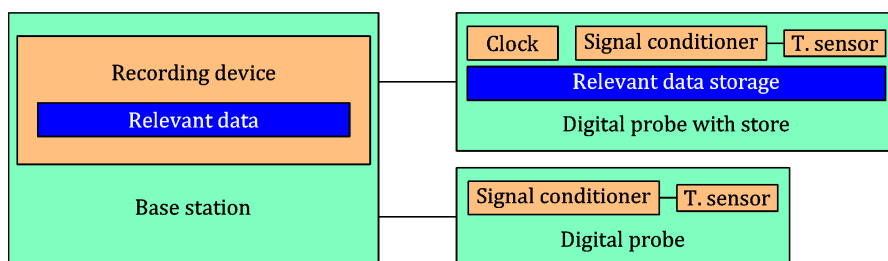


Figure 4 — Temperature recorder with digital probes

The connection of the digital probes with the base station can be made via a cable or via a wireless digital link. Wireless digital probes normally will include some storage capacity to avoid loss of data in case of link temporal failure.

Physical probe sealing is limited to wire connected probes, whereas virtual or software seals will support both wire and wireless connections.

Figure 5 shows that auxiliary communication components, such as routers, repeaters or switches, can be included to extend the range of the base stations both in distance and in number of probes.

Base stations, digital probes and communications components are subject to the challenges defined for monolithic instruments. Additionally, this architecture presents the following Probe—base station connection and protocol designed to prevent data manipulation, data loss, phishing and identity impersonation.

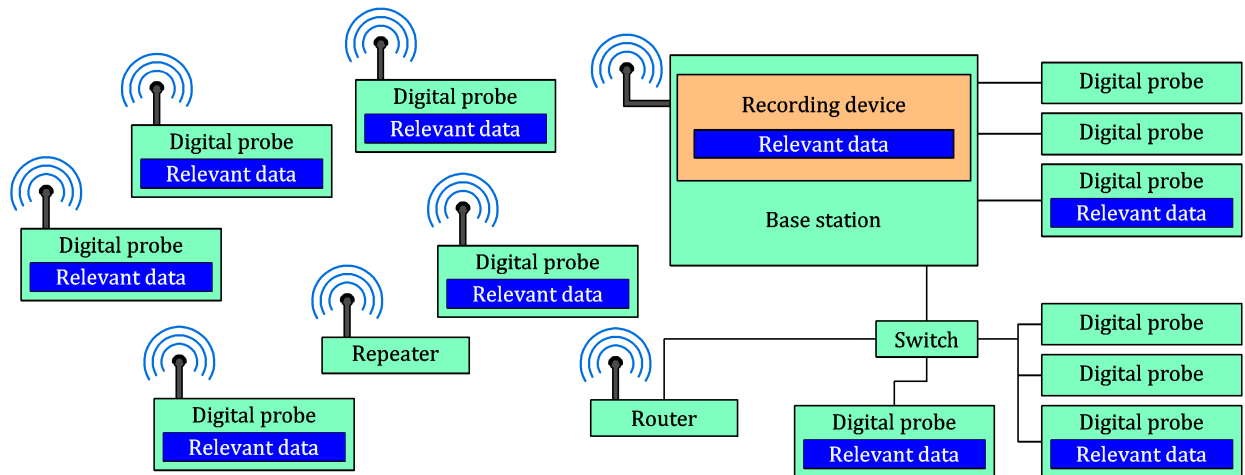


Figure 5 — Temperature recording system with wire and wireless connections

4.3.5 Temperature recorder on the cloud

An extension of 4.3.2 consists of using the cloud as the external storage medium. In that case, as Figure 6 shows, the temperature recorder system includes the transmission, processing and storage of the relevant data in the cloud.

If the data are packaged before it is sent to the cloud, transmission and storage of the encoded relevant data can be done with off the shelf applications. If that is not the case, the transmission and packaging application is instrumental to the traceability of the data, and is considered a subunit of the temperature recorder system.

