SLOVENSKI STANDARD
oSIST prEN 13486:2022

01-september-2022

Registratorji temperature in termometri za merjenje temperature okolice ali notranje temperature pri prevozu, skladiščenju in distribuciji toplotno občutljivega blaga - Periodično preverjanje

Temperature recorders and thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Periodic verification

Temperaturregistriergeräte und Thermometer zur Messung der Umgebungs- und Innentemperatur für den Transport, die Lagerung und die Verteilung von temperaturempfindlichen Waren - Regelmäßige Prüfungen

Enregistreurs de température et thermomètres de mesure de la température ambiante ou interne pour le transport, le stockage et la distribution des marchandises thermosensibles - Vérification périodique

Ta slovenski standard je istoveten z: **prEN 13486**

ICS:

17.200.20	Instrumenti za merjenje temperature	Temperature-measuring instruments
67.260	Tovarne in oprema za živilsko industrijo	Plants and equipment for the food industry

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Will supersede EN 13486:2001

English Version

Temperature recorders and thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Periodic verification

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 423.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 13486:2022) 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 13486:2001.

In comparison with the previous edition, the following technical modifications have been made:

a) clarification of the scope;

b) Clause 4 has been completely revised;

c) addition of class 0,2 to the standard;

d) Clause 5.6 has been revised;

e) addition of a new methodology to Clause 6 to account for new technologies for time synchronisation;

f) addition of Clause 7 for functional test of recorders with cloud SaaS for storage and display;

g) Clause 8 regarding expression of results has been updated and clarified;

h) addition of Annex C as guideline to the verification process;

i) addition of Annex D as guideline to determine the expanded uncertainty.

1 Scope

This document specifies the verification procedure for temperature recorders and thermometers for measuring the air and the products between −80 °C and +85 °C, which are intended to equip the means used for the transport, storage and distribution of temperature sensitive goods and which comply with standards EN 12830 and EN 13485 (measurement classes and ranges).

It specifies the test methods which allow the verification of the equipment's conformity against class requirements identified in EN 12830 and EN 13485.

NOTE Examples for the transport, storage and distribution of temperature sensitive goods between −80 °C and +85 °C include chilled, frozen, deep frozen and quick-frozen food; ice cream; fresh and hot food; pharmaceuticals; blood and organs; chemicals; biologicals; electronic and mechanical devices; flowers, plants and bulbs; raw materials and liquids; animals; art and furnishings.

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 12830:2018, *Temperature recorders for the transport, storage and distribution of temperature sensitive goods - Tests, performance, suitability*

EN 13485, *Thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods - Tests, performance, suitability*

EN ISO 10012, *Measurement management systems - Requirements for measurement processes and measuring equipment (ISO 10012)*

3 Terms, definitions and abbreviations

For the purposes of this document, the terms and definitions given in EN 12830, EN 13485 and the following apply.

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

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1 Terms and definitions

3.1.1
verification
confirmation and provision of evidence that the specified requirements have been fulfilled

Note 1 to entry: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

Note 2 to entry: The result of verification leads to a decision to either restore to service, perform adjustments, repair, downgrade or declare obsolete. A written trace of the verification performed is kept on the measuring instrument's individual record.

[SOURCE: EN ISO 9000:2015, 3.8.12]

3.1.2
maximum permissible error
limits of permissible error
<measuring instrument> extreme values of an error permitted by specifications, regulations etc., for a given measuring instrument

[SOURCE: VIM [1]]

3.1.3
working standard
check standard
standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials

Note 1 to entry: A working standard is usually calibrated against a reference standard.

Note 2 to entry: A working standard used routinely to ensure that measurements are being carried out correctly is called a check standard.

[SOURCE: VIM [1]]

3.1.4
error of measurement
measured quantity value minus a reference quantity value

[SOURCE: EN 12830:2018, 3.11]

3.1.5
value

<quantity> magnitude of a particular quantity generally expressed as a unit of measurement multiplied by a number

EXAMPLE 15 °C

[SOURCE: VIM [1]]

3.1.6
measurement
set of operations having the object of determining a value of a quantity

[SOURCE: VIM [1]]

3.1.7
uncertainty of measurement
parameter, associated with the result of a measurement, which characterizes the dispersion of the values that could reasonably be attributed to the measurand

[SOURCE: VIM [1]]

3.1.8
thermometer
any device to measure and display temperature

Note 1 to entry: See 3.16.

3.1.9
temperature sensor
element of a measuring instrument or measuring chain that is directly affected by the temperature

Note 1 to entry: See 3.X.

3.1.10
recording device
part of a measuring instrument that provides a record of an indication

[SOURCE: EN 12830:2018, 3.14]

3.1.11
measuring range
working range
set of values for which the error of a measuring instrument is intended to lie within specified limits

[SOURCE: VIM [1]]

3.1.12
resolution
<displaying device> smallest difference between indications of a displaying device that can be meaningfully distinguished

[SOURCE: VIM [1]]

3.1.13
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

[SOURCE: VIM [1]]

