MEDITSIINISEADMED. OSA 1: KASUTATAVUSPROJEKTEERIMISE RAKENDAMINE MEDITSIINISEADMETELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 62366-1:2015 +A1:2020 sisaldab Euroopa standardi EN 62366-1:2015 ja selle muudatuse A1:2020 ja paranduste AC:2015 ja AC:2018 ingliskeelset teksti.	This Estonian standard EVS-EN 62366-1:2015 +A1:2020 consists of the English text of the European standard EN 62366-1:2015 and its amendment A1:2020 and its corrigendae AC:2015 and AC:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.04.2015, muudatus A1 07.08.2020.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 24.04.2015, for A1 07.08.2020.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega ▌A1⟩ ⟨A1▐. Parandusega AC:2015 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega ▌AC⟩ ⟨AC▐. Parandusega AC:2018 lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega ▌AC2⟩ ⟨AC2▐. Standard on kättesaadav Eesti Standardi-keskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by symbols ▌A1⟩ ⟨A1▐. The start and finish of text introduced or altered by corrigendum AC:2015 is indicated in the text by symbols ▌AC⟩ ⟨AC▐. The start and finish of text introduced or altered by corrigendum AC:2018 is indicated in the text by symbols ▌AC2⟩ ⟨AC2▐. The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62366-1 + A1

April 2015, August 2020

ICS 11.040

AC supersedes EN 62366:2008 AC

English Version

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

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

This European Standard was approved by CENELEC on 2015-03-31. Amendment A1 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 European Standard and its 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 European Standard and its amendment A1 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.

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 E + EN 62366-1:2015/A1:2020 E

Foreword

The text of document 62A/977/FDIS, future edition 1 of IEC 62366-1, 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.

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)	2015-12-31
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-03-31

〖AC〗 This document supersedes EN 62366:2008. 〖AC〗

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.

Endorsement notice

The text of the International Standard IEC 62366-1:2015 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 60601-1:2005	NOTE	Harmonized as EN 60601-1:2006.
IEC 60601-1:2005/A1:2012	NOTE	Harmonized as EN 60601-1:2006/A1:2013.
IEC 60601-1-6:2010	NOTE	Harmonized as EN 60601-1-6:2010.
IEC 60601-1-6:2010/A1:2013	NOTE	Harmonized as EN 60601-1-6:2010/A1:2013.
IEC 60601-1-8:2006	NOTE	Harmonized as EN 60601-1-8:2007.
IEC 60601-1-8:2006/A1:2012	NOTE	Harmonized as EN 60601-1-8:2007/A1:2013.
IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
ISO 7010:2011	NOTE	Harmonized as EN ISO 7010:2012.
ISO 9000:2005	NOTE	Harmonized as EN ISO 9000:2005.
ISO 9001:2008	NOTE	Harmonized as EN ISO 9001:2008.
ISO 9241-11:1998	NOTE	Harmonized as EN ISO 9241-11:1998.
ISO 13485:2003	NOTE	Harmonized as EN ISO 13485:2012.

A1 Amendment A1 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)

A1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL DEVICES –

Part 1: Application of usability engineering to medical devices

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 62366-1 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC technical committee 62: Electrical medical equipment in medical practice, and ISO technical committee 210: Quality management and corresponding general aspects for MEDICAL DEVICES.

It is published as double logo standard.

This first edition of IEC 62366-1, together with the first edition of IEC 62366-2, cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1 (2014).

Part 1 has been updated to include contemporary concepts of USABILITY ENGINEERING, while also streamlining the process. It strengthens links to ⟦A1⟩ ISO 14971:2019 ⟨A1⟧ and the related methods of RISK MANAGEMENT as applied to SAFETY related aspects of ⟦A1⟩ MEDICAL DEVICE USER INTERFACES ⟨A1⟧. Part 2 contains tutorial information to assist ⟦A1⟩ MANUFACTURERS ⟨A1⟧ in complying with Part 1, as well as offering more detailed descriptions of USABILITY ENGINEERING methods that can be applied more generally to MEDICAL DEVICES that go beyond safety-related aspects of MEDICAL DEVICE USER INTERFACES.

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

FDIS	Report on voting
62A/977