Kliinilised termomeetrid. Osa 5: Infrapunaste kõrvatermomeetrite töö (maksimumseadmega)

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12470-5:2003 sisaldab Euroopa standardi EN 12470-5:2003 ingliskeelset teksti. Käesolev dokument on jõustatud 16.05.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12470-5:2003 consists of the English text of the European standard EN 12470-5:2003. This document is endorsed on 16.05.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: 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	**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

ICS 17.200.20

Võtmesõnad: clinical thermometers, heat transfer, instructions, laboratory equipment, medical, medical sciences, medicine, operating requirements, production, radiative heat transfer, specification (approval), specifications, storage, testing, thermometers, thermotips, units

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12470-5

April 2003

ICS 17.200.20

English version

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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 12470-5:2003 E

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