

STN	Zdravotnícke elektrické prístroje Časť 2-56: Osobitné požiadavky na základnú bezpečnosť a hlavné vlastnosti klinických teplomerov na meranie teploty tela (ISO 80601-2-56: 2017)	STN EN ISO 80601-2-56 25 8194
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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)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/17

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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)

This European Standard was approved by CEN on 28 June 2017.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by January 2018, and conflicting national standards shall be withdrawn at the latest by July 2020.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.

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, 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

Annex ZA (informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.2	201.11.6.6	ER 7.2 is covered only in respect to the patient, operator and user.
8.7	201.7.2.1.101 c)	
9.1	201.7.9.2.101 f), 201.16, 201.101.1 2 nd para, 201.102.1 3 rd para, 201.103, 201.103.2	ER 9.1 is covered by 201.103 in respect of probes, probe cable extenders and probe covers only.
9.2	201.9, 201.12.1.101, 201.12.2, 201.15, 202	ER 9.2 is covered by the listed standard clauses as follows: — 201.9 to the extent set out in the specified EN version of IEC 60601-1:2005+A1, Clause 9, — 201.12.1.101 for accuracy of controls and

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		instruments only, — 201.12.2 for display size and display integrity only, — 201.15 to the extent set out in the specified EN version of IEC 60601-1:2005+A1, Clause 15, — 202 Electromagnetic Compatibility. The 4th indent of ER 9.2 is not covered.
9.3	201.13	ER 9.3 is covered by 201.13 to the extent set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 13 only.
10.1	201.7.9.2.101 d), 201.7.9.2.101 e), 201.12, 201.101, 201.102, 201.103	
10.2	201.12.2	
10.3	201.7	ER 10.3 is covered by 201.7.4.3.101 and 201.7.9.2.101 i)
11.3.1	202	
12.1	201.14	ER 12.1 is covered by 201.14 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 14 only.
12.1 a)	201.14	ER 12.1 a) is covered by 201.14 to the extent set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 14 only.
12.4	201.12	ER 12.4 is covered by 201.12 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 12 only. Directive Annex 1 ER 12.4 is only covered if the alarm alerts the user to situations which could lead to death or severe deterioration of the patient's state of health.
12.5	202	
12.6	201.8	ER 12.6 is covered by 201.8 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 8 only.
12.7.1	201.9	ER 12.7.1 is covered by 201.9 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 9 only.
12.7.2	201.9	ER 12.7.2 is covered by 201.9 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 9 only.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
12.7.3	201.9	ER 12.7.3 is covered by 201.9 to the extent set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 9 only.
12.7.4	201.8, 201.11, 201.15	ER 12.7.4 is covered — by 201.8 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 8 only, — by 201.11 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 11 only, — by 201.15 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 15 only.
12.7.5	201.11, 201.15	ER 12.7.4 is covered — by 201.11 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 11 only, — by 201.15 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 15 only.
12.9	201.7, 201.12.2, 201.15, 206	
13.1	201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9	The requirement for information on the sales packaging is not addressed. The last para of ER 13.1 is not covered.
13.2	201.7, 201.7.2.1, 201.8, 201.9	ER 13.2 is covered provided that any used symbols conform to harmonized standards and where no harmonized standards exist, the symbols and colours are specified in the instructions for use.
13.3 b)	201.7, 201.7.2.1.101 b)	ER 13.3 b) is covered by 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7.2.2 only.
13.3 c)	201.7.2.1.101 c)	ER 13.3 c) is covered by 201.7.2.1.101 provided that the information specified appears on the device label.
13.3 e)	201.7.2.1.101 d)	ER 13.3 e) is covered by 201.7.2.1.101 provided that the information appears on the device label and that the 'Use by' date is expressed as a year and month in that order.
13.3 i)	201.7, 201.7.2.1.101 e)	ER 13.3 i) is covered by 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		ER 13.3 i) is covered by 201.7.2.1.101 e) provided that the information appears on the device label.
13.3 j)	201.7	ER 13.3 j) is covered by 201.7 to the extent set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only and provided that the information is shown on the device label.
13.3 k)	201.7	ER 13.3 k) is covered by 201.7 to the extent set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only and provided that the information is shown on the device label.
13.3 m)	201.7.2.1.101 c)	Presumption of conformity is only provided if symbols 4 to 7 are utilized. ER 13.3 m) is covered by 201.7.2.1.101 c) provided that the information is shown on the device label.
13.6 a)	201.7, 201.7.9.1, 201.16	ER 13.6 a) is covered by 201.7, 201.7.9.1, and 201.16 provided that all relevant information in ER 13.3 a) to c) and f) to n) are covered in the instructions for use.
13.6 b)	201.7.9.2.101 d), 201.7.9.2.101 e)	ER 13.6 b) is covered by 201.7.9.2.101 d) and 201.7.9.2.101 e) for the parameters listed in these clauses only.
13.6 c)	201.7, 201.7.9.2.101 f), 201.16	ER 13.6 c) is covered by — 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only, provided the information is included in the instructions for use, — 201.7.9.2.101 f) for the information set out in this clause only, — 201.16 as set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 16 only for the parameters listed in that standard provided the information is included in the instructions for use.
13.6 d)	201.7, 201.7.9.2.101 h), 201.16	ER 13.6 d) is covered by — 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only, provided the information is included in the instructions for use, — 201.7.9.2.101 h) for the information set out in this clause only,

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
		— 201.16 as set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 16 only for the parameters listed in that standard provided the information is included in the instructions for use.
13.6 f)	201.7, 201.16	ER 13.6 f) is covered by — 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only, provided the information is included in the instructions for use, — 201.16 as set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 16 only for the parameters listed in that standard provided the information is included in the instructions for use.
13.6 h)	201.7, 201.7.2.9.2.101 k), 201.11, 201.16	The requirement for information on the packaging is not addressed. ER 13.6 h) is covered by — 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only, provided the information is included in the instructions for use, — 201.7.9.2.101 k) for the information set out in this clause only, — 201.16 as set out in the specified EN version of IEC 60601-1:2005 +A1:2012, Clause 16 only for the parameters listed in that standard provided the information is included in the instructions for use.
13.6 i)	201.7	ER 13.6 i) is covered by 201.7 as set out in the specified EN version of IEC 60601-1:2005+A1:2012, Clause 7 only, provided the information is included in the instructions for use.
13.6 n)	201.7.9.2.101 j)	
13.6 p)	201.7.9.2.101 e)	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 (see 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 (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This second edition cancels and replaces the first edition (ISO 80601-2-56:2009), which has been technically revised. It also incorporates the Amendments IEC 60601-1:2005/AMD1:2012, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-8:2006/AMD1:2012, 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^[1];

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

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN