BRITISH STANDARD

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Clinical thermometers —

Part 4: Performance of electrical thermometers for continuous measurement

The European Standard EN 12470-4:2000 has the status of a British Standard

ICS 11.040.55

National foreword

This British Standard is the official English language version of EN 12470-4:2000.

The UK participation in its preparation was entrusted to Technical Committee LBI/36, Laboratory equipment and related glassware, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

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This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 June 2001

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of an identical text or by endorsement, at the latest by April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.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

7.2.1.4 ***Temperature probe tester*****,** to convert a measured physical property of the probe to a temperature value by measuring a change in that property as a function of temperature, with an expanded measurement uncertainty of the temperature probe tester 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.

NOTE: For a resistance-type probe, an appropriate instrument for measuring its output signal is an ohmmeter that can apply power to the probe at a level below that specified in 6.11.1 and the temperature value is obtained from the manufacturer's data of resistance versus temperature.

7.2.2 Reference conditions

The reference conditions for the requirements shall be a room temperature of (23 ± 5) °C and a relative humidity of (50 ± 20) % with the instrument operating within the specified range of the supply voltage.

7.2.3 Procedure

7.2.3.1 Complete thermometer

NOTE: In case of a complete thermometer the manufacturer can either carry out the test described in 7.2.3.1 or carry out the individual tests described in 7.2.3.2 and 7.2.3.3.

Immerse the temperature probe of a complete thermometer according to the manufacturer's specification in a reference water bath at a constant temperature until temperature equilibrium is established. Compare the temperature indicated by the thermometer to that indicated by the reference thermometer. Then increase or decrease the bath temperature, re-establish the temperature equilibrium and repeat the measurement process. The difference between the measured and reference temperatures shall meet the requirements for maximum permissible errors as specified in 6.3.

The number of measuring points required depends upon the measuring range of the instrument; however, measurements shall be carried out at least every full degree Celsius of the measuring range. To detect possible effects of hysteresis, the measurements of values with odd degree Celsius shall be performed at increasing temperatures and the measurements of values with even degree Celsius shall be performed at decreasing temperature.

7.2.3.2 Indicating unit

The performance of an indicating unit shall be tested using a device according to 7.2.1.3.

The number of measuring points required shall be the same as specified in 7.2.3.1.

The difference between the temperature values displayed by the indicating unit and the corresponding simulated values of temperature shall meet the requirements for maximum permissible errors specified in 6.3.

7.2.3.3 Temperature probe

Immerse an interchangeable or single-use probe in a reference water bath as specified in 7.2.1.2. Connect the temperature probe to the temperature probe tester according to 7.2.1.4. Compare each temperature value obtained for the probe in this way to that indicated by the reference thermometer in the bath. The difference between these temperature values shall meet the requirements for maximum permissible errors as specified in 6.3.

7.3 Testing for compliance with time response

7.3.1 Apparatus

Use the apparatus described in 7.2.1

7.3.2 Procedure

Immerse the temperature probe at a temperature of (23 ± 2) °C into a water bath at (44 ± 1) °C. Compare the temperature indication with the indication of the reference thermometer after 150 s.

7.4 Testing for compliance with the minimum environmental operating range

7.4.1 Apparatus

Temperature chamber, capable of producing temperatures and humidities necessary for testing.

7.4.2 Procedure

Place the indicating unit into the climatic chamber and put the temperature sensor in the water bath.

Test according to 7.2 at three different water bath temperatures spaced equally over the measuring range at the following combinations of temperature and humidity:

(11 ± 1) °C and 30 % relative humidity;
(39 ± 1) °C and 30 % relative humidity;
(11 ± 1) °C and 75 % relative humidity;
(39 ± 1) °C and 75 % relative humidity.

NOTE: The manufacturer of the indicating unit can test the indicating unit separately with a temperature probe simulator described in 7.2.1.3.

7.5 Testing for compliance with the effect of storage and humidity

7.5.1 Apparatus

Climatic chamber, capable of producing the necessary climates.

7.5.2 Procedure

Perform the test according to IEC 60068-2-14:1986 using the change rate of (1 ± 0,2) °C/min.

Place the thermometers in a climatic chamber and subject them to the following test cycle:

Lower the temperature to (-25 ± 3) °C. Keep this temperature for 16 h then raise the temperature to (55 ± 2) °C and relative humidity of 85 % (non-condensing). Keep this climate for 72 h. Lower the temperature to (-25 ± 3) °C and keep it for 16 h. Raise the temperature to (25 ± 3) °C. Remove the thermometers from the chamber and keep them at room temperature for at least 24 h before testing according to 7.2 at three temperatures equally spaced over the measuring range.

