ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 80601-2-56:2017

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von

07/2017

National Foreword

This European Standard EN ISO 80601-2-56:2017 was adopted as Luxembourgish Standard ILNAS-EN ISO 80601-2-56:2017.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 80601-2-56

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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 80601-2-56:2017)

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.

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.

CEN members are the national standards bodies of 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 United Kingdom.

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

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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 2nd para, 201.102.1 3rd 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.