There are two fundamentally different design options for the cloud server. The first is an owner hosted system and the second is the Solution as a Service (SaaS) approach.

a) *Owner hosted system:*

The cloud server and database are stored, managed and maintained by the organization owner of the temperature recorders, which is also responsible for maintaining the cloud system and ensuring its correct performance.

b) *Solution as a Service (SaaS):*

The monitoring system hardware (sensors, recorders and base stations) is installed at the organization site, but the software, server and database are hosted by a service provider. The data are collected, stored and managed by the service provider whilst the organization owner of the recorders has access to the data through a secure web interface or other remote procedure. In this scenario, the service provider ensures the cloud system maintenance, correct performance and qualification.

This solution includes all the challenges described on the previous sections. Additionally, this architecture presents the following challenge: Dimensioning, maintenance and operation of the cloud system.

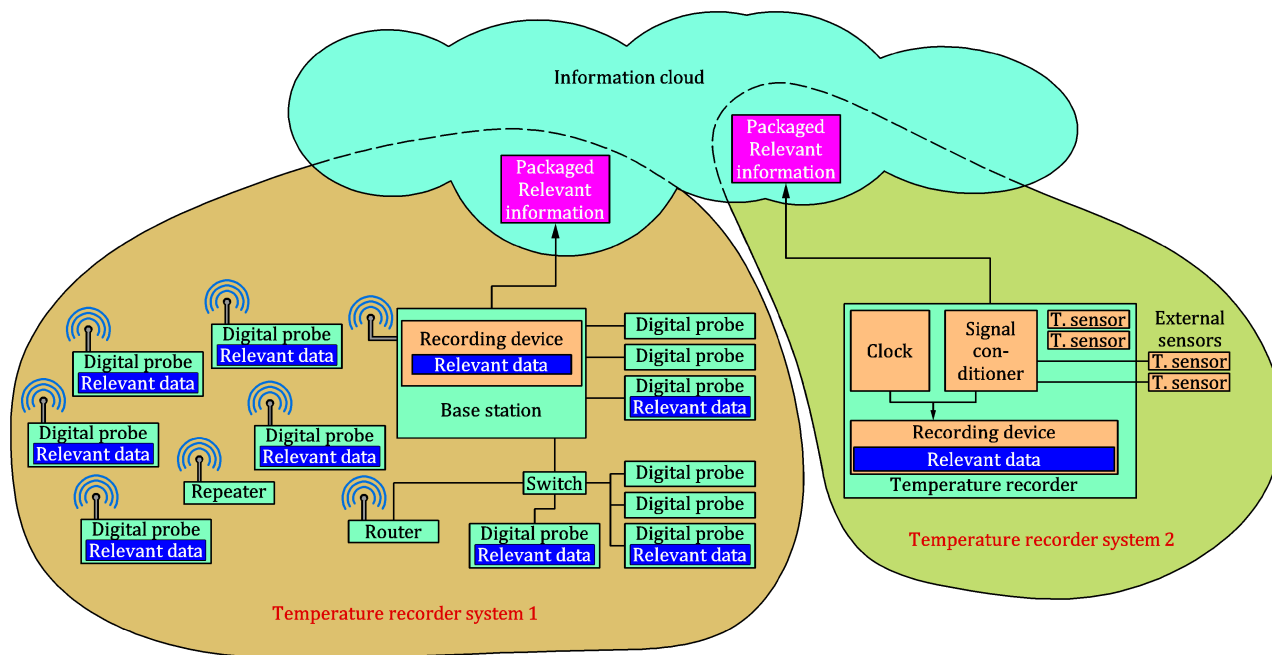


Figure 6 — Two temperature recorders with relevant data in the cloud

5 Requirements

5.1 General

The means of temperature measurement used by the recorder shall be independent of any temperature measurement which is used to control the refrigerating system.

Manufacturers shall make recommendations on the specification of ancillary equipment in order to meet the performance requirements of this European Standard.

The manufacturer shall define the use of the transport, storage and operational conditions. Examples are given in the informative Annexes C and D.

NOTE Further information is included in EN 60721-3-3 and EN 60721-2-3.

The manufacturer shall verify the defined requirements of his applications.