7.6 Testing for compliance with the variation of the supply voltage

7.6.1 Power supplied by mains

7.6.1.1 Apparatus

Power supply with a voltage range of at least ± 15 % of the specified supply voltage of the thermometer and a frequency range of at least ± 3 % of the specified supply frequency of the thermometer.

7.6.1.2 Procedure

If tested according to 7.2 with a supply voltage of ± 10 % of the specified supply voltage the thermometer shall comply with 6.3. Carry out the test at the lower and upper temperature measuring range at ambient temperature.

If tested according to 7.2 with a supply voltage frequency of ± 2 % of the specified voltage the thermometer shall comply with 6.3. Carry out the test at the lower and upper temperature measuring range at ambient temperature.

7.6.2 Voltage supplied by battery or auxiliary power supply

7.6.2.1 Apparatus

Direct current voltage supply.

7.6.2.2 Procedure

Replace the internal power supply by a variable d.c. voltage supply (7.6.2.1).

Reduce the voltage of the supply until a low battery indication or warning signal is activated at a level specified by the manufacturer. Carry out the test at the lower and upper ends of the temperature measuring range at ambient temperature.

If tested according to 7.2 the thermometer shall comply with 6.3.

7.7 Testing for compliance with the maximum energy dissipation of probe (resistance type)

7.7.1 Apparatus

Use the apparatus described in7.2.1

7.7.2 Procedure

Place the temperature probe in the reference water bath (see 7.2.1.2) at a temperature of (37 ± 1) °C. Carry out measurements at three or more different specified currents. The maximum power shall be 2 mW.

Measure each applied current and the corresponding voltage.

7.7.3 Expression of results

The equivalent resistance values shall be calculated and then converted to temperature values using the manufacturer's characteristic table (resistance / temperature) for the probe type. A linear (least squares fit) curve of temperature as a function of applied power shall be drawn. From this curve, power corresponding to the maximum energy dissipation that will cause a change in indicated temperature by 0,02 °C shall be determined. This value is the maximum power that can be provided by an indicating unit for the probe type and the manufacturer's specified value shall be equal to or less than the value determined.

7.8 Testing for compliance with long-term stability

7.8.1 Apparatus

Temperature chamber, capable of producing temperatures necessary for testing.

7.8.2 Procedure

Place the temperature probe into the temperature chamber for 288 h at a temperature of (55 ± 2) °C or for 96 h at a temperature of (80 ± 2) °C.

Test according to 7.2.3.3 at three different temperatures spaced equally over the measuring range.

7.9 Testing for compliance with protection against human liquids

7.9.1 Apparatus

Use the apparatus described in 7.2.1

7.9.2 Procedure

Immerse the probe without cover at room temperature to a length equal to that intended to be in contact with the body, or 50 mm, whichever is greater, in a saline solution (9,5 g of sodium chloride per litre of demineralized water).

After at least one week, measure the resistance between the electrical connections of the probe taken together and an electrode immersed in the physiological saline solution using an instrument that applies a voltage of (10 ± 1) V between the probe connections and the electrode. The resistance measured shall be greater than the shunt resistance that would correspond to a change in the indicated temperature of ± 0,02 °C within the measuring range.

7.10 Testing for compliance with cleaning, disinfection and sterilization

The applied part of the temperature probe of the thermometer shall be cleaned and/or disinfected and/or sterilized at least 20 times according to the manufacturer's instructions.

Test according to 7.2.3 at three different temperatures spaced equally over the measuring range.

8 Information supplied by the manufacturer

8.1 General

Information supplied by the manufacturer shall comply with EN 1041. If symbols are used, they shall be in accordance with EN 980.

8.2 Marking

8.2.1 Complete thermometer

In addition to the marking required by 8.1, the thermometer shall be marked with at least the symbol „°C" adjacent to the numerical value, if not indicated at the display.

8.2.2 Temperature probe

In addition to the marking required by 8.1, the temperature probe or its primary package shall be marked with at least the following information:

a) the measuring range in °C;
b) body site (e.g. mouth, rectum), if restrictions apply.

