SLOVENSKI STANDARD
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Kliniļ ni termometri ï 5. del: Delovanje infrardeļ ih termometrov za uġesa (s popolno opremo)

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

Medizinische Thermometer - Teil 5: Anforderungen an Infrarot- Ohrthermometer (mit Maximumvorrichtung)

Thermometres médicaux - Partie 5: Performance des thermometres auriculaires (avec dispositif a maximum)

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

Thermomètres médicaux - Partie 5: Performance des thermomètres tympaniques à infrarouges (avec dispositif à maximum)

Medizinische Thermometer - Teil 5: Anforderungen an Infrarot- Ohrthermometer (mit Maximumvorrichtung)

This European Standard was approved by CEN on 27 December 2002.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Contents

Foreword

This document (EN 12470-5:2003) 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of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

This document 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 document.

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

Annexes A, B, C, and D 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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This Part of EN 12470 specifies the metrological and technical requirements for clinical infra-red (IR) ear thermometers with maximum device for intermittent determination of human body temperature.

This European Standard applies to devices that when taking temperatures are powered by a power supply either internal or by mains and that provide an indication of the subject's body temperature through measurement of thermal radiation from all or part of the ear canal.

NOTE Devices designed to measure tympanic membrane temperature only are also covered by this standard.

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 (including amendments).

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

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

EN 60601-1, *Medical electrical equipment - Part 1: General requirements for safety (IEC: 60601-1:1988).*

EN 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard - Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001).*

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 European Standard the following terms and definitions apply.

3.1
ambient operating range
ambient temperature and humidity which allows correct operation of an IR ear thermometer

3.2
black body
reference source of infra-red radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having effective emissivity at the cavity opening sufficiently near to one

3.3
body temperature
temperature measured at a human body site, e.g. pulmonary artery, distal œsophagus, urinary bladder, ear canal, oral, rectal or axillary

3.4
clinical accuracy
ability of an IR ear thermometer to give a reading close to the temperature of the site that it purports to represent as measured by the reference thermometer

3.5
clinical bias
clinical bias and its standard deviation specifies an average difference between temperatures estimated by the device under test and temperatures of subjects as measured by the reference thermometer

3.6
clinical repeatability
experimental standard deviation of changes in multiple ear canal temperature readings as taken from the same subject from the same ear with the same IR ear thermometer by the same operator

3.7
contact thermometer
instrument which is adapted for measuring temperature by means of thermal contact when negligible thermal energy flows between the thermometer and the object of measurement

3.8
infra-red ear thermometer (IR ear thermometer)
opto-electronic instrument that is capable of non-contact infra-red temperature measurement when applied to the ear canal of a subject

3.9
maximum device
part or function of the thermometer which stores and indicates the numerical value of the maximum temperature measured

3.10
modes

3.10.1
ear mode
mode in which the IR ear thermometer displays the temperature measured from a subject's ear canal. This mode allows for corrections to compensate for variations such as ambient conditions and emissivity

3.10.2
calibration mode
mode in which an IR ear thermometer displays the temperature measured from a reference black body

3.10.3
estimated mode
mode in which an IR ear thermometer displays an estimated temperature for a body site other than the ear canal

3.11
probe
part of an IR ear thermometer that channels net infra-red radiation between the subject and the sensor

3.12
site offset
numerical value of the difference between a temperature reading in ear mode and in an estimated mode

4 Unit

The unit of temperature shall be the degree Celsius, symbol ^{o}C.

5 Type of thermometers

IR ear thermometers determine body temperature of a subject via thermal radiation of the ear canal and/or tympanic membrane.

6 Requirements

6.1 General

If the IR ear thermometer is designed for use with protective probe covers, the thermometer together with the probe cover (complete thermometer) shall meet the requirements specified in this standard.

6.2 Range of displayed temperature

The IR ear thermometer shall cover in all modes the range of displayed temperature from 35,5 °C to 42,0 °C.

NOTE The range of displayed temperature can differ from the measuring range by an instrumental offset.

Testing shall be performed in accordance with 7.3.

6.3 Maximum permissible error

6.3.1 Maximum permissible error within ambient operating range

The maximum permissible error within ambient operating range as in 6.4.1 and the range of the displayed temperature as in 6.2 shall be ± 0,2 °C.