The system shall have the possibilities to prevent and/or detect manipulation and to prove the validity of the data;

The system shall have the possibility to log changes in the parameters that influence the relevant data for example:

- a) measurement value;
- b) time stamp;
- c) correlation between measurement value and time stamp;
- d) settings:
 - 1) measurement interval;
 - 2) measurement limits;

- 3) measurement mode (e.g. start/stop);
- 4) location.

Manipulation of the log has to be prevented and/or at least detected; the logs have to be kept at least as long as the data itself.

5.2 Measuring range

- The temperature recorder shall be able to measure in the measuring range that it is defined by the manufacturer.
- For climate classes see the relevant legislation and quality specifications.

5.3 Protection of the data from manipulation

5.3.1 General

The software shall prevent and/or at least detect both intended and not intended manipulation of the relevant data. This is true for all relevant data as long as they are managed by the measurement system, including during storage and transmission.

5.3.2 Audit trail

The software of the measurement can have an audit trail.

5.3.3 Clearly readable data copies

The software shall be able to present the relevant data in a way that is directly readable by persons or authorities in an easy way.

5.3.4 Safekeeping of accessibility of the data

The software shall have a possibility to make sure the user can access the relevant data any time, provided he/she has the rights to do so (see access restrictions 5.3.7).

- the data readability at the temperature logger shall be provided as a minimum requirement over an interface (USB, wireless, etc.), for example as pdf-file or in another digital format;
- or
- an access shall be provided directly at the display of the device at any time to display the actual recorded temperature by an (PIN) entry code in case of it's not directly accessible;
- or
- a printout of the data on an internal printer shall be provided for devices without an internal display i.e. at devices like telematic systems;
- or
- an access shall be provided by a software application for smart phone or tablets.

The informative Annex E (Table E.1) shows some examples of possible access to data and functions.

5.3.5 Safekeeping of readability of the data

The software shall have a possibility to ensure that the relevant data are directly readable by persons.

5.3.6 Safekeeping of correctness of the data

The software shall have a possibility to ensure that the data are inviolate.

5.3.7 Access restrictions

The software shall make sure that critical parts of the software can't be accessed without user verification. This means it has to have a user management system with user names and passwords to identify the users, and options to declare user rights to define various user roles (e.g. administrator vs. regular user).

5.3.8 Detailed documentation of the software

The documentation of the software shall be compiled in a way that the software mechanics are comprehensible for qualified personnel, e.g. computer scientists.

5.4 Locking of settings

The date and time of the beginning of recording shall be readable from the recorded data or it shall be possible to make them readable.

The possibility for adjusting settings which configure the recording shall:

- either be protected against accidental or unauthorised modifications;
- or record each adjustment of any settings that remain accessible.

5.5 Recording

5.5.1 General

At least the temperature and the time shall be recorded. The record shall also indicate the date and the time zone e.g. GMT or UTC. Other information as the place of measurement (e.g. return air, back door) could be also recorded, however it shall not impact the temperature data.

5.5.2 Traceability

It shall be possible to identify and retrieve the recorded data. It shall be possible to read those data, intended for archiving for a period of at least a year.

The recorder shall allow the user to keep the data for at least one year.

After one year the responsibility for the recorded values should be managed between the contracting parties within the cold chain for the different goods after the transfer in regards to relevant regulations and quality requirements including enlarged storage periods i.e. pharmaceutical products, EU food regulations and others.

The manufacturer of the device shall define instructions in its documentation for operation and maintenance taking in account, i.e. life time of batteries, storage periods and operational limitations of the device.

5.5.3 Chart only for mechanical recorder

The scrolling speed of the chart shall be greater than or equal to:

- for transport:
 - 6 mm/h for a recording duration lower than or equal to 24 h;
 - 2 mm/h for a recording duration higher than 24 h and lower than or equal to 7 d;
 - 0,5 mm/h for a recording duration higher than 7 d.

The choice of the recorder shall be made according to the use, including the duration of transport.

- for storage: 1 mm/h.

The speed shall be verified on the following graduations:

- -20 °C for deep-frozen applications;
- 0 °C for chilled applications.

5.6 Autonomous power supply

For devices with an autonomous power supply, this shall be indicated on the recorder or on the power supply or in the technical documentation, with the corresponding usage temperature.

