SLOVENSKI STANDARD
SIST EN 13486:2024

01-februar-2024

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 Produkten - 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: **EN 13486:2023**

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

SIST EN 13486:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13486

December 2023

ICS 17.200.20; 67.260

Supersedes 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 European Standard was approved by CEN on 20 November 2023.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

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Ref. No. EN 13486:2023 E

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European foreword

This document (EN 13486:2023) 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 June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

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 13486:2001.

EN 13486:2023 includes the following significant technical changes with respect to EN 13486:2001:

a) enhancement of the scope by defining adapted temperature ranges and broadening it to more temperature sensitive goods in accordance with EN 12830 and EN 13485;

b) complete revision of Clause 4;

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

d) revision of 5.6;

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) update and clarification of Clause 8 regarding expression of results;

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

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

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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

1 Scope

This document specifies the verification procedure for temperature recorders and thermometers for measuring the ambient or internal temperature of 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) and also others used for transport, distribution and/or storage of temperature sensitive goods.

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)*

JCGM 200:2012, *International Vocabulary of Metrology — Basic and general concepts and associated terms (VIM)* [1]

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 12830, EN 13485, the VIM (JCGM 200:2012) and the following apply.

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

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

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

3.1.1
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

[1] Available at: https://www.bipm.org/en/committees/jc/jcgm/publications

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: EN ISO 9000:2015, 3.8.12]

3.1.2
error of measurement
measured quantity value minus a reference quantity value

[SOURCE: EN 12830:2018, 3.11]

3.1.3
thermometer
any device to measure and display temperature

[SOURCE: EN 13485:2023, 3.2]

3.1.4
temperature sensor
element of a measuring instrument or measuring chain that is directly affected by the temperature

[SOURCE: EN 13485:2023, 3.3]

3.1.5
recording device
part of a measuring instrument that provides a record of an indication

[SOURCE: EN 12830:2018, 3.14]

3.2 Abbreviations

For the purposes of this document, the following abbreviations apply.

AIT	Atomic International Time
DUT	device under test
GPS	global positioning system
MPE	maximum permissible error (equal to the equipment class)
NTP	network timebase protocol

4 Frequency and kind of verification

The verification shall be done for:

— all new thermometers and recorders,

— in the case of any change of the measurement chain,

— in the case of indicated issues and/or problems or

— in the case of repairs with the measurement system.

The frequency and the type of the checks depends on the requirements of the contracting parties, i.e. recorder owner and its client(s), taking into account the requirements of the manufacturer and user while

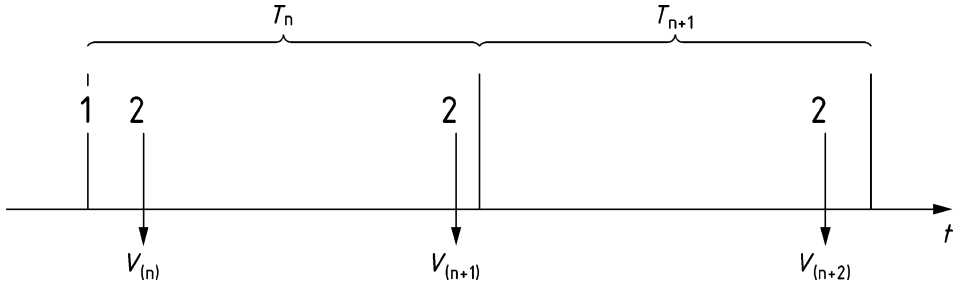
respecting mandatory regulations as well as operational impact or usage like storage/transport, fresh/frozen, frequently changed temperatures, vibration, etc.

Data gathered during the recorder operations may be used as support evidence to evaluate/adjust the frequency period.

It is recommended to have a systematic verification following a period of non-use exceeding the period adopted by the user or when an operating incident or a deterioration is noted or supposed, or during an intervention such as the introduction of a new sensor, except in the case of calibrated digital sensors when permitted by the manufacturer.

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 with EN 13486
t	time
T_n	verification period n
T_{n+1}	verification period n+1
V(n)	equipment is conform and ready to operate (verification period n)
V(n+1)	equipment is conform and ready to operate (verification period n+1)
V(n+2)	equipment is conform and ready to operate (verification period n+2)

Figure 1 — Timeline for verifications of equipment

Table 1 indicates the requested periodical kind of verifications for thermometer or temperature recorders.

Table 1 — Kind of verifications per type of equipment

Clause	Thermometer	Temperature 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.

Table 2 — Maximum uncertainty of the working standard

Class	0,2 [a]	0,5 [a]	1	2
Maximum uncertainty of the working standard	0,1 °C	0,25 °C	0,5 °C	1 °C
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). [a] Recommended for class 0,2 and 0,5, as long as class conformity declaration is done taking into account the uncertainty and the error				

5.4 Additional equipment

Additional equipment are climatic chambers or thermostatic baths or any suitable equipment for on-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 most frequent range among the ones specified by:

— the intended classification declaration by the manufacturer and / or

— the declaration of the recorder and/or thermometer usages to confirm each class within intended usage(s)

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 intended use is storage or transport of fresh and deep frozen perishable foodstuffs it would be class 0,5 from −25 °C till +7 °C and for pharmaceutical products class 0,5 from +3 °C till +25 °C.

For temperature recorders without direct cloud storage access by the laboratories, the verification process shall be started with a validation of a local time and clock registration together with a specific temperature shock larger than 10 K to indicate the start point of verification.

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

EXAMPLE 3 If the customer is using a range larger than 10 K like: +12 °C to −20 °C the three verification points are (+12, −20) °C and optionally −6 °C.

If the verification is conducted on site:

a) 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 longer than the response time of the probe).

   If a suitable equipment proposed by the manufacturer which complies to these requirements, it may be used if available.

b) Thermostatic bath as referred to in 5.4 should be used if class 0,2 is recommended. Climatic chamber may be used for class 0,5 or 1 or 2 if thermostatic bath would be not practicable. The verification will be limited to these classes only.

   NOTE This can include a de-classification of sensors if the installation gives practical limitations.