SLOVENSKI STANDARD
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Klinični termometri – 3. del: Delovanje zaprtih trdnih električnih termometrov (brez umerjanja ali z njim)

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

Medizinische Thermometer - Teil 3: Elektrische (extrapolierende und nicht extrapolierende) Kompaktthermometer mit Maximumvorrichtung

Thermometres médicaux - Partie 3: Performances des thermometres électriques compacts (a comparaison et a extrapolation) avec dispositif a maximum

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

Thermomètres médicaux - Partie 3: Performances des thermomètres électriques compacts (à comparaison et à extrapolation) avec dispositif à maximum

Medizinische Thermometer - Teil 3: Elektrische (extrapolierende und nicht extrapolierende) Kompaktthermometer mit Maximumvorrichtung

This European Standard was approved by CEN on 13 May 1999.

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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.

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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of an identical text or by endorsement, at the latest by July 2000, and conflicting national standards shall be withdrawn at the latest by July 2000.

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.

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.

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:[1)] Performance of electrical thermometers for continuous measurements

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

Annexes A, B and ZA are informative.

1) In preparation.

1 Scope

This Part of EN 12470 specifies the performance requirements for compact clinical electrical thermometers with maximum device (non-predictive and predictive).

This European Standard applies to devices that, when taking temperatures, are powered by an internal power supply and that provide a digital indication of temperature.

This European Standard does not apply to clinical electrical thermometers for continuous measurement and thermometers intended to measure skin temperature.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. 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*
prEN 12470-1: 1998	*Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device*
EN 60601-1	*Medical electrical equipment - Part 1: General requirements for safety*
EN 60601-1-2	*Medical electrical equipment - Part 1: General requirements for safety - 2: Collateral Standard - Electromagnetic compatibility - Requirements and tests*
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 compact electrical thermometer: Contact thermometer that consists of a temperature probe and an indicating unit permanently connected together.

3.2 compact predictive thermometer: Device which calculates the maximum temperature of a probe in contact with a body cavity, without waiting for thermal equilibrium to occur, by
heat transfer data and a mathematical algorithm and maintains the calculated maximum temperature value for a specified time or until reset by its user.

3.3 compact non-predictive thermometer: Device with a part or function of the thermometer that monitors over a required period of time the temperature measured by a temperature probe in contact with a body cavity after which it indicates and maintains the maximum temperature value for a specified time or until reset by its user.

3.4 indicating unit: Component of the thermometer that processes the output signal of the temperature sensor and displays the value of the temperature.

3.5 maximum device: Part or function of the thermometer which stores and indicates the numerical value of the maximum temperature.

3.6 temperature probe: Component of the thermometer, part of which is applied to a body cavity and establishes temperature. It comprises a temperature sensor with associated parts including coverings, seals, and inner leads when necessary.

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

4 Unit

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

5 Types of thermometers

The types of compact clinical electrical thermometers with maximum device shall be:

a) non-predictive thermometers;

b) predictive thermometers.

6 Performance requirements

6.1 Probe cover

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

6.2 Metrological requirements

6.2.1 *Measuring range*

The thermometer shall cover the minimum measuring range from 35,5 °C to 42,0 °C.

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

Testing shall be carried out in accordance with 7.2.

6.2.2 *Digital increment*

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

Testing shall be performed by visual inspection.

6.2.3 *Maximum permissible error under reference conditions*

The maximum permissible error for the measuring range 35,5 °C to 42,0 °C shall be 0,1 °C within the ambient temperature range from 18 °C to 28 °C. Outside the measuring range of 35,5 °C to 42,0 °C or outside the ambient temperature range, the maximum permissible error shall not be greater than twice the specified value.

Testing shall be in accordance with 7.3.

For predictive and non-predictive thermometers with an offset, the manufacturer shall provide information on:

a) data obtained from the result of a clinical investigation;

NOTE: For this investigation predictive thermometers can be modified by incorporating a switch to allow operation alternatively in predictive and non-predictive mode.

