SLOVENSKI STANDARD
SIST EN 12470-4:2001

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Klinični termometri – 4. del: Delovanje električnih termometrov za nepretrgano merjenje

Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

Medizinische Thermometer - Teil 4: Anforderungen an elektrische Thermometer zur kontinuierlichen Messung

Thermometres médicaux - Partie 4: Fonctionnement des thermometres électriques de mesurage continu

Ta slovenski standard je istoveten z: **EN 12470-4:2000**

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Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

Thermomètres médicaux - Partie 4: Fonctionnement des thermomètres électriques de mesurage continu

Medizinische Thermometer - Teil 4: Anforderungen an elektrische Thermometer zur kontinuierlichen Messung

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 Central Secretariat 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
COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.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 (predictive and non-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 the metrological and technical requirements for electrical thermometers for continuous measurements.

This European Standard applies to devices that are operated by an electrical power supply either by mains or internal power sources.

The devices can be equipped to accommodate secondary indicators, printing devices, and other auxiliary devices. The metrological requirements for such accessories are not covered by this European Standard.

Thermometers intended to measure skin temperatures are not covered by this European Standard.

This European Standard does not intend to exclude the use of any device based on other measuring principles that provides an equivalent performance in continuously measuring body temperature.

NOTE: Devices can have functions which are covered by different parts of EN 12470. In this case, it is the responsibility of the manufacturer to indicate by which part of EN 12470 the function is covered, e.g. electrical thermometer with maximum device and exchangeable temperature probes.

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 60068-2-14:1999	*Environmental testing - Part 2: Tests - Test N: Change of temperature* (IEC 60068-2-14:1984+A1:1986)
EN 60601-1:1990	*Medical electrical equipment -Part 1: General requirements for safety (IEC 60601-1:1988)*
EN 60601-1-2	*Medical electrical equipment -Part 1: General requirements for safety - 2: Collateral Standard : Electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:1993)*
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
continuously measuring electrical thermometer
device that continuously measures and displays the temperature of the human body and consists of an indicating unit and a connected temperature probe

3.2
indicating unit
component of the thermometer that processes the output signal of the temperature sensor and displays the value of the temperature.

3.3
temperature probe
component of the thermometer which is used to establish body temperature and comprises a temperature sensor with associated parts including coverings, seals, inner leads and connecting plug(s) when necessary.

4 Unit

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

5 Types of thermometers

Electrical thermometers for continuous measurements (complete thermometers) shall consist of an indicating unit and a temperature probe (which may or may not be exchangeable).

6 Requirements

6.1 General

If protective probe covers are recommended or supplied by the manufacturer, the thermometer together with the probe cover shall conform to the requirements specified in this standard.

6.2 Measuring Range

The measuring range shall be at least 25 °C to 45 °C. Larger measuring ranges can be subdivided into several partial measuring ranges; however, the range from 25 °C to 45 °C shall be continuous.

Testing shall be performed in accordance with 7.2.

6.3 Maximum permissible error

The maximum permissible error of a complete thermometer shall be ± 0,2 °C in the temperature range from 25 °C to 45 °C.

For the manufacturing of components of complete thermometers the following values apply within the temperature range 25 °C to 45 °C:

a) indicating unit : ± 0,1 °C;
b) temperature probe : ± 0,1 °C.

For thermometers where the specified measuring range is greater than 25 °C to 45 °C, the maximum permissible error shall not be greater than twice the specified values for temperatures <25 °C and >45 °C.

Testing shall be performed in accordance with 7.2.

6.4 Time response

When subjected to rapid temperature change the indicated temperature of the complete thermometer shall not differ from the reference temperature after 150 s by more than the maximum permissible error.

Testing shall be performed in accordance with 7.3 .

6.5 Environmental operating range

The minimum environmental operating range of the complete thermometer shall be from + 10 °C to + 40°C and 30 % to 75 % relative humidity.

When tested in accordance with 7.4 the thermometer shall comply with 6.3.

6.6 Effect of Storage

When tested in accordance with 7.5 the complete thermometer shall comply with 6.3.

6.7 Humidity

When tested in accordance with 7.6 the complete thermometer shall comply with 6.3.

6.8 Electromagnetic compatibility

The complete thermometer shall comply with EN 60601-1-2.

6.9 General requirements for safety

The complete thermometer shall comply with EN 60601-1.