The manufacturer is recommended to install an indicating device (warning light or message) warning the user that the power source needs replacing.

The battery lifetime shall be indicated by the manufacturer for relevant operation temperatures taking into account typical operation of e.g. display, transmission of data, LEDs, number and kind of sensors (see 5.9.2).

NOTE See also Annex D.

The manufacturer shall indicate, if the battery is fixed or replaceable and/or rechargeable.

5.7 Degree of protection provided by the enclosure

The minimum degree of protection provided by the enclosure shall be:

- IP 20 for recorders used in heated/air conditioned closed premises or in the cabin of transport vehicles ;
- IP 55 for recorders used inside cold enclosures (storage or transport vehicles) and for external sensor ;
- IP 65 for recorders used outside buildings or transport vehicles, with sensor inside the cold enclosure.

5.8 Electrical safety (if applicable)

The recorder shall conform to the requirements of EN 61010-1.

5.9 Operating characteristics linked to external electrical influences

5.9.1 External supply voltage (if applicable)

A recorder which requires an external electrical supply shall be suitable for connection to one of the supplies given in Table 1.

Table 1 — Limits of external supply voltage

Alternating current (AC)	U_n	+ 10 %, - 15 %	
Direct current (DC)	U_n	Rated operating conditions	Limiting conditions
	12 V	10 V to 16 V	0 V to 18 V
	24 V	20 V to 32 V	0 V to 36 V

The recorder shall indicate the possible losses of data. The manufacturer shall indicate the remaining recording period in case of interrupted power supply.

External accessories should take into account the requested power consumption of the recorder using the same power source (e.g. battery of vehicle)

5.9.2 Autonomous supply (if applicable)

The manufacturer shall specify the operating time without external power at a reference temperature. The device shall give an indication if the battery status is low.

5.9.3 Frequency (AC) (if applicable)

The manufacturer shall specify the operating frequency with a tolerance of ± 3 Hz.

5.9.4 Power cut-offs

The recorded data shall not be lost during a power cut-off. The manufacturer shall state the duration for which the data are protected when the recorder is disconnected from the primary source of power.

5.9.5 Electrical power disturbances and susceptibility to radiated electromagnetic field

The recorder shall conform with the requirements of EN 61000-6-2 and EN 61000-6-3, or any other specific standard, if applicable.

5.10 Metrological characteristics and usage profiles

5.10.1 General

The metrological characteristics of the recorders result from usage profiles which determine the operating criteria.

5.10.2 Metrological characteristics

5.10.2.1 Maximum permissible errors and resolution

The recorder, under rated operating conditions, shall conform to at least one of the classes indicated in Table 2.

Table 2 — Accuracy classes

Class	0,2	0,5	1	2
Maximum permissible errors	$\pm 0,2\text{ }^{\circ}\text{C}$	$\pm 0,5\text{ }^{\circ}\text{C}$	$\pm 1\text{ }^{\circ}\text{C}$	$\pm 2\text{ }^{\circ}\text{C}$
Resolution	$< 0,1\text{ }^{\circ}\text{C}$	$< 0,2\text{ }^{\circ}\text{C}$	$\leq 0,5\text{ }^{\circ}\text{C}$	$\leq 1\text{ }^{\circ}\text{C}$

5.10.2.2 Operational requirements

Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream should have the minimum accuracy class 0,5 within the temperature range of $-25\text{ }^{\circ}\text{C}$ to $+7\text{ }^{\circ}\text{C}$.

NOTE E.g. red meat at $+7\text{ }^{\circ}\text{C}$, frozen butter at $-10\text{ }^{\circ}\text{C}$, deep-frozen/quick-frozen food, e.g. quick frozen fish at $-18\text{ }^{\circ}\text{C}$ and ice-cream at $-20\text{ }^{\circ}\text{C}$.

For traceability a minimum storage time for frozen food application of 1 year is required. This does not refer to the storage capacity of the measurement instrument.

5.10.2.3 Recording interval and storage capacity

The manufacturer shall define the recording intervals, periods and storage capacity with its minimum and maximum limits. The maximum time window for calculated temperatures shall be measured with 5 % of the recording interval and a maximum period of 15 min.

