SVENSK STANDARD
SS-EN ISO 80601-2-56:2017

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Elektrisk utrustning för medicinskt bruk – Del 2-56: Särskilda krav för grundläggande säkerhet och väsentliga prestanda för medicinska termometrar för mätning av kroppstemperatur (ISO 80601-2-56:2017)

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)

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Europastandarden EN ISO 80601-2-56:2017 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 80601-2-56:2017.

Denna standard ersätter SS-EN ISO 80601-2-56:2012, utgåva 1.

The European Standard EN ISO 80601-2-56:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 80601-2-56:2017.

This standard supersedes the Swedish Standard SS-EN ISO 80601-2-56:2012, edition 1.

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Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-56

July 2017

ICS 11.040.55

Supersedes EN ISO 80601-2-56:2012

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.

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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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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.

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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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