SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-56:2015

01-september-2015

Medicinska električna oprema - 2-56. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kliničnih termometrov za merjenje telesne temperature (ISO/DIS 80601-2-56:2015)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO/DIS 80601-2-56:2015)

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Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO/DIS 80601-2-56:2015)

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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/DIS 80601-2-56:2015)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-56**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
17.200.20	Instrumenti za merjenje temperature	Temperature-measuring instruments

oSIST prEN ISO 80601-2-56:2015 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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DRAFT INTERNATIONAL STANDARD IEC/DIS 80601-2-56

ISO/TC **121**/SC **3** Secretariat: **ANSI**

Voting begins on **2015-06-25** Voting terminates on **2015-09-25**

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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

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

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ICS 11.040.55

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This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

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ISO 80601-2-56 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* in cooperation with Subcommittee 62D, *Electrical equipment*, of Technical Committee IEC/TC 62: *Electrical equipment in medical practice*.

This second edition of ISO 80601-2-56 cancels and replaces the first edition of ISO 80601-2-56 (2009). This edition of ISO 80601-2-56 constitutes a minor technical revision of ISO 80601-2-56:2009 and includes an alignment with Amendment 1 of third edition of IEC 60601-1, Amendment 1 of third edition of IEC 60601-1-6 and Amendment 1 of second edition of IEC 60601-1-8, as well as IEC 60601-1-12, the second edition of IEC 60601-1-11 and the fourth edition of IEC 60601-1-2.

The most significant changes are the following modifications:

— change in the clinical evaluation exclusion criteria related to antipyretics;

— deletion of Annex CC as this material is covered by IEC 60601-1-9;

and the following additions:

— disclosure requirement for a summary of the USE SPECIFICATION;

— tests for mechanical strength (via IEC 60601-1-11 and IEC 60601-1-12);

— tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11 and IEC 60601-1-12);

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130 — tests for cleaning and disinfection PROCEDURES (via IEC 60601-1-11 and IEC 60601-1-12);

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

132 — Requirements and definitions: roman type.

133 — *Test specifications: italic type.*

134 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
135 Normative text of tables is also in a smaller type.

136 — TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL
137 CAPITALS.

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

139 — "clause" means one of the 20 numbered divisions within the table of contents, inclusive of all
140 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

141 — "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of
142 Clause 7).

143 References to clauses within this International Standard are preceded by the term "Clause" followed by
144 the clause number. References to subclauses within this International Standard are by number only.

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

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

149 — "shall" means that compliance with a requirement or a test is mandatory for compliance with this
150 standard;

151 — "should" means that compliance with a requirement or a test is recommended but is not mandatory
152 for compliance with this standard;

153 — "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

156 ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

157 — *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

158 — *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic*
159 *workstation*

160 — *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas*
161 *monitors*

162 — *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers*
163 *for body temperature measurement*

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— *Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

— *Part 2-67: Particular requirements for the basic safety and essential performance of oxygen conserving equipment*

— *Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment*

— *Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing equipment*

IEC 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

— *Part 2-35: Particular requirements for basic safety and essential performance of blankets, pads and mattresses intended for heating in medical use*

— *Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

— *Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening*

— *Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

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European Foreword

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 the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

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

Table – Correlations between normative references and dated EN and ISO/IEC standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 14155:2011	EN ISO 14155:2011	ISO 14155:2011
ISO 14937:2009	EN ISO 14937:2009	ISO 14937:2009
ISO 15223-1:2015 [1] (Ed 3)	EN ISO 15223-1:— [1]	ISO 15223-1:2015 [1]
ISO 17664:2004	EN ISO 17664:2004	ISO 17664:2004
IEC 60601-1:2005+A1:2012	EN 60601-1:2006+A1:2013 +AC:2014+A12:2014	IEC 60601-1:2005+A1:2012
IEC 60601-1-2:2014	EN 60601-1-2:—[1]	IEC 60601-1-2:2014
IEC 60601-1-6:2010 +A1:2013+A2:—[1]	EN 60601-1-6:2010 +A1:—[1] +A2:—[1]	IEC 60601-1-6:2010 +A1:2013+A2:—[1]
IEC 60601-1-8:2006+A1:2012	EN 60601-1-8:2007 +A1:2013 +AC:2014	IEC 60601-1-8:2006 +A1:2012
IEC 60601-1-9:2007+A1:2013	EN 60601-1-9:2008 +A1:2013	IEC 60601-1-9:2007 +A1:2013
IEC 60601-1-10:2007+A1:2013	EN 60601-1-10:2007 +A1:—[1]	IEC 60601-1-10:2007 +A1:2013
IEC 60601-1-11:2015	EN 60601-1-11:—[1]	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:—[1]	IEC 60601-1-12:2014
IEC 62366-1:2015	EN 62366-1:—[1]	IEC 62366-1:2015

[1] To be published.

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Introduction

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, 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.[42] [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.[4] 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.

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[2] Figures in square brackets refer to the Bibliography.

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Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications

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 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.

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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.

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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 case 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+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 standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a CLINICAL THERMOMETER, as defined in 201.3.206, and its ACCESSORIES.

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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 particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012, 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 60601-1:2005+A1:2012 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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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:

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"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 60601-1-3, etc.

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

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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 64.

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 compatibility — 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
Amendment 2:—[3]

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:

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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 15223-1:2015 (Ed. 3), *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 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*
Amendment 1:2013

[3] To be published.

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