If there is any possibility of overwriting the recorded values it shall be indicated by the manufacturer.

Information is given in informative Annex D.

The recording intervals do not apply to recorders where the record is only printed in a chart or printed as values on paper.

5.10.2.4 Maximum relative timing error

The maximum relative timing error shall be:

- 0,1 % of the recording duration when the date is reset up to 31 d ;
- 0,02 % of the recording duration including the error of the date and time when the date is reset after 31 d.

5.10.2.5 Response time

The response time shall be:

- for recorders with external air sensors maximum 5 min;
- for recorders with internal sensors maximum 20 min.

The response time is the time needed for the recorded value to reach 90 % of the actual change of applied temperature in the conditions mentioned in 6.4.

5.10.3 Usage profiles

5.10.3.1 Climatic environment

The manufacturer shall give a clear statement for the climatic environmental limits for:

- the complete temperature recorder or each individual subunit of the temperature recorder;
- specified temperature ranges for batteries including their expected operation lifetime at certain temperatures (including minimum and maximum of operating temperature) and at specific recording intervals (see 5.10.2.3).

5.10.3.2 Mechanical vibrations

Equipment for use on transport vehicles shall be able to operate in the following environment conditions:

- vibration frequency: 5 Hz to 8,6 Hz ; displacement amplitude: 10 mm;
- vibration frequency: 8,6 Hz to 150 Hz ; acceleration: 3 g.

5.10.3.3 Shock resistance

Equipment for use on transport vehicles shall be able to operate in the conditions as defined in 6.6.6.

5.10.3.4 Different versions and combinations of components

The manufacturer shall give a clear description of possible combinations and versions of devices, interfaces and sensors including e.g. connectors, length of wires and distances (maximum equipment).

5.11 Data security

The data shall be protected against alteration.

5.12 Software verification levels

Depending on the type of application and on the type of system, these systems have to comply with one of the software verification levels described in the following Tables 3 and 4.

Table 3 — Software verification levels for recorders without cloud Solution as a Service (SaaS) approach

Level	No level	I ^a	II ^a	III ^a
Type of system	Mechanical systems	Electronic systems	Electronic systems	Electronic systems
Requirements	-	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7 and Annex A
Verification	-	Compliance with manufacturer declaration	Compliance with manufacturer's declaration and test report	Compliance with the additional requirements given in Annex A
^a Systems without cloud Solution as a Service (SaaS).				

Table 4 — Software verification levels for recorders with cloud Solution as a Service (SaaS) approach

Level	No level	I ^b	II ^b	III ^b
Type of system	Mechanical systems	Electronic systems	Electronic systems	Electronic systems
Requirements	-	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7	According to subclauses 5.1, 5.3, 5.4, 5.5 and 6.7 and Annex A
Additional requirement for the SaaS		For example compliance with ISO/IEC 27001	For example compliance with ISO/IEC 27001	For example compliance with ISO/IEC 27001
Verification	-	Compliance with manufacturer declaration	Compliance with manufacturer's declaration and test report	Compliance with the additional requirements given in Annex A
^b Systems with cloud Solution as a Service (SaaS).				

6 Test methods

6.1 Test list

The recorder shall be subjected to the tests listed in Table 5.

Table 5 — Tests and applications

Tests	Storage	Transport	Subclause
- Determination of temperature measurement error	+	+	6.3
- Determination of response time	+	+	6.4
- Determination of time recording error	+	+	6.5
- Variation in supply, voltage ^a	+	+	6.6.2
- Dielectric strength ^a	+	+	6.6.9
- Influence of ambient temperature	+	+	6.6.3
- Temperature testing for the recorder under storage and transport conditions	+	+	6.6.4
- Shock resistance		+	6.6.5
- Mechanical vibrations		+	6.6.6
- Degrees of protection provided by enclosure	+	+	6.6.7
- Electromagnetic compatibility (EMC) ^{a, b}	+	+	-
- Software test ^a	+	+	6.7
^a If applicable.			
^b The recorder shall conform with the requirements of EN 61000-6-2 and EN 61000-6-3 or any other specific standard when applicable.			