3.2 Abbreviations

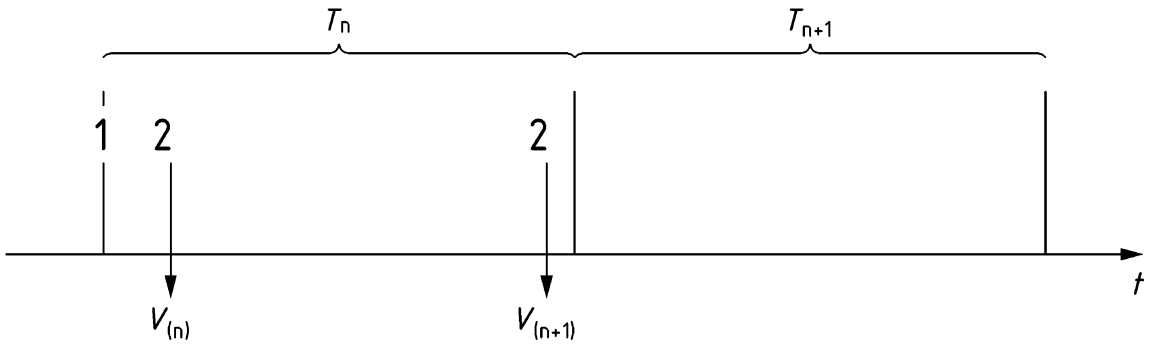
AIT	Atomic International Time
DUT	device under test
GPS	global positioning system
MPE	maximum permissible error
NTP	network timebase protocol

4 Frequency and kind of verification

The frequency and the type of the checks depends on the requirements of the contracting parties, taking into account the requirements of the manufacturer and user while respecting mandatory regulations.

For accuracy class lower than 0,5 particular attention should be given ensuring standard equipment and uncertainty requirements when verifications are done on-site.

Verification shall allow traceability of the measurement done prior to verifications and that the equipment is within the specifications for the next period. See Figure 1.



Key

1	new recorder - Installation and commissioning
2	verification in accordance to EN 13486
T_n	period n
T_{n+1}	period n+1
V(n)	equipment is conform and ready to operate (Period n)
V(n+1)	equipment is conform and ready to operate (Period n+1)

If V(n+1) is successful, measurements on Period n are validated.

If V(n+1) is not successful, measurements on Period n need to be analysed to evaluate potential non-conformity.

Figure 1 — Timeline for verifications of equipment

Accordance of the equipment to the standard is determined taking into consideration the uncertainty, the error of measurement plus the uncertainty shall be equal or less than the class of equipment.

A guidance is found in Annex C while Annex D gives guidance to the determination of the expanded uncertainty.

The applicable kind of verifications for the respective type of equipment is shown in Table 1.

Table 1 — Kind of verifications per type of equipment

Clause	Thermometer	Recorder
5	X	X
6		X
7		X

5 Method of verification of temperature measurement

5.1 General

The method used is the measurement by direct comparison of the instrument under test and the working standard thermometer.

5.2 Environmental conditions

It shall be ascertained that the environmental conditions for the tests are compatible with the apparatus to be verified and with the measuring instruments used (disturbances caused by, for example welding unit, inverters, high voltage cables).

5.3 Working standard

Table 2 gives the maximum calibration uncertainty for the verification measurement range, with a one-year calibration interval.

Table 2 — Maximum uncertainty of the reference equipment

Class	0,2	0,5	1	2
Maximum uncertainty of the reference equipment	±0,1 K	±0,25 K	±0,5 K	±1 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, generator ...). A coefficient k = 2 is used to indicate uncertainty (95 % Interval for normal distribution).				

5.4 Additional equipment

Climatic container or thermostatic bath or any suitable equipment for one-site verification.

The choice shall be in accordance with the requirements in Table 2.

5.5 Procedure

5.5.1 General

A detailed procedure of the operating method shall be drawn up, indicating the operating sequence and complying with the verification operations according to EN ISO 10012.

5.5.2 Preliminary operations

If necessary:

— cleaning of the thermometer or the temperature recorder and the sensor(s);

— verification of the display or recorder (self-test) and connector(s);

— possible change of battery or its recharge;

— verification of the electrical connections.

Then:

— stabilization of the temperature of the sensors (pay attention to the response time, temperature delay, heat radiation, etc.);

— for recorders, verify the proper functioning of the clock or of the diagram recording system according to manufacturers' specifications.

5.5.3 Verification measurement(s)

The verification operation shall be conducted at least for the lowest and the highest temperature of the range as specified by the user at which the equipment is most frequently used and confirm each class within this range. If the total range is larger than 10 K an additional mean temperature value should be added.

EXAMPLE 1 If the customer is using two ranges: 2 to 8 °C and 15 to 25 °C the verification points would be (2, 8) and (15, 25).

EXAMPLE 2 If the customer is using the range: 0 to −20 °C the verification points would be (0, −20) and −10.

Climatic container or thermostatic bath as referred to in 5.4 shall be used when practicable.

If the verification is conducted on site, suitable equipment for the verification proposed by the manufacturer, if any, shall be used; if not, an appropriate measurement method shall be applied to comply with the following requirements:

— maximum thermal coupling between the sensors;

— maximum stability of the measured temperature;

— sufficient time for the reading to become stable (at least response time of the probe ≥).

5.6 Condition of acceptance

This operation consists of comparing the results of measurements and calculating errors noted, taking into account the uncertainty of the measurement to verify if these measurements comply with the relevant specification of limit of permissible error as given in the standards (equipment class). If the equipment has multiple classes, each range should be verified separately. This specification should be done at a class of the standards on temperature recorders (EN 12830) and thermometers (EN 13485) irrespective of the original class of the appliance.

NOTE If applicable by the usage of the recorder, verification of the data storage system can need additional verification processes by related quality requirements and regulations.

6 Method of verification of duration of temperature recordings

6.1 General

The purpose of this verification is to ensure that the duration of recordings is within specification.

For a recorder with an internal clock, the purpose of this verification is to ensure that the duration of recordings is within specification when using the internal clock.

Table 3 describes the different possible cases related to the time recording (type of clock) and associated method of verification (see 6.2.3 for method description).