Testing shall be performed in accordance with 7.4.

6.3.2 Maximum permissible error under extended operating conditions

If the IR ear thermometer gives a temperature reading outside the conditions in 6.2 and 6.4.1, the maximum permissible error under those conditions shall be ± 0,3 °C.

Testing shall be performed in accordance with 7.5.

6.3.3 Maximum permissible error under changing environmental conditions

The maximum permissible error shall comply with 6.3.1 under changing ambient conditions. If the thermometer is not capable of meeting the accuracy requirements, it shall not provide a temperature reading.

Testing shall be performed in accordance with 7.6.

6.3.4 Maximum permissible clinical repeatability

Clinical repeatability shall be determined separately for each device model, every patient age group (new-born, children, and adults) for which the IR ear thermometer is intended to be used including febrile subjects.

Clinical repeatability shall not exceed ± 0,3 °C.

Testing shall be performed in accordance with 7.7.

6.4 Environmental requirements

6.4.1 Ambient operating conditions

The minimum ambient temperature operating range of the IR ear thermometer shall be from +16 °C to +35 °C and the relative humidity range shall be up to at least 85 % (non-condensing).

Testing shall be performed in accordance with 7.4.

6.4.2 Effects of storage and long term stability

The IR ear thermometer shall meet the requirements specified in 6.3 after having been stored in an environment of -25 °C to +55 °C and a relative humidity up to 85 % (non-condensing) for a period of 28 days.

Testing shall be performed in accordance with 7.8.

6.4.3 Electromagnetic compatibility

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

6.4.4 Mechanical shock

IR ear thermometers with a housing of plastic or metal shall comply with 6.3 after testing according to 7.9.

If the IR ear thermometer does not meet the requirement after being subjected to mechanical shock, it shall not provide a temperature reading.

6.5 Indicating unit

6.5.1 Digital increment

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

Testing shall be performed by visual inspection.

6.5.2 Display

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

Testing shall be performed by visual inspection.

6.5.3 Warning signals

The IR ear thermometer shall provide a visual warning or it shall not provide a temperature reading when one or more of the following are outside the limits specified by the manufacturer:

a) power supply voltage;

b) measuring range;

c) ambient temperature operating range.

Testing shall be performed by visual inspection.

6.5.4 Variations of the voltage supply

For power supply by mains, the indicated temperature shall not show a change for variations from nominal values of ± 10 % for voltage or ± 2 % for frequency.

For power supply by battery or an auxiliary power source, the IR ear thermometer shall provide a recognizable indication or warning signal, or shall not display a temperature reading, when the voltage is outside the limits specified by the manufacturer. If the supply voltage is within these specified limits, the thermometer shall meet the requirements specified in 6.3.

Testing shall be performed in accordance with 7.10.

6.5.5 Modes

An IR ear thermometer shall have an ear mode.

For calibration purposes a calibration mode shall be accessible by either setting the instrument into that mode directly or by a conversion technique from the ear mode.

NOTE 1 This can be identical to the ear mode.

If estimated modes are available, e.g. core, rectal, oral, the displayed values shall be clearly identified as estimates. In addition, the manufacturer shall provide information on clinical accuracy and derivation of these estimates. The information shall include site offsets, clinical bias and its standard deviation.

NOTE 2 See annex A for further information.

Testing shall be performed by visual inspection.

6.6 Construction

6.6.1 Material

All materials that can come in contact with the operator or subject shall be free from biological hazards.

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

6.6.2 General requirements for safety

The complete IR ear thermometer shall comply with EN 60601-1.

6.6.3 Mechanical

The temperature probe or probe tip, alone or in combination with probe covers, shall be smoothly rounded in order to prevent tissue damage and injury to a subject of any age during use.

Testing shall be performed by visual and tactile inspection.

6.6.4 Cleaning, disinfection and/or sterilization

6.6.4.1 Thermometer

If the manufacturer indicates that the IR ear thermometer can be cleaned, disinfected and/or sterilized, instructions for these processes shall be given.