6.2 General conditions for tests

6.2.1 Pre-tests adjustments

The tests shall be carried out without change to the adjustments made in the factory by the manufacturer. All elements of the recorder shall be put in place according to the manufacturer's instructions.

When possible or necessary the recorder is configured in order to conduct the following tests.

6.2.2 Normal atmospheric conditions

Unless otherwise prescribed the tests are carried out in the atmospheric conditions defined as follows:

- Temperature: $23\text{ °C} \pm 3\text{ °C}$ measured at 10 cm from the recorder;
- relative humidity: $60\text{ \% RH} \pm 20\text{ \% RH}$;
- atmospheric pressure: To be indicated as measured.

Before testing the recorders are placed in these conditions for 24 h. The charts and ink devices are stored in these conditions.

6.2.3 Reference conditions

The reference conditions for the tests are given in Table 6.

Table 6 — Reference conditions for the tests

Influence quantity	Reference conditions	Tolerance
Supply voltage ^a	Nominal voltage	$\pm 2\text{ \%}$
Frequency ^a	Nominal frequency	$\pm 1\text{ \%}$
Position	Defined by the manufacturer	$\pm 2\text{ \%}$
Recorder support vibrations	$< 0,5\text{ g}$	
Chart	Supplied by the manufacturer	
^a If applicable.		

6.3 Determination of temperature measurement error

6.3.1 Test method

The temperature sensor, or the recorder when the sensor is internal, is placed:

- either in an enclosure with forced air circulation at $1 \text{ m/s} \pm 0,3 \text{ m/s}$;
- or in a thermostatic bath. The manufacturer shall state whether the equipment is designed to be immersed.

To validate if the operational measuring range of the declared accuracy classes (see 5.10.2.1) can be fulfilled.

For a cycle of measurements, the temperature is successively held at 0 %, 50 %, and 100 % of the span, or at the following fixed values: - 30 °C, 0 °C and + 30 °C if the span is greater than those values.

For electronic recorders, one cycle is carried out with increasing and then decreasing values.

For mechanical recorders, three similar cycles are carried out.

The stabilization time of the recorder for each temperature value is at least 1 h, or a duration sufficient to obtain temperature stabilization of the enclosure or thermostatic bath better than the resolution of the recorder under test.

The temperature surrounding the sensor is measured with at least one standard thermometer.

6.3.2 Reading the recording

Following the test, the recorded values are read using devices provided by the manufacturer.

6.3.3 Expression of results

The errors at each temperature value shall be tabulated and all shall fall within the maximum permissible errors for the class of the recorder.

These values shall be given with the uncertainty of the measurement.

Table 7 — Maximum uncertainty of the reference equipment

Class	0,2	0,5	1	2
Maximum uncertainty of the reference equipment	$\pm 0,1 \text{ K}$	$\pm 0,25 \text{ K}$	$\pm 0,5 \text{ K}$	$\pm 1 \text{ K}$
NOTE The maximum uncertainty mentioned in this table reflects all components of uncertainty associated with the calibration and use (recording, sensor, cable, drift, calibration, resolution, ...). A coefficient $k = 2$ is used to indicate uncertainty.				

6.4 Determination of response time

For this test, the recording interval shall if possible be held at its minimum value. The temperature sensor of the recorder is initially placed at a temperature at 25 °C measured using a working standard thermometer.

The recorder sensor is placed as rapidly as possible in an air flow the temperature of which is stabilized at a value that is 20 K lower and/or higher than the initial temperature with regard to the specified operation temperature.

The air speed is 1 m/s $\pm$ 0,3 m/s.

The response time is the time needed for the recorded value to reach 90 % of the actual change of applied temperature.

6.5 Determination of time recording error

If applicable recording device using diagrammatic charts is started before the beginning of the measurement, for a time sufficient to take up any mechanical play.

Since time instruments are sensible to their operational temperature, the test should be performed for each of the following three reference conditions:

- a) device minimum operated conditions as specified by manufacturer;
- b) device maximum operated conditions as specified by manufacturer;
- c) device normal or average operated conditions.

For this test the recording interval shall if possible be held at its minimum value.

