SLOVENSKI STANDARD
SIST EN 60601-1-6:2010/A1:2015

01-september-2015

Medicinska električna oprema - 1-6. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Uporabnost - Dopolnilo A1

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit

Appareils électromédicaux - Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Aptitude à l'utilisation

Ta slovenski standard je istoveten z: **EN 60601-1-6:2010/A1:2015**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-6:2010/A1:2015 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1-6:2010/A1

May 2015

ICS 11.040

English Version

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
(IEC 60601-1-6:2010/A1:2013)

Appareils électromédicaux - Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Aptitude à l'utilisation
(IEC 60601-1-6:2010/A1:2013)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale
(IEC 60601-1-6:2010/A1:2013)

This amendment A1 modifies the European Standard EN 60601-1-6:2010; 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.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

Foreword

The text of document 62A/890/FDIS, future IEC 60601-1-6:2010/A1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1-6:2010/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 90/385/EEC, see informative Annex ZZ, which is an integral part of this document.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-1-6:2010.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A1:2013 was approved by CENELEC as a European Standard without any modification.

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

Replacement in Annex ZA of EN 60601-1-6:2010:

Publication	Year	Title	EN/HD	Year
Replace the existing references to IEC 60601-1, IEC 60601-1-8 and IEC 62366 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	2013 2014
			+A12	2014
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
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
+A1	2014		A1	2015

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex 1 of EU Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

IEC 60601-1-6

Edition 3.0 2013-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Appareils électromédicaux –
Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX F

ICS 11.040 ISBN 978-2-8322-1132-8

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.

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

FDIS	Report on voting
62A/890/FDIS	62A/898/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.

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.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1-6 was published in 2010. The third edition created a bridge that enables a MANUFACTURER to conform to the requirements in IEC 60601-1 that make normative reference to IEC 60601-1-6 by employing a USABILITY ENGINEERING PROCESS complying with IEC 62366:2007. However, IEC 62366 contains certain life-cycle process elements that are inconsistent with a TYPE TEST.

This amendment is intended to clarify the elements of the USABILITY ENGINEERING PROCESS that are required for compliance with the IEC 60601 series.

FOREWORD

In the existing paragraph beginning "This document cancels and replaces…", delete the second sentence.

In the existing third paragraph from the end of the Foreword, beginning "To assist the user…", replace "IEC 62366:2007" *with* "IEC 62366:2007+A1—[1)]" *in two places.*

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

[1)] To be published.

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 mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

In the first sentence of the fourth paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012".

In the second sentence of the existing sixth paragraph, replace "IEC 62366:2007" *with* "IEC 62366".

Add, after the last paragraph of the introduction, the following new paragraph:

Amendment 1 removes the reference to the complete life-cycle process (including post-production monitoring and surveillance). IEC 60601 (the series) is confined to performing a TYPE TEST of ME EQUIPMENT. It does not extend to the entire life cycle including post-production monitoring and periodic maintenance of the USABILITY ENGINEERING PROCESS.

1.3.1 IEC 60601-1

Replace the existing first bullet with:

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

Replace the existing second bullet with:

– "this collateral standard" designates IEC 60601-1-6 alone (IEC 60601-1-6:2010+A1:2013).

2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-8 and IEC 62366 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

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

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
Amendment 1:—[2)]

3 Terms and definitions

In the existing introductory paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012", "IEC 60601-1-8:2006" *with* "IEC 60601-1-8:2006+A1:2012" *and* "IEC 62366:2007" *with* "IEC 62366:2007+A1:—[2)]".

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2) To be published.