After cleaning, disinfection and/or sterilization in accordance with the manufacturer's specification, the IR ear thermometer shall comply with the requirements specified in 6.3 and the marking of the housing shall not be affected.

Testing shall be performed in accordance with 7.11.1.

6.6.4.2 Multiple use probe covers

When the manufacturer indicates that the probe cover is for multiple use, the complete IR ear thermometer shall meet the requirements specified in 6.3 after it has been subjected to the cleaning, disinfection and/or sterilization procedure as specified by the manufacturer.

Testing shall be performed in accordance with 7.11.2.

6.6.5 Probe covers

If a probe cover is required by the manufacturer, it shall maintain its physical integrity while being placed on the probe or probe tip, and during temperature measurement to ensure a sanitary barrier between a subject and the probe or probe tip.

If a probe cover is required by the manufacturer, the IR ear thermometer shall either not display a temperature reading when it is used without a probe cover or shall contain appropriate information on the display that a new probe cover shall be used prior to the next measurement.

The probe cover and the thermometer shall comply with the requirements specified in 6.3 when tested in accordance with 7.4.

6.6.6 Functional safety test

The IR ear thermometer shall have an automatic self-test sequence. The correct operation shall be indicated by an appropriate display.

The manufacturer shall provide information as to how the self-test sequence operates.

Testing shall be performed by visual inspection.

7 Test Methods

7.1 General

Laboratory accuracy of a particular type or model of an IR ear thermometer (with the specified probe covers if applicable) shall be tested in ear mode or, if available, in calibration mode on samples selected in accordance with 7.2 to verify compliance with the requirements specified in 6.3.

7.2 Sampling

Each individual lot of IR ear thermometers and probe covers shall be subjected to testing, either individual or statistical. For statistical testing the lot shall be homogenous and the mixing of the thermometers or probe covers from various sources is not allowed.

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 B.

7.3 Testing for compliance of the range of displayed temperature

7.3.1 Apparatus

7.3.1.1 Black body radiator

Under laboratory conditions, the IR ear thermometer under test shall be tested against a black body radiator whose radiance temperature is calibrated with an uncertainty not greater than 0,07 °C (coverage factor k=2). The calibration shall be performed by either a national metrological institute or by a calibration laboratory competent for radiation thermometric calibrations and shall be traceable to a national measurement standard.

The operating radiance temperature range of the black body radiator shall be sufficient to cover the full radiance temperature range required for laboratory testing in accordance with this standard.

NOTE See annex C for information.

7.3.1.2 Climatic chamber

Climatic chamber, capable of producing the ranges of temperature and humidity given in 7.3, 7.4, 7.5, 7.6 and 7.8.

7.3.2 Reference laboratory conditions

The reference laboratory conditions shall be an ambient temperature of (23 ± 5) °C and a relative humidity of (50 ± 20) %.

7.3.3 Procedure

Take a reading of the temperature of the black body with the IR ear thermometer under test in accordance with a procedure recommended by the manufacturer for the particular IR ear thermometer under reference laboratory conditions.

Repeat the tests at two black body temperatures, t_{BB} set within ± 0,2 °C of the following temperatures:

a) minimum displayed temperature minus offset as specified by the manufacturer +0,5 °C.

b) maximum displayed temperature minus offset as specified by the manufacturer –0,5 °C.

The temperature reading shall be displayed and the result recorded.

Report the temperature reading and assess the compliance with requirement 6.2.

7.4 Testing for compliance of the maximum permissible error within ambient operating range

7.4.1 Apparatus

The apparatus described in 7.3.1 shall be used.

7.4.2 Procedure

Take a reading of the temperature of the black body with the IR ear thermometer under test in accordance with the procedure recommended by the manufacturer for the particular IR ear thermometer.

Repeat the tests for three black body temperatures approximately equally spaced throughout the range of displayed temperature.

At each black body temperature, repeat the tests under the ambient conditions stated in Table 1.

Table 1 — Conditions of ambient temperature and humidity for testing an IR ear thermometer with a black body for each of three black body settings

Operating Temperature (°C)	Relative Humidity (%)
16 to 18	less than 50
16 to 18	80 to 85
24 to 26	40 to 60
33 to 35	less than 25
33 to 35	80 to 85