SLOVENSKI STANDARD
SIST EN 60601-1-10:2008/A1:2015

01-september-2015

Medicinska električna oprema - 1-10. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Zahteve za razvoj fizioloških krmilnikov s sklenjeno zanko - Dopolnilo A1

Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers

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Medizinische elektrische Geräte - Teil 1-10: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen an die Entwicklung von physiologischen geschlossenen Regelkreisen

SIST EN 60601-1-10:2008/A1:2015
https://standards.iteh.ai/catalog/standards/sist/9b2d28ee-ad62-4904-814a-b43fdd20145f/sist-en-60601-1-10-2008-a1-2015

Appareils électromédicaux - Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée

Ta slovenski standard je istoveten z: EN 60601-1-10:2008/A1:2015

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-10:2008/A1:2015 en

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

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SIST EN 60601-1-10:2008/A1:2015

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-10:2008/A1

May 2015

ICS 11.040

English Version

Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601-1-10:2007/A1:2013)

Appareils électromédicaux - Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée
(IEC 60601-1-10:2007/A1:2013)

Medizinische elektrische Geräte - Teil 1-10: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen an die Entwicklung von physiologischen geschlossenen Regelkreisen
(IEC 60601-1-10:2007/A1:2013)

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This amendment A1 modifies the European Standard EN 60601-1-10:2008; it was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CENELEC member.

SIST EN 60601-1-10:2008/A1:2015
https://standards.iteh.ai/catalog/standards/sist/9b2d28ee-ad62-4904-814a-b4578d201451/sist-en-60601-1-10-2008-a1-2015

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC 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 Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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SIST EN 60601-1-10:2008/A1:2015

Foreword

The text of document 62A/888/FDIS, future IEC 60601-1-10:2007/A1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" and ISO/SC 1 "Breathing attachments and anaesthetic machines" and ISO/SC 3 "Lung ventilators and related devices" of ISO/TC 121 "Anaesthetic and respiratory equipment" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-10:2008/A1:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-1-10:2008.

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Endorsement notice

SIST EN 60601-1-10:2008/A1:2015

The text of the International Standard IEC 60601-1-10:2007/A1:2013 was approved by CENELEC as a European Standard without any modification.

SIST EN 60601-1-10:2008/A1:2015

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Modifications in Annex ZA of EN 60601-1-10:2008:

Publication	Year	Title	EN/HD	Year
Replace the existing references to IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
+A1	2012		+A1 +A1/AC +A12	2013 2014 2014
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+A1	2013		+A1	2015
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	EN 60601-1-8 + corr. March	2007 2010
+A1	2012		+A1 +A1/AC	2013 2014
Delete the following reference:				
IEC 62304	2006	Medical device software - Software life-cycle processes	EN 62304	2006
Add the following reference:				
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008

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SIST EN 60601-1-10:2008/A1:2015

IEC 60601-1-10

Edition 1.0 2013-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers

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Appareils électromédicaux –
Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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SIST EN 60601-1-10:2008/A1:2015

FOREWORD

This amendment has been prepared by subcommittee 62A: *Common aspects of electrical equipment used in medical practice*, of IEC technical committee 62: *Electrical equipment in medical practice*, and ISO subcommittees SC1: *Breathing attachments and anaesthetic machines*, and SC3: *Lung ventilators and related devices* of ISO technical committee 121: *Anaesthetic and respiratory equipment*.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/888/FDIS	62A/896/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 15 P-members out of 15 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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SIST EN 60601-1-10:2008/A1:2015
https://standards.iteh.ai/catalog/standards/sist/9b2d28ee-ad62-4904-814a-b4578d201451/sist-en-60601-1-10-2008-a1-2015

INTRODUCTION TO THE AMENDMENT

The first edition of IEC 60601-1-10 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update IEC 60601-1-6:2006 to IEC 60601-1-6:2010, including its Amendment 1 and to update references to IEC 60601-1-8:2006 to include its Amendment 1:2012. This amendment also removes the normative reference to IEC 62304:2006. This collateral standard made reference to IEC 62304 because elements of the software process were not fully covered by Clause 14 of IEC 60601-1:2005. Amendment 1 to IEC 60601-1:2005 incorporates the needed software process requirement into Clause 14. Therefore, it is redundant and potentially confusing to have IEC 62304 explicitly called out in this collateral standard.

FOREWORD

Add the following note at the end of the Foreword:

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

SIST EN 60601-1-10:2008/A1:2015

1 Scope, object and related standards

1.3.1 IEC 60601-1

Replace the existing first dashed item with:

– "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);

Replace the existing second dashed item with:

– "this collateral standard" designates IEC 60601-1-10 alone (IEC 60601-1-10:2007+A1:2013)

2 Normative references

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.

Replace the existing references to IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:

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

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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

SIST EN 60601-1-10:2008/A1:2015
https://standards.iteh.ai/catalog/standards/sist/9b2d28ee-ad62-4904-814a-b4578d201451/sist-en-60601-1-10-2008-a1-2015

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

Delete the following normative reference:

IEC 62304:2006, *Medical device software – Software life cycle processes*

Add the following normative reference:

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

3 Terms and definitions

Replace the existing introductory paragraph with:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-6:2010+ A1:2013, IEC 60601-1-8:2006+A1:2012, IEC 62366:2007 and the following apply.

7 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Replace the existing text of the clause with the following: