SLOVENSKI STANDARD
SIST EN 12470-1:2000+A1:2009

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Kliniļ ni termometri - 1. del: Zaprti stekleni termometri s tekoļ imi kovinami

Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device

Medizinische Thermometer - Teil 1: Mit metallischer Flüssigkeit gefüllte Glasthermometer mit Maximumvorrichtung

Thermomètres médicaux - Partie 1: Thermomètres à dilatation de liquide métallique dans une gaine de verre, avec dispositif à maximum

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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 Management Centre has the same status as the official versions.

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Foreword

This document (EN 12470-1:2000+A1:2009) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", 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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-05-16.

This document supersedes EN 12470-1:2000.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

For A-deviations, see annex ZB.

This European Standard applies to clinical thermometers which are used for measuring the body temperature of humans.

EN 12470 consists of the following Parts under the general title 'Clinical thermometers':

Part 1: Metallic liquid-in-glass thermometers with maximum device

Part 2: Phase change-type (dot matrix) thermometers

Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device

Part 4: Performance of electrical thermometers for continuous measurements

Part 5: Performance of infra-red ear thermometers (with maximum device)

Annexes A, B, C, ZA and ZB are informative.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This Part of EN 12470 specifies performance requirements and test methods for clinical liquid-in-glass thermometers with maximum device and applies only to thermometers filled with metallic liquid.

NOTE 1 Note that in some European countries the use of mercury is prohibited in clinical thermometers.

NOTE 2 Substances other than metallic liquids can be used in the manufacturing of liquid-in-glass thermometers. No reference is made to these in this European standard because there is no experience of clinical thermometers which use other substances.

This European Standard does not apply to clinical thermometers designed for special applications (e.g. thermometers for premature babies, ovulation thermometers) which, owing to their measurement range, scale interval or maximum permissible error, fall outside the scope of this standard.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publication. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

ISO 719, *Glass - Hydrolytic resistance of glass grains at 98 degrees C - Method of test and classification*

ISO 2859-2:1985, *Sampling procedures for inspection by attributes – Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

3 Definitions

For the purposes of this Part of EN 12470, the following definitions apply:

3.1
correction
value added algebraically to the uncorrected result of a measurement to compensate for systematic error

3.2
error
result of measurement minus a true value of the measurand

3.3
maximum device
device which prevents the liquid column from falling when the temperature of the liquid in the bulb returns to the ambient temperature

3.4
scale panel (enclosed-scale type)
panel to which the scale is fixed longitudinally behind the capillary tube

3.5
stabilized thermometer reading

result given by a thermometer which, after attaining thermal equilibrium with a water bath of a temperature within the thermometers measuring range, has been removed from the water bath and cooled to a temperature of between 15 ˚C and 30 ˚C

3.6
zero point correction
correction of the reading of the thermometer at 0 ˚C

NOTE $K = 0\ ^\circ C - t_1$

3.7
zero point depression
change of zero point correction after heating and fast cooling of the thermometer

4 Unit

The unit of temperature shall be the degree Celsius, symbol ˚C.

5 Types of thermometer

The types of metallic liquid-in-glass thermometers with maximum device shall be:

a) solid-stem, or

b) enclosed-scale

6 Requirements

6.1 Scale

6.1.1 Measuring range and scale interval

The thermometer shall cover the minimum range from 35,5 ˚C to 42,0 ˚C with a scale interval of 0,1 ˚C.

Testing shall be performed by visual inspection.

6.1.2 Scale marks and numbering

6.1.2.1 General

The scale marks shall be uniformly spaced and of uniform width.

The scale marks and numbers shall be at right angles to the axis of the thermometer and shall be visible at the same time as the liquid column.

Testing shall be performed by visual inspection.

6.1.2.2 Scale spacing

The distance between adjacent scale marks shall be at least 0,5 mm for solid-stem thermometers and at least 0,6 mm for enclosed-scale thermometers.

Testing shall be performed using an appropriate device, which magnifies the scale by at least x 4.

6.1.2.3 Width and length of the scale marks

The scale marks shall be durably marked and shall be of uniform width not exceeding one-quarter of the length of a scale spacing plus 0,05 mm for solid-stem thermometers, or one-fifth of the length of a scale spacing plus 0,05 mm for enclosed-scale thermometers.

