

SLOVENSKI STANDARD
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Registratorji temperature za transport, skladiščenje in prodajo blaga, občutljivega za toploto - Preskusi, značilnosti, ustreznost

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

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

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

Ta slovenski standard je istoveten z: prEN 12830

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**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 (prEN 12830:2017) 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 12830:1999.

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”.

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1 Scope

This European Standard specifies the technical and functional characteristics of temperature recorders for the transport, storage and distribution of temperature sensitive goods between -80 °C and +85 °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°C and +85°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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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)*

3 Terms and definitions

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

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 of measurement****accuracy**

closeness of the agreement between the result of a measurement and a true value of the measurand

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**uncertainty of measurement**

parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

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)

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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 instruments 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 interval between the instant when a stimulus is subjected to a specified abrupt change and the instant when the response reaches and remains within specified limits around its final steady value

3.25**storage and transport conditions**

the 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 food**

food 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**

a distinct part or component of the temperature recorder that generates, encodes, transports, prints, indicates and/or stores relevant data. It is housed in its own enclosure.

prEN 12830:2017 (E)**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. For 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. 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 may consist of only one measuring instrument.

4 Concepts

4.1 General

The objective of the temperature recorder is to generate accurate temperature—time—location tuples and to record them.

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

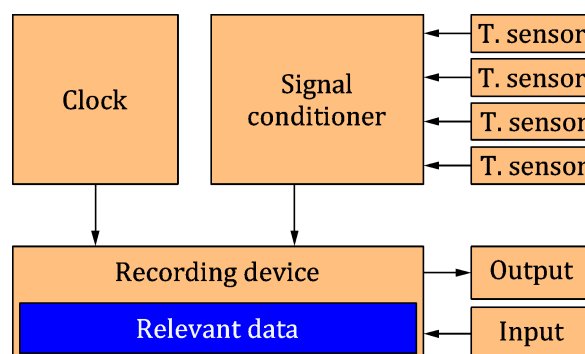


Figure 1 — Abstract view of the temperature recorder showing its main elements

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 can be air or insertion type.

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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 is 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 we will describe some of the possible alternatives, pointing some of the major design challenges.

4.3.2 Monolithic instrument

A monolithic temperature recorder includes all 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 is 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.