SLOVENSKI STANDARD
SIST EN 12470-2:2001

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Klinični termometri – 2. del: Termometri, ki zaznavajo spremembo faze (točkovna matrica)

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

Medizinische Thermometer - Teil 2: Phasenumschlagthermometer (Punktmatrix)

Thermometres médicaux - Partie 2: Thermomètres à changement de phase (matrice a points)

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Thermomètres médicaux - Partie 2: Thermomètres à changement de phase (matrice à points)

Medizinische Thermometer - Teil 2: Phasenumschlagthermometer (Punktmatrix)

This European Standard was approved by CEN on 16 September 2000.

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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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Contents **Page**

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

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.

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 measurement

Part 5[1] Performance of infra-red ear thermometers (with maximum device)

Annexes A and ZA 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

[1] In preparation

1 Scope

This Part of EN 12470 specifies performance requirements and test methods for phase change-type (dot matrix) thermometers for measuring temperature in body cavities.

NOTE: A body cavity can be the mouth, rectum or armpit.

This European Standard does not apply to clinical thermometers designed for special applications (e.g. thermometers for hypothermia) which owing to their measurement range, scale interval or maximum permissible error do not meet the requirements specified in 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 (including amendments).

EN 980	*Graphical symbols for use in the labelling of medical devices*
EN 1041	*Information supplied by the manufacturer with medical devices*
EN 556+A1	*Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "Sterile"*
ISO 2859-2:1985	*Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

3 Terms and definitions

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

3.1
measurement time
length of time required to measure body temperature.

3.2
phase change (dot matrix) thermometer
device utilising a change in state of chemical components designed to measure and indicate human body temperature.

3.3
retention time
duration of time for which the optimal signal for reading persists.

3.4
sensor matrix
temperature measuring area consisting of temperature dots.

NOTE: The dots contain different chemical mixtures, which change their state at specific temperatures. This change is accompanied by a change in appearance, e. g. change of colour. When in contact with the temperature site being measured, the change of state takes place in the sequence of dots up to and including the dot corresponding to the temperature of the site. This dot indicates the site temperature.

3.5
temperature offset
designed difference between preadjusted thermometer reading and water bath temperature after reaching thermal equilibrium.

3.6
preadjusted thermometer
thermometer which is designed to have a temperature offset.

3.7
skipped dot
a dot which fails to activate when exposed to a temperature which would have caused activation.

3.8
adjacent dots
dots which are numerically sequential according to the scale.

3.9
storage package
smallest original shipping unit used by the manufacturer.

4 Unit

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

5 Type of thermometers

Thermometers covered by this Part of EN 12470 are either of the single-use type or the multiple-use type. Thermometers are classified by their measuring range into the following types:

a) short scale type with a measuring range of 35,5 °C to 40,4 °C;

b) long scale type with a minimum measuring range of 35,5 °C to 42,0 °C.

6 Requirements

6.1 Scale

6.1.1 Measuring range and scale interval

The thermometer shall cover one of the measuring ranges specified in clause 5 with a scale interval no greater than 0,1 °C.

Testing shall be performed by visual inspection.

6.1.2 Scale marks and numbering

Numerals shall be placed at least at every degree graduation on the scale.

Testing shall be performed by visual inspection.

6.1.3 Temperature indication

There shall be a distinct difference in appearance before and after the change of the state of the thermometer dots.

Testing shall be performed by visual inspection.

6.2 Measurement retention

Any temperature measurement reading of the thermometer shall be maintained for a minimum period of 20 s after the thermometer has been removed from the test site and has been allowed to stabilise at room temperature (23 ± 5) °C.

Testing shall be performed in accordance with 7.2.

6.3 Regeneration

The thermometer shall be designed in such a way that if it has been partially or totally activated, it can be returned to functional condition and accuracy by a method specified by the manufacturer.

Testing shall be performed in accordance with 7.4.

6.4 Effect of storage

After testing in accordance with 7.3 the thermometer shall meet the requirements specified in 6.5.

6.5 Maximum permissible error under reference conditions

The maximum permissible error shall not exceed $^{+0,1\,°C}_{-0,2\,°C}$ for each individual dot.

Testing shall be performed in accordance with 7.2.

The temperature difference necessary to activate two adjacent dots shall not exceed 0,2 °C.

Testing shall be performed in accordance with 7.5.

If the thermometer has an offset, the offset shall be uniform throughout the measuring range of the thermometer.

6.6 Skipped dots

The thermometer shall not have two adjacent skipped dots. The total number of skipped dots shall not be greater than 5 % of the total number of dots for that thermometer.

Testing shall be performed in accordance with 7.6.

6.7 Thermometers supplied sterile

Thermometers which are labelled "STERILE" shall comply with EN 556+A1.

NOTE: Sterilization processes should be validated and routinely controlled.

6.8 Biocompatibility

The thermometer shall be free from biological hazard.

NOTE: EN ISO 10993-1 should be used as guidance.

6.9 Measurement time (clinical) for preadjusted thermometers

The manufacturer shall demonstrate and document that the specified measurement time conforms with the chosen offset by either :

a) compilation and analysis of relevant scientific literature; or
b) analysis of data obtained from the result of clinical investigation.

6.10 Additional requirements for multiple-use thermometers

Thermometers for multiple use shall be designed to fulfil the requirements of this standard for at least the number of uses specified by the manufacturer after use, cleaning and regeneration as specified by the manufacturer.

Testing shall be performed in accordance with 7.7.

6.11 Mechanical safety

The temperature probe shall be smoothly rounded in order to prevent tissue damage during use.

Testing shall be performed by visual inspection.

7 Test methods

7.1 General

Each individual lot 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 A.

7.2 Test of compliance of the maximum permissible error

7.2.1 Apparatus

7.2.1.1 *Reference thermometer,* with an uncertainty in temperature reading not greater than ± 0,02 °C (coverage factor k=2) shall be used to determine the temperature of the water bath. Its calibration shall be traceable to national measurement standards.

NOTE: The definition of the coverage factor "k" is found in the "Guide to the expression of uncertainty in measurement".

7.2.1.2 *Reference water bath,* well regulated and stirred and containing at least 5 l in volume shall be used to establish reference temperatures over the measuring range. It shall be controlled to have a temperature stability of better than ± 0,02 °C over the specified measuring range of temperature of the thermometer to be tested. It shall have a temperature gradient of not greater than ± 0,01 °C within its working space at a specified temperature.

This temperature gradient shall be assured under all conditions and patterns of loadings of thermometer samples.

7.2.2 Procedure

7.2.2.1 Immerse the test thermometer in the water bath (7.2.1.2) for the length of time specified by the manufacturer, and compare the readings obtained to those from the reference thermometer (7.2.1.1).

7.2.2.2 Select a minimum of 20 temperature points representing an even distribution within the measuring range for the test.

7.2.2.3 Measure for each manufacturing lot not less than 10 test thermometers at each specified temperature point. Use every thermometer only once.

7.2.2.4 Move the test thermometers into room temperature of (23 ± 5) °C.

7.2.2.5 Perform the reading of the result after equilibration of the test thermometer(s).

7.2.2.6 Read the results 20 s after the first reading to confirm the retention time as specified in 6.2.

7.2.3 Expression of results

Calculate the error of the thermometer from the following expression:

$$e = t_i - t_{WB}$$

where

t_i is the temperature indicated by the test thermometer;
t_{WB} is the temperature of the water bath determined by the reference thermometer.