The applied part shall be according to EN 60601-1:1990 Type BF or for direct cardiac application of Type CF.

6.10 Additional requirements for the indicating unit

6.10.1 Digital increment

The digital increment of the indicating unit shall be 0,1 °C or less.

Testing shall be carried out by visual inspection.

6.10.2 Display

Numerical values on the display shall be at least 4 mm high or optically magnified so as to appear that height and shall be visible and/or legible to an operator having a visual acuity (corrected if necessary) of at least 1,0 when the operator is located 1 m in front of the indicating unit at an illuminance of 215 lx. The indicating unit shall provide an update at least every 10 s.

The thermometer shall provide a visual or audible signal when the measured value of temperature is not within its specified measuring range.

For segment based displays, all segments shall be activated after power on for at least 2 s, where applicable.

Testing shall be carried out by visual inspection.

6.10.3 Maximum energy dissipation

The energizing potential provided by the indicating unit for the temperature probe shall be sufficiently low so that the energy dissipation in the probe conforms to the requirements specified in 6.11.1.

Testing shall be performed in accordance with the manufacturer's specification.

6.10.4 Auxiliary device

The indicated temperature of the complete thermometer shall be unaffected when auxiliary devices are connected to it.

Evidence of compliance shall be supplied by the manufacturer.

6.10.5 Self checking device

The indicating unit shall include a device for self checking that shall be equal to or better than the maximum permissible error of the indicating unit specified by the manufacturer. The self checking device shall test at power on and periodically and automatically, at least once an hour, the signal processing part of the indicating unit covering the specified measuring range. A failure shall provide a recognizable indication or warning signal.

Compliance shall be tested according to the manufacturer's specification.

6.10.6 Variations of the voltage supply

For power supply by mains, the indicated temperature of the thermometer shall not show a change from nominal values of ± 10 % for voltage and of ± 2 % for frequency. For power supply by battery or an auxiliary power source, the thermometer shall have a device that provides a recognizable indication or warning signal when the voltage is at or below the level specified by the manufacturer. If the supply voltage varies within the specified limits the thermometer shall not show a change of more than 1 unit of the least significant digit.

Testing shall be performed in accordance with 7.6.

6.11 Additional requirements for the temperature probe

6.11.1 Maximum energy dissipation

For a resistance–type probe, the manufacturer shall specify the maximum power that can be supplied to it by an indicating unit to minimize self-heating. The maximum power supplied shall not cause an energy dissipation (I^2R) that gives rise to an increase in temperature of more than 0,02 °C for reusable or single-use probes, when immersed in a reference water bath at 37 °C ± 0,1 °C.

Testing shall be performed in accordance with 7.7.

6.11.2 Long-term stability

The long-term stability of the temperature probe, before and after exposing it for a minimum of 288 h to a temperature of (55 ± 2) °C, or for a minimum of 96 h to a temperature of (80 ± 2) °C, shall be such that values for maximum permissible errors specified in 6.3 are met.

Testing shall be performed in accordance with 7.8.

6.11.3 Protection against human liquids

The insulation of the temperature probe without probe cover shall be sufficient to prevent a change in the indicated temperature greater than ± 0,02 °C when the probe is immersed in an electrically conducting liquid.

Testing shall be performed in accordance with 7.9.

6.11.4 Cleaning, disinfection and sterilization

The probe shall meet the requirements for maximum permissible errors in 6.3 after it has been subjected to the cleaning, disinfection and sterilization procedures specified by the manufacturer.

Testing shall be performed in accordance with 7.10.

6.11.5 Biocompatibility

Parts of the thermometer that are intended to come in contact with biological tissues, cells or body fluids shall be assessed and documented.

NOTE: For information see EN ISO 10993-1 as guidance.

Conformity shall be verified by visual inspection of the information provided by the manufacturer.

6.11.6 Mechanical safety

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

Testing shall be carried out by visual and tactile inspection.

7 Test methods

7.1 General

Each individual lot shall undergo either individual or statistical testing. 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 Testing for compliance with 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.

7.2.1.3 ***Temperature probe simulator***, with an expanded measurement uncertainty of the temperature probe simulator of not greater than a value equivalent to 0,01 °C (calculated for a coverage factor k=2), referring to the manufacturer's data within the measuring range. The calibration shall be traceable to national measurement standards.