SLOVENSKI STANDARD
SIST EN 62366-1:2015/A1:2020

01-november-2020

Medicinske naprave - 1. del: Izvedba tehnik uporabe pri medicinskih napravah - Dopolnilo A1 (IEC 62366-1:2015/A1:2020)

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

Medizinprodukte - Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (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)

Ta slovenski standard je istoveten z: **EN 62366-1:2015/A1:2020**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 62366-1:2015/A1:2020 **en**

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

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

INTERNATIONAL
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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, 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.

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".

3 Terms and definitions

Replace, in the first paragraph, "ISO 14971:2007" *with* "ISO 14971:2019".

3.1
*** ABNORMAL USE**

Replace, in the existing definition and its example, "intentional" *with* "deliberate" *in 3 places.*

3.2
ACCOMPANYING DOCUMENTATION

Replace the existing definition, notes to entry and source with the following:

3.2
ACCOMPANYING DOCUMENTATION
materials accompanying a MEDICAL DEVICE and containing information for the USER or those accountable for the installation, use, maintenance, decommissioning and disposal of the MEDICAL DEVICE, particularly regarding safe use

Note 1 to entry: The ACCOMPANYING DOCUMENTATION can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: ACCOMPANYING DOCUMENTATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

Note 3 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: ISO 14971:2019, 3.1, modified – Note 3 to entry has been added.]

3.20
USE ENVIRONMENT

Add, in Note 1 to entry, the following second sentence:

Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

3.23
*** USE SPECIFICATION**

Replace, in Note 3 to entry, "ISO 14971:2007" *with* "ISO 14971:2019".

3.25
USER GROUP

Replace the definition with the following:

subset of USERS who are differentiated from other USERS by factors that are likely to influence their interactions with the MEDICAL DEVICE

NOTE 1 to entry: Attributes of USER GROUPS can include age, culture, expertise.

3.29
USER PROFILE

Replace the existing definition with the following:

summary of the mental, physical and demographic traits of a USER GROUP, as well as characteristics, such as knowledge, skills and abilities, which can have a bearing on design decisions

4.1.1 * USABILITY ENGINEERING PROCESS

Replace, in the third paragraph, "ISO 13485:2003" *with* "ISO 13485:2016".

Replace, in NOTE 1, "ISO 13485:2003" *with* "ISO 13485:2016".

Replace, in the fourth paragraph, "ISO 14971:2007" *with* "ISO 14971:2019" *and* "Figure A.4" *with* "Figure A.5".

Replace, in the fifth paragraph, "Figure A.4" *with* "Figure A.5" *and* "carried out" *with* "carried out iteratively or".

4.1.2 * RISK CONTROL as it relates to USER INTERFACE design

Replace the first paragraph and list items a) to c) with the following:

To reduce use-related RISK, the MANUFACTURER shall use one or more of the following options, in the priority listed (as required by ISO 14971:2019, 7.1):

a) inherently safe design and manufacture;

b) protective measures in the MEDICAL DEVICE itself or in the manufacturing PROCESS; and

c) information for SAFETY and, where appropriate, training to USERS.

4.1.3 Information for SAFETY as it relates to USABILITY

Replace, in the second paragraph, “intentional” *with* “deliberate” *in 2 places.*

4.3 Tailoring of the USABILITY ENGINEERING effort

Delete the compliance check.

5.1 * Prepare USE SPECIFICATION

Replace the fifth dash with:

– * intended USE ENVIRONMENT; and

5.2 * Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

Replace, in the first paragraph, “ISO 14971:2007, 4.2” *with* “ISO 14971:2019, 5.3”.

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

This identification shall include consideration of the PRIMARY OPERATING FUNCTIONS if they are provided in applicable product-specific MEDICAL DEVICE SAFETY standards.

Replace, in NOTE 1, “ISO 14971:2007, C.2.29 to C.2.34” *with* “ISO/TR 24971:—[6], A.2.31 to A.2.37”.

Insert the following footnote:

[6] Under preparation. Stage at the time of circulation: ISO /TR APUB 24971:2020.

Replace the paragraph preceding the compliance check with the following:

The results of this identification of characteristics related to SAFETY and potential USE ERRORS shall be stored in the USABILITY ENGINEERING FILE.

5.3 * Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

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

This identification shall be conducted as part of a RISK ANALYSIS performed according to ISO 14971:2019, 5.4.

5.5 * Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION

Replace the text of the subclause with the following:

The MANUFACTURER shall select the HAZARD-RELATED USE SCENARIOS to be included in the SUMMATIVE EVALUATION.

The MANUFACTURER shall select:

– all HAZARD-RELATED USE SCENARIOS;