SLOVENSKI STANDARD
SIST EN 60601-1-6:2010/A2:2021

01-september-2021

Medicinska električna oprema - 1-6. del: Splošne zahteve za osnovno varnost in bistvene tehnične lastnosti - Spremljevalni standard: uporabnost - Dopolnilo A2 (IEC 60601-1-6:2010/A2:2020)

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010/A2:2020)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit (IEC 60601-1-6:2010/A2:2020)

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/A2:2020)

Ta slovenski standard je istoveten z: **EN 60601-1-6:2010/A2:2021**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1-6:2010/A2:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-6:2010/A2

July 2021

ICS 11.040.01

English Version

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010/A2:2020)

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/A2:2020)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit (IEC 60601-1-6:2010/A2:2020)

This amendment A2 modifies the European Standard EN 60601-1-6:2010; it was approved by CENELEC on 2020-08-26. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

CENELEC

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-1-6:2010/A2:2021 E

European foreword

The text of document 62A/1391/FDIS, future IEC 60601-1-6/A2, 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/A2:2021.

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) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14155	NOTE	Harmonized as EN ISO 14155

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where 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.

Replace Annex ZA by the following one:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	2020
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

IEC 60601-1-6

Edition 3.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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
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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/1391/FDIS	62A/1406/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.

NOTE The attention of users of this document 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 mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1-6 was published in 2010 and amended in 2013. Since the publication of IEC 60601-1-6:2010+A1:2013, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fourth edition of IEC 60601-1-6, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, nine items were presented to the National Committees present. All nine items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1-6.

The "short list" of issues was documented in the design specification for Amendment 2. Because these issues are closely related to the application of IEC 62366-1 to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, the work was assigned to IEC/SC 62A-ISO/TC 210 Joint Working Group (JWG) 4. JWG 4 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the document was justified by the problem statement.

This amendment updates the references from the now obsolete IEC 62366:2007 to the current USABILITY ENGINEERING PROCESS standard, IEC 62366-1:2015+A1:2020.

Because this is an amendment to IEC 60601-1-6:2010, the style in force at the time of publication of IEC 60601-1-6 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, references to amendments take the following form: "IEC 60601-1:2005+A1:2012+A2:2020".

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

FOREWORD

Replace, in the existing fourth paragraph beginning with " This edition of IEC 60601-1-6 was revised…", *the reference to* "IEC 62366" *with* "IEC 62366-1*".*

Replace, in the second dash of the existing ninth paragraph beginning with "In this collateral standard, the following print types…"*, the reference to* "IEC 62366" *with* "IEC 62366-1".

Replace the existing second paragraph before the last (including the footnote), beginning with "To assist the user of this collateral standard…*" and modified by Amendment 1, with the following new paragraph and footnote:*

To assist the user to implement the USABILITY ENGINEERING PROCESS, the Technical Report IEC TR 62366-2 [1] [1)] is available. IEC TR 62366-2 contains tutorial information to assist MANUFACTURERS in complying with this standard. The Technical Report also goes beyond safety-related aspects and offers more detailed descriptions of USABILITY ENGINEERING methods that can be applied to the development of ME EQUIPMENT.

[1)] Figures in square brackets refer to the Bibliography.

INTRODUCTION

Replace, in the second sentence before the last of the existing first paragraph, the term "OPERATOR-EQUIPMENT INTERFACE" *with* "OPERATOR INTERFACE".

Replace the last sentence of the existing first paragraph with the following new sentence:

The design of the OPERATOR INTERFACE to achieve safe use (adequate USABILITY) requires a very different skill set than that of the technical implementation of that interface.

Replace, in the second paragraph, the reference "Figure A.1 of IEC 62366:2007" *with* "Figure A.4 of IEC 62366-1:2015".

Replace, in the existing paragraph before the last, the last sentence with:

It should be noted that clinical investigations conducted according to ISO 14155 [2] and USABILITY TESTS for FORMATIVE EVALUATION or SUMMATIVE EVALUATION according to this standard are two fundamentally different activities and should not be confused.

1.1 * Scope

Replace, in the existing first paragraph, the words "design, VERIFY and VALIDATE USABILITY" *with* "develop and evaluate the USABILITY".

Replace the existing third paragraph with the following new paragraph and note:

If the USABILITY ENGINEERING PROCESS detailed in this collateral standard has been complied with, then the USABILITY of ME EQUIPMENT as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.

1.3.1 IEC 60601-1

Replace, in the first two bullet points of the existing second paragraph, the parentheses, added by Amendment 1, with the words ", including any amendments".