Scale marks representing whole degrees and half degrees shall be longer than the other scale marks.

Testing shall be performed using an appropriate device, which magnifies the scale by at least x 4.

6.1.2.4 Numbering

Scale marks representing whole degrees shall be numbered.

NOTE The scale mark representing the temperature of 37 °C can be rendered conspicuous by means of a different colour from that used for the numbering and/or by additional marking.

Testing shall be performed by visual inspection.

6.1.2.5 Special requirements for solid-stem thermometers

The scale shall be indelibly marked directly on the thick-walled capillary stem.

When tested in accordance with 7.2, the appearance of the scale lines shall not be significantly affected.

6.1.2.6 Special requirements for enclosed-scale thermometers

The thermometer shall have a separate scale panel adjacent to the capillary tube. The capillary tube and the scale panel shall be enclosed in a transparent tube impermeably fixed to the bulb and forming a protection sheath.

The scale shall be marked on a scale panel fixed longitudinally behind the capillary tube.

Testing shall be performed by visual inspection.

6.1.2.7 Resistance to breakage of enclosed-scale thermometers

The thermometer shall not break when subjected to a force of at least 50N in accordance with 7.8.

6.2 Material

6.2.1 Thermometer bulb

6.2.1.1 General

The thermometer bulb shall be made of a type of glass which satisfies the requirements specified in 6.2.1.2 and 6.2.1.3. This glass shall be clearly and indelibly identified by either:

a) an integral mark introduced by the glass manufacturer in such a way as to be clearly recognizable on the bulb after manufacture of the thermometer or;

b) by a mark chosen by the glass manufacturer and affixed by the thermometer manufacturer and clearly indicating the type of glass used.

6.2.1.2 Hydrolytic resistance

When tested in accordance with ISO 719 the quantity of alkali obtained in solution from 1 g of the glass shall not exceed 263,5 µg of Na_2O.

6.2.1.3 Zero point depression

When tested in accordance with the method given in 7.3, the glass shall have an average zero point depression not exceeding 0,05 °C.

6.2.2 Maximum device and capillary

The glass used for the maximum device and the capillary shall have the same hydrolytic resistance as the glass for the thermometer bulb.

6.2.3 Scale panel of enclosed-scale thermometer

The scale panel of enclosed-scale thermometers shall be of opal glass, metal or another material of a dimensional stability such that, when tested in accordance with 7.4, the length of the scale sample after heating shall not differ from that before heating by more than 0,2 %.

6.2.4 Thermometric liquid filling

The metallic liquid filling used in the thermometer shall have the purity, properties and characteristics that will enable the finished thermometers to comply with all requirements specified in this European Standard.

The bulb, the capillary tube and the liquid column of the finished thermometer shall be free of gas, water, glass fragments or other foreign material.

Testing shall be performed by visual inspection using an appropriate device which magnifies by at least x 4.

6.3 Manufacture

6.3.1 Freedom from defects

The thermometer and its surface shall be free from defects that are likely to interfere with its proper functioning or to mislead the user, e.g. errors in graduation, flaws in the glass and constructional defects.

Testing shall be performed with an appropriate device, which magnifies the scale by at least x 4.

6.3.2 Capillary tube

The capillary tube shall ensure that the entire length of the liquid column and the meniscus are clearly visible from at least one angle. It shall be prismatic in form and have a magnifying effect, or shall be so designed as to ensure consistent ease of reading.

Testing shall be performed by visual inspection.

6.3.3 Thermometer ends

The ends of the thermometer shall be smoothly rounded in order to prevent tissue damage during use.

Testing shall be performed by visual and tactile inspection.

6.3.4 Liquid column

When the thermometer is heated slowly, the liquid column shall rise uniformly without appreciable surges.

NOTE Surges larger than half a scale interval are considered as defects.

Testing shall be performed by visual inspection.

When tested in accordance with 7.6, the liquid column shall fall below the lowest numbered scale mark.

The thermometer shall not break when subjected to this test.