The device is placed in reference conditions. The elapsed time is measured using a suitable reference clock.

The reference clock should be a suitable calibrated clock.

The beginning and the end of the time recording duration are defined by any one of the following methods:

- Method 1: A sudden variation in the temperature measured;
- Method 2: An automatic or manual data gathering event that should record both the unit time

and the reference clock time with a maximum skew of one second and a resolution of one second.

The test is carried out during a recording duration of at least three days for method 1 and at least 6 h for method 2.

If applicable, the correspondence between the real time and the time recorded is checked.

The requirements of 5.10.2.4 shall be satisfied.

The error value shall be tabulated and all shall fall within the maximum permissible error. This value shall be given with the uncertainty of the measurement

6.6 Action of influence quantities

6.6.1 General

Unless otherwise indicated, during or at the end of these tests, the determination of the temperature measurement error is carried out using the method given in 6.3 but with only one cycle.

6.6.2 Variation in voltage supply (if applicable)

The temperature measurement error is determined while supplying the recorder successively at the minimum and maximum value of the rated operating conditions.

For each value of the supply voltage, the pre-heating time is one hour at the minimum.

The measurement errors shall not exceed the maximum permissible errors in 5.10.2.1.

6.6.3 Influence of ambient temperature

6.6.3.1 General

The recorder is subjected to its limiting temperatures, and then, the measurement performance is tested at the maximum and minimum operating temperatures.

6.6.3.2 Test applicable to recorders with external sensor

The recorder in operation is placed in a case which is brought successively through the temperature phases of the Table 8.

Table 8 — Phases for recorder with external sensor

Phase	Temperature
1	Maximum limiting temperature
2	Maximum operating temperature
3	Minimum limiting temperature
4	Minimum operating temperature

Each phase shall last a minimum 4 h.

The temperature measurement error is determined during phases 2 and 4 with the enclosure maintained at the maximum and minimum operating temperatures stabilized within $\pm 2^\circ\text{C}$.

6.6.3.3 Test applicable to recorders with internal sensor

The recorder in operation is placed in a case which is brought successively through the temperatures phases of the Table 9. The ambient temperature shall be stabilized within $\pm 2^\circ\text{C}$.

Table 9 — Phases for recorder with internal sensor

Phase	Temperature
1	Maximum limiting temperature
2	Minimum limiting temperature

Each phase shall last a minimum of 4 h. Following the test, the temperature measurement error is determined after a resettling time of 4 h at the reference temperature. ($23^\circ\text{C} \pm 3^\circ\text{C}$).

6.6.4 Temperature testing under storage and transport conditions for the recorder

The test shall be carried out under the following conditions:

- the recorder is not in operation;
- minimum and maximum temperatures for storage and transport conditions defined by the manufacturer;
- temperature variation speed is 1 °C/min;
- air speed is between 1m/s and 2 m/s;
- dwell time: 3 h;
- number of cycles is 5.

Following the test, the temperature measurement error is determined after a resettling time of 2 h at the reference temperature.

6.6.5 Shock resistance test (if applicable)

The test shall be carried out according to the method of EN 60068-2-27 under the following conditions:

- acceleration: 10 g;
- time duration: 10 ms;
- recorder in normal operating position;
- number of shocks: 1.

If there is more than one operating position, the test shall be repeated for each of the operating positions. The shock is applied in the upward vertical direction.

Following the test, the temperature measurement error is determined after a resettling time of 2 h at the reference temperature.

6.6.6 Mechanical vibrations (if applicable)

The test applies to the recorder and its temperature sensor.

The recorder is in operation during the entire duration of the test.

The internal or external temperature sensor is kept at a constant temperature within the span.

The equipment under test is attached to the vibration table by means of a rigid component which holds the device by its usual system of attachment.

The recorder is subjected to sinusoidal rectilinear vibrations that are applied to it in three trirectangular directions. The sweep (frequency range path) is continuous and its speed is logarithmic according to time (1 octave/min).

Twenty successive sweep cycles are carried out in each of the three directions.

During the test all resonance phenomena are observed.

After the test, the variations in the value recorded during the test are determined.