

Elektrilised meditsiiniseadmed. Osa 2-56: Erinõuded kehatemperatuuri mõõtmise kliiniliste termomeetrite esmasele ohutusele ja olulistele toimimisinäitajatele

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-56:2012 sisaldab Euroopa standardi EN ISO 80601-2-56:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-56:2012 consists of the English text of the European standard EN ISO 80601-2-56:2012.
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English Version

**Medical electrical equipment - Part 2-56: Particular requirements
for basic safety and essential performance of clinical
thermometers for body temperature measurement (ISO 80601-
2-56:2009)**

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO 80601-2-56:2009)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2009)

This European Standard was approved by CEN on 16 September 2012.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 80601-2-56:2009 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 80601-2-56:2012 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 April 2013, and conflicting national standards shall be withdrawn at the latest by October 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12470-4:2000+A1:2009, EN 12470-5:2003, EN 12470-3:2000+A1:2009.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-56:2009 has been approved by CEN as a EN ISO 80601-2-56:2012 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11	7.3	Only the part of the first sentence relating to design is addressed.
201.7.9.2.14.101	7.5	Only the third paragraph of ER 7.5 is addressed.
201.11, 201.103	7.6	
201.11	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137.
201.7.2.1.101	8.7	
201.4, 201.4.2.101, 201.7, 201.7.9.2.101 e), 201.16, 201.101.1, 201.102.1, 201.103, 201.103.2	9.1	
201.9, 201.12.1.101, 201.12.2, 201.15, 202	9.2	The 4th indent of ER 9.2 is not addressed.
201.11, 201.13	9.3	
201.7.9.2.101 d), 201.12, 201.101, 201.102, 201.103	10.1	
201.12.2	10.2	
201.7	10.3	

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.12	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.11, 201.15	12.7.4	
201.11, 201.15	12.7.5	
201.7, 201.12.2, 201.15, 206	12.9	
201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9	13.1	The requirement for information on the sales packaging is not addressed.
201.7, 201.7.2.1, 201.8, 201.9	13.2	
201.7, 201.7.9.1	13.3 a)	
201.7, 201.7.2.1.101 b)	13.3 b)	
201.7.2.1.101 c)	13.3 c)	
201.7	13.3 d)	This ER is only covered if the batch number is preceded by the word LOT.
201.7.2.1.101 d)	13.3 e)	
201.7.2.1.101, 201.7.2.1.101 e)	13.3 f)	
201.7, 201.7.2.1.101 f)	13.3 i)	
201.7	13.3 j)	
201.7	13.3 k)	
201.7.2.1.101 c)	13.3 m)	Presumption of conformity is only provided if symbols 4 to 7 are utilized.
201.7, 201.7.9.1, 201.16	13.6 a)	
201.7.9.2.101 c), 201.7.9.2.101 d)	13.6 b)	
201.7, 201.7.9.2.101 e), 201.16	13.6 c)	
201.7, 201.7.9.2.101 g), 201.16	13.6 d)	
201.7, 201.16	13.6 f)	
201.7, 201.7.2.9.2.101 j), 201.11, 201.16	13.6 h)	The requirement for information on the packaging is not addressed.

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7	13.6 i)	
201.7.2.9.2.101 i)	13.6 n)	
201.7.2.9.2.101 d)	13.6 p)	
201.7.2.9.2.101 k)	13.6 q)	

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

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Introduction

In this International Standard, the following print types are used.

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this International Standard, the term

- “clause” means one of the 20 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this International Standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this International Standard are by number only.

In this International Standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This international standard deals with electrical CLINICAL THERMOMETERS, either already available or that will come available in the future.

The purpose of a CLINICAL THERMOMETER is to assess the true temperature of a REFERENCE BODY SITE. The temperature of the PATIENT'S body is an important vital sign in assessing overall health, typically in combination with blood pressure and pulse rate. Determining whether a PATIENT is afebrile or febrile is an important purpose of a CLINICAL THERMOMETER, since being febrile suggests that the PATIENT is ill.

There are different temperatures at each REFERENCE BODY SITE according to the balance between the production, transfer, and loss of heat.^[38] CLINICAL ACCURACY of a CLINICAL THERMOMETER is VERIFIED by comparing its OUTPUT TEMPERATURE with that of a REFERENCE THERMOMETER, which has a specified uncertainty for measuring true temperature. For an equilibrium CLINICAL THERMOMETER, the CLINICAL ACCURACY can be sufficiently determined under laboratory conditions that create an equilibrium state between the two thermometers.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE, laboratory VERIFICATION alone is not sufficient because the adjustment algorithm for deriving the OUTPUT TEMPERATURE includes the characteristics of the PATIENT and the environment.^[3] Therefore the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE has to be VALIDATED clinically, using statistical methods of comparing its OUTPUT TEMPERATURE with that of a REFERENCE CLINICAL THERMOMETER which has a specified CLINICAL ACCURACY in representing a particular REFERENCE BODY SITE temperature.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE, the LABORATORY ACCURACY is VERIFIED in a DIRECT MODE and the CLINICAL ACCURACY is VALIDATED in the ADJUSTED MODE (OPERATING MODE) with a sufficiently large group of human subjects.

The intention of this International Standard is to specify the requirements and the test procedures for the VERIFICATION of the LABORATORY ACCURACY for all types of electrical CLINICAL THERMOMETERS as well as for the VALIDATION of the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE.

Medical electrical equipment —

Part 2-56:

Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

201.1 * Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT. This standard specifies the general and technical requirements for electrical CLINICAL THERMOMETERS. This standard applies to all electrical CLINICAL THERMOMETERS that are used for measuring the body temperature of PATIENTS.

CLINICAL THERMOMETERS can be equipped with interfaces to accommodate secondary indicators, printing equipment, and other auxiliary equipment to create ME SYSTEMS. This standard does not apply to auxiliary equipment.

ME EQUIPMENT that measures a temperature not as a primary purpose, but as a secondary function, is outside the scope of this standard.

EXAMPLE 1 Swan-Ganz thermodilution determination of cardiac output is not in the scope of this standard.

EXAMPLE 2 A Foley catheter that includes a temperature PROBE is in the scope of this standard.

EXAMPLE 3 PATIENT heating ME EQUIPMENT that includes a skin temperature measurement such as infant incubators, heating blankets, heating pads and heating mattresses are not in the scope of this standard, unless they indicate a temperature of a REFERENCE BODY SITE in which they are in the scope of this standard.

Requirements for ME EQUIPMENT intended to be used for non-invasive human febrile temperature screening of groups of individuals under indoor environmental conditions are given in IEC 80601-2-59:2008 and such ME EQUIPMENT is not covered by this standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005, 4.2.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a CLINICAL THERMOMETER, as defined in 201.3.206, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the CLINICAL THERMOMETER and the ACCESSORIES needs to be safe. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, Clause 2, as well as Clause 2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the IEC 60601-1 or applicable collateral standard.

"Amendment" means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 6060-1-3, etc.

The term "this standard" is used to make reference to the IEC 60601-1, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the IEC 60601-1 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the IEC 60601-1 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 43.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2006, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
Amendment 1:2008

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-6:2006, IEC 60601-1-8:2006, and the following definitions apply.

NOTE An alphabetized index of defined terms is found beginning on page 45.

Additions:

201.3.201

* ADJUSTED MODE

OPERATING MODE where the OUTPUT TEMPERATURE is calculated by adjusting the signal from the input SENSOR