6.3.5 Scale panel of enclosed-scale thermometer

The scale panel shall be either directly fixed to the capillary tube or be in direct contact with the capillary tube and fixed sufficiently firmly in the sheath to prevent any displacement with respect to the capillary tube. The scale panel shall be so positioned as to ensure that any displacement can be easily detected either by means of an indelible mark on the sheath level with a numbered scale mark or by some equivalent means. The marking shall be in accordance with 6.1.2.3 and shall be placed at 38 ˚C with a lateral tolerance of one-fifth of a scale spacing. The sheaths of enclosed-scale thermometers shall be free of moisture, liquid, glass fragments and foreign material.

Testing shall be performed by visual inspection.

6.4 Effect of storage

When tested in accordance with 7.7, the thermometer shall meet the requirements specified in 6.5.

6.5 Maximum permissible error under reference conditions

Within the measuring range specified in 6.1.1 the maximum permissible error of the thermometer shall be + 0,1 ˚C and - 0,15 ˚C. This value applies to the stabilized thermometer readings.

Test shall be performed in accordance with 7.9.

6.6 Influence of immersion time

The thermometer at an ambient temperature t_1 of (23 ± 2) ˚C is rapidly immersed for 20 s in a vigorously stirred water bath at a constant temperature t_2 of (38 ± 2) ˚C, withdrawn and read after at least 1 min. Then the procedure is repeated with an immersion time of 60 s. The readings for 60 s and 20 s shall not differ more than $0{,}006 \cdot (t_2 - t_1)$.

Testing shall be performed in accordance with 7.5.

7 Test methods

7.1 General

Each individual lot not exceeding 100 000 units shall be subjected to testing, either individual or statistical. For statistical testing, the lot shall be homogenous and thermometers from various sources shall not be mixed.

The sampling plan shall correspond to ISO 2859-2:1985, level II with a limiting quality level LQ = 5%.

NOTE 1 Other sampling plans can be used if they are statistically equivalent.

NOTE 2 For suggested types of testing, see Annex

7.2 Method of test of the performance of pigment

7.2.1 General

Testing of each batch shall be performed in accordance with 7.1.

NOTE This requirement applies only to solid-stem thermometers.

7.2.2 Procedure

Immerse the stem of the thermometer for 20 min in a solution of 700 g/l ethanol in water at 38 ˚C and then wipe it dry.

7.3 Method of test for the determination of the average zero point depression

7.3.1 Construction of test thermometer

Using the glass under consideration for the bulb, construct test thermometers with the following specifications:

a) scale range at least: - 3,0 ˚C to + 3,0 ˚C;

b) scale interval: 0,02 ˚C, 0,05 ˚C or 0,1 ˚C;

c) distance between consecutive scale lines: at least 1,0 mm;

d) expansion chamber: of sufficient volume for the thermometer to be heated to 400 ˚C without damage;

e) stabilization: thermometers stabilized (see 7.3.2).

7.3.2 Confirmation of stabilization

7.3.2.1 Heat the thermometer in a suitable device e.g. a liquid bath or metal block oven, from room temperature to (350 ± 10) ˚C and keep it at this temperature for at least 5 min.

7.3.2.2 Cool the thermometer to 50 ˚C at a rate between 10 ˚C/h and 15 ˚C/h.

7.3.2.3 Remove the thermometer from the bath or oven, determine the correction at a temperature of 0 ˚C, and record its value (k_1).

7.3.2.4 Heat the thermometer again to a temperature of (350 ± 10) ˚C and keep it at this temperature for 24 h.

7.3.2.5 Cool the thermometer as in 7.3.2.2.

7.3.2.6 Redetermine the correction as in 7.3.2.3 and record its value (k_2).

7.3.2.7 If (k_2 - k_1) exceeds 0,15 ˚C, reject the sample, stabilize fresh samples and repeat the procedure described in 7.3.2.1 to 7.3.2.6. If (k_2 - k_1) does not exceed 0,15 ˚C carry out the depression of zero test (see 7.3.3).

7.3.3 Depression of zero test

7.3.3.1 Select *m* stabilized test thermometers (where *m* is not less than 3) tested by the procedure described in 7.3.2 which have not subsequently been heated above room temperature. Carry out the following procedure for each of the thermometers.