

**ELEKTRILISED MEDITSIINISEADMED. OSA 2-56:
ERINÕUDED KEHATEMPERATUURI MÕÕTMISE
KLIINILISTE TERMOMEETRITE ESMASELE OHUTUSELE
JA OLULISTELE TOIMIMISNÄITAJATELE**

**Medical electrical equipment - Part 2-56: Particular
requirements for basic safety and essential
performance of clinical thermometers for body
temperature measurement (ISO 80601-2-56:2017)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN ISO 80601-2-56:2017 sisaldab Euroopa standardi EN ISO 80601-2-56:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-56:2017 consists of the English text of the European standard EN ISO 80601-2-56:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2017)

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 80601-2-56:2017)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2017)

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European foreword

This document (EN ISO 80601-2-56:2017) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with 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of an identical text or by endorsement, at the latest by January 2018, and conflicting national standards shall be withdrawn at the latest by July 2020.

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

This document supersedes EN ISO 80601-2-56:2012.

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.

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The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 201.2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
IEC 60601-1	EN 60601-1:2006 + Cor. :2010 + A1:2013	IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012
IEC 60601-1-2	EN 60601-1-2:2015	IEC 60601-1-2:2014
IEC 60601-1-6	EN 60601-1-6:2010 + A1:2015	IEC 60601-1-6:2010 + A1:2013
IEC 60601-1-8	EN 60601-1-8:2007 + Cor.:2010 + A1:2013	IEC 60601-1-8:2006 + A1:2012
IEC 60601-1-11	EN 60601-1- 11:2015	IEC 60601-1-11:2015
IEC 60601-1-12	EN 60601-1- 12:2015	IEC 60601-1-12:2014
IEC 62366-1	EN 62366-1:2015	IEC 62366-1:2015
ISO 14155:2011	EN ISO 14155:2011 + AC:2011	ISO 14155:2011 + AC:2011
ISO 14937	EN ISO 14937:2009	ISO 14937:2009
ISO 15223-1	EN ISO 15223- 1:2016	ISO 15223-1:2016
ISO 17664	EN ISO 17664:2004	ISO 17664:2004

Endorsement notice

The text of ISO 80601-2-56:2017 has been approved by CEN as EN ISO 80601-2-56:2017 without any modification.

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Introduction

This document 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, febrile or hypothermic 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^[2]. 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 document 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.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, 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 DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.), and
- “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 document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “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.

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+A1:2012, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT. This document specifies the general and technical requirements for electrical CLINICAL THERMOMETERS. This document 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 document does not apply to auxiliary equipment.

ME EQUIPMENT that measures a BODY TEMPERATURE is inside the scope of this document.

This document does not specify the requirements for screening thermographs intended to be used for the individual non-invasive human febrile temperature screening of groups of individual humans under indoor environmental conditions, which are given in IEC 80601-2-59^[4].

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 document are not covered by specific requirements in this document except in IEC 60601-1:2005+A1:2012, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005+A1:2012, 4.2.

201.1.2 Object

Replacement:

The object of this particular document 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 and effective. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012, Clause 2, as well as 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208, 211 and 212, respectively. IEC 60601-1-3^[5] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 document takes priority over IEC 60601-1 and its collateral standards.

For brevity, IEC 60601-1:2005+A1:2012 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this document 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 document.

"Addition" means that the text of this document 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 document.

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 60601-1-3, etc.

The term "this document" is used to make reference to the IEC 60601-1:2005+A1:2012, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, 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 document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+A1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*
+Amendment 1:2013

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*
+Amendment 1:2012

Addition:

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
+Amendment 1:2012

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*