In the non-predictive mode the thermometer should meet the requirements of 6.2.3 when tested according to 7.2. In this case the thermometer is tested in the predictive mode and read, then the mode is switched to non-predictive and the temperature is read again after achieving thermal equilibrium. The two temperature readings should not differ by more than 0,2°C for more than 98% of the subjects.

In the case that the thermometer to be investigated cannot be modified accordingly, it should be compared against a calibrated clinical reference thermometer, preferably at the same body site.

Selection of test persons should be in accordance with the intended use of the thermometer.
The clinical test should be performed in accordance with Annex X of the Medical Device Directive (MDD).

b) the procedure for testing in a water bath.

6.2.4 *Time response*

When a non-predictive thermometer at a temperature of (23 ± 2) °C is immersed into a water bath at (37 ± 1) °C for 60 s the indicated temperature shall not differ from the reference temperature by more than the maximum permissible error.

Testing shall be performed in accordance with 7.4.

6.2.5 *Maximum energy dissipation*

The indicating unit shall provide an energizing potential sufficiently low so that the energy dissipation ($I^2 \cdot R$) in the probe shall not cause an increase in indicated temperature by more than 0,01 °C when the probe is immersed in a reference water bath at (37 ± 0,1) °C.

Testing shall be performed in accordance with 7.5.

6.2.6 *Long term stability*

The long term stability of the thermometer, 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 the values for maximum permissible errors specified in 6.2.3 are met.

Testing shall be performed in accordance with 7.6.

6.3 Environmental requirements

6.3.1 *Ambient operating range*

The minimum ambient operating range of the thermometer shall be from + 10 °C to + 35 °C.

When tested in accordance with 7.7, the thermometer shall comply with 6.2.3.

6.3.2 *Effect of storage*

When tested in accordance with 7.8, the thermometer shall comply with 6.2.3.

6.3.3 *Thermal shock*

When tested in accordance with 7.9, the thermometer shall comply with 6.2.3.

6.3.4 *Humidity*

When tested in accordance with 7.10, the thermometer shall comply with 6.2.3.

6.3.5 *Electromagnetic compatibility*

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

6.3.6 *Mechanical shock*

When tested in accordance with 7.11, thermometers with a housing of plastic or metal shall comply with 6.2.3.

6.3.7 *Water resistance*

When tested in accordance with 7.12, the thermometer shall comply with 6.2.3.

6.4 Construction requirements

6.4.1 *Functional units*

6.4.1.1 *Voltage limit indication*

The thermometer shall automatically provide a visual or auditory warning when its supply voltage is not within specified limits and shall meet the maximum permissible errors in 6.2.3 when the voltage is within these specified limits.

Testing shall be performed in accordance with 7.13.

6.4.1.2 *Indicating unit*

Numerical values on the display shall be at least 4 mm high or optically magnified so as to appear that height.

After power-on all segments shall be activated for at least 1 s.

Testing shall be performed by visual inspection.

6.4.1.3 *Functional safe test*

The thermometer shall have a self-testing routine. The correct operation shall be indicated by a given display.

The manufacturer shall provide information as to how the self-testing routine operates and what display is to be expected.

6.4.2 *Material*

The thermometer shall be free from biological hazards.

NOTE: See EN ISO 10993-1 for the selection of appropriate test methods.

6.5 Electrical safety

The thermometer shall comply with EN 60601-1.

6.6 Mechanical safety

6.6.1 *Thermometer*

Thermometers shall not have sharp ends or angles that could injure the user or patient.

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

Testing shall be performed by visual and tactile inspection.

6.6.2 *Resistance to breakage*

A thermometer with a housing of glass shall comply with 6.1.2.7 of prEN 12470-1: 1998.

7 Test methods

7.1 General

7.1.1 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 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 Method for the determination of the measuring range

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 loading of thermometer samples.