

Clinical thermometers —

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

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National foreword

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The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee LBI/36, Laboratory glassware and related apparatus, to Subcommittee LBI/36/3, Thermometers.

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

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English Version

**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 and includes Amendment 1 approved by CEN on 16 May 2009.

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Foreword

This document (EN 12470-3:2000+A1:2009) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-05-16.

This document supersedes EN 12470-3:2000.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** and **A1**.

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 measurements

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

Annexes A, B 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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,  *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 basic safety and essential performance (IEC 60601-1:2005)* 

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.

[A1] If the probe cover is a single use device, it shall bear an indication on the probe cover or on its packaging, which is consistent across the European Community, that it is intended for single use only. **[A1]**

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 $(37 \pm 0,1)$ °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.