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

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English Version

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

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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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.

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Foreword

This document (EN 12470-4:2000+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of an identical text or by endorsement, at the latest by December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 12470-4:2000.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1〉 〈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 (predictive and non-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 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 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, ⟦A1⟩ *Symbols for use in the labelling of medical devices* ⟨A1⟧

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)*

⟦A1⟩ EN 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)* ⟨A1⟧

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