8.2.3 Indicating unit

In addition to the marking required by 8.1, the indicating unit or its primary package shall be marked with at least the following information:

- indication of the orientation (attitude) or position in use, if necessary;

8.3 Instructions for use

In addition to the marking required by 8.1, the thermometer shall be accompanied by instructions for use containing at least the following information:

a) information about the proper environmental conditions of use, storage, transport including temperature and humidity;
b) disposal of the thermometer and batteries, if applicable;
c) instructions and precautions for proper cleaning and disinfection;
d) measuring range and maximum permissible error under reference conditions;
e) description of the self-checking device and other warnings;
f) instructions for selection and replacement of battery, if applicable;
g) probe cover usage, if applicable;
h) body site (e.g. mouth, rectum);
i) minimum measuring time required to obtain accurate readings at the specific body site;
j) recommended maintenance and calibration procedure, including frequency of recalibration;
k) installation, operation procedures, mains voltage and frequency, if applicable;
l) an identification of components and suitable interchangeable parts such as probes and, if applicable, cables and batteries including nominal voltage;
m) precautions with respect to the safety of operators and patients;

n) troubleshooting guide;

o) use of or optional use of preadjustment of the displayed temperature and specification of any offset used, if applicable.

Annex A (informative)

Suggested types of testing for the requirements of this standard

In order to comply with the requirements of the EU declaration of conformity thermometers have to comply with the requirements of either:

a) Annex II; or,
b) Annex VII coupled with annex IV or annex V or annex VI,

of the EU Directive for Medical Devices 93/42/EEC of 14 June 1993.

Annex A informs and recommends on the volume of testing suggested to comply with the requirements of the Medical Device Directive.

The tests described in this standard should be performed as follows:

1) Type A: Tests that should be performed like type examination tests. After initial verification of the corresponding requirements these tests are to be repeated as frequently as required to guarantee a uniform production or product. The tests are to be repeated whenever a relevant design or component is changed.

   These tests are appropriate where compliance with the requirements of the standard can be demonstrated by investigating a small number (typically 10) of samples of the product.

2) Type B: Tests that show each lot of product complies with the requirements of the standard.

Tests according to Table A.1 should be performed on each sample or according to a statistical sampling plan that complies with the requirements of chapter 6 of Annex IV of the EU Directive for Medical Devices 93/42/EEC.

Table A.1 - Suggested tests

Subclauses on the requirements and test methods	Lot by lot testing, Type B
6.2/7.2 (measuring range)	
6.3/7.2 (maximum permissible errors)	X
6.4/7.3 (time response)	
6.5/7.4 (environmental operating range)	
6.6/7.5 (effect of storage)	
6.7/7.6 (humidity)	
6.8/EN 60601-1-2 (EMC)	
6.9/EN 60601-1 (elecrical safety)	
6.10.1/visual inspection (digital increment)	
6..10.2 / visual inspection (indicating unit)	X
6.10.5/visual inspection (self-checking device)	X
6.11.1/7.7 (maximum energy dissipation)	
6.11.2/7.8 (long term stability)	
6.11.6 / visual inspection (mechanical safety)	X
8.2 / visual inspection (marking)	X
8.3 / visual inspection (instructions for use)	X
Note: Type A testing is compulsory for all clauses.	

Annex ZA (informative)

Clauses of this European Standard addressing Essential Requirements or other provisions of EU Directives

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 for Medical Devices 93/42/EEC.

Warning: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA1 – Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirements of Directive 93/42/EEC	Comments
4	10.3, 12.9	
5	1, 2	
6	1, 2, 3, 4, 5	
6.3	10.1	
6.6	5, 9.2	
6.7	5, 9.2	
6.8	9.2, 12.5	
6.9	9.2, 9.3, 12.6	
6.10.1	10.2	
6.10.2	10.2	
6.10.3	10.1	
6.10.4	10.1	
6.10.5	9.2, 12.4	
6.10.6	12.4	
6.11.1	10.1	
6.11.2	5, 9.2	
6.11.3	7.1	
6.11.4	8.1, 13.6 h)	
6.11.5	7.1	
6.11.6	9.2	
8.1	13.1, 13.2, 13.3 a) to m)	
8.2	13.1, 13.3 a) to m)	
8.2.1	12.9	
8.2.2	12.9	
8.2.3	12.9	
8.3	9.2, 13.1, 13.6 a)	
8.3 a)	13.6 d)	
8.3 b)	13.6 n)	
8.3 c)	8.1, 13.6h)	
8.3 d)	10.1, 13,.6 b), 13.6 p)	
8.3 e)	13.6 d)	
8.3 i)	13.6 b)	
8.3 j)	13.6 d)	
8.3.l)	13.5	

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IEC 1000-4-3:1995 *Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic field immunity test*

IEC 1000-4-4:1995 *Electromagnetic compatibility (EMC) - Part 4: Testing and measuring techniques - Section 4: Electrical fast transient/burst immunity test - Basic EMC publication*

EN ISO 10993-1 *Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)*

EN 12470-1 *Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device*

GUM 1993 *Guide to the expression of uncertainty in measurement*

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