ICS 11.040 SLOVENSKÁ TECHNICKÁ NORMA December 2020

STN	**Zdravotnícke pomôcky Časť 1: Uplatnenie stanovenia použiteľnosti na zdravotnícke pomôcky Zmena A1**	**STN EN 62366-1/A1 36 4894**

Medical devices - Part 1: Application of usability engineering to medical devices

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/20

STN EN 62366-1 z októbra 2015 sa bez tejto zmeny A1 môže používať do 22. 7. 2023.

Obsahuje: EN 62366-1:2015/A1:2020, IEC 62366-1:2015/AMD1:2020

131911

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62366-1:2015/A1

August 2020

ICS 11.040

English Version

Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)

Dispositifs médicaux - Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux (IEC 62366-1:2015/A1:2020)

Medizinprodukte - Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (IEC 62366-1:2015/A1:2020)

This amendment A1 modifies the European Standard EN 62366-1:2015; it was approved by CENELEC on 2020-07-22. 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.

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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 62366-1:2015/A1:2020 E

EN 62366-1:2015/A1:2020 (E)

European foreword

The text of document 62A/1386/FDIS, future IEC 62366-1/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 62366-1:2015/A1:2020.

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) 2021-04-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-07-22

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.

Endorsement notice

The text of the International Standard IEC 62366-1:2015/A1:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-11:2015	NOTE	Harmonized as EN 60601-1-11:2015 (not modified)
ISO 9000:2015	NOTE	Harmonized as EN ISO 9000:2015 (not modified)
ISO 9001:2015	NOTE	Harmonized as EN ISO 9001:2015 (not modified)
ISO 13485:2016	NOTE	Harmonized as EN ISO 13485:2016 (not modified)

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.

Publication	Year	Title	EN/HD	Year
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

IEC 62366-1

Edition 1.0 2020-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical devices –
Part 1: Application of usability engineering to medical devices

Dispositifs médicaux –
Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

IEC 62366-1:2015-02/AMD1:2020-06(en-fr)

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IEC 62366-1

Edition 1.0 2020-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical devices –
Part 1: Application of usability engineering to medical devices

Dispositifs médicaux –
Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01 ISBN 978-2-8322-8384-4

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 technical committee 210: Quality management and corresponding general aspects for medical devices.

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

FDIS	Report on voting
62A/1386/FDIS	62A/1397/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.

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FOREWORD

In the fourth paragraph, replace “ISO 14971:2007” *with* “ISO 14971:2019”*, format “*medical device user interfaces*” in small caps and replace “*manufactures*” with “*MANUFACTURERS*” to correct the spelling and the format.*

INTRODUCTION to Amendment 1

The first edition of IEC 62366-1 was published in 2015. Since its publication, experts working in the field have identified several inaccuracies that warrant correction. In total, 22 issues were identified and presented to the National Committee members of IEC/SC 62A and to the Member Bodies of ISO/TC 210. A majority of the members of both committees that stated a position supported developing this amendment to address the identified issues while making no fundamental changes to the USABILITY ENGINEERING PROCESS as originally conceived in IEC 62366-1:2015.

To assist the USER to implement the USABILITY ENGINEERING PROCESS, the technical report IEC TR 62366-2 is available, which contains tutorial information to assist MANUFACTURERS in complying with this document, as well as more generally to design MEDICAL DEVICES that goes beyond SAFETY-related aspects of USER INTERFACES and offers more detailed descriptions of USABILITY ENGINEERING methods that can be applied.

INTRODUCTION

Replace, in the second paragraph, “Figure A.4” *with* “Figure A.5”.

Replace, in the NOTE, “functionality” *with* “performance”.

Replace, in the last paragraph, “benefits” *with* “advantages”.

Replace the existing footnote 1 with the following:

1 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.

1 * Scope

In the second sentence, replace “with CORRECT USE and USE ERRORS, i.e., NORMAL USE” *with* “with NORMAL USE, i.e., CORRECT USE and USE ERROR”.

Replace NOTE 1 with the following:

NOTE 1 SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to HAZARDS including loss or degradation of clinical performance.

Replace the existing footnote 2 with the following:

2 IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*.

2 Normative references

Replace “ISO 14971:2007” *with* “ISO 14971:2019”.