Kliinilised termomeetrid. Osa 2: Faasimuundurtüüpi (punktmaatriks) termomeetrid KONSOLIDEERITUD TEKST

Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12470-2:2001+A1:2009 sisaldab Euroopa standardi EN 12470-2:2000+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 12470-2:2001+A1:2009 consists of the English text of the European standard EN 12470-2:2000+A1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 17.06.2009.	Date of Availability of the European standard text 17.06.2009.
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English Version

Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers

Thermomètres médicaux - Partie 2: Thermomètres à changement de phase (matrice à points)

Medizinische Thermometer - Teil 2: Phasenumschlagthermometer (Punktmatrix)

This European Standard was approved by CEN on 16 September 2000 and includes Amendment 1 approved by CEN on 16 May 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

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 12470-2:2000+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 12470-2:2000.

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 (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 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 performance requirements and test methods for phase change-type (dot matrix) thermometers for measuring temperature in body cavities.

NOTE A body cavity can be the mouth, rectum or armpit.

This European Standard does not apply to clinical thermometers designed for special applications (e.g. thermometers for hypothermia) which owing to their measurement range, scale interval or maximum permissible error do not meet the requirements specified in this Standard.

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 556+A1, *Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "Sterile"*

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
measurement time
length of time required to measure body temperature

3.2
phase change (dot matrix) thermometer
device utilising a change in state of chemical components designed to measure and indicate human body temperature

3.3
retention time
duration of time for which the optimal signal for reading persists

3.4
sensor matrix
temperature measuring area consisting of temperature dots

NOTE The dots contain different chemical mixtures, which change their state at specific temperatures. This change is accompanied by a change in appearance, e.g. change of colour. When in contact with the temperature site being measured, the change of state takes place in the sequence of dots up to and including the dot corresponding to the temperature of the site. This dot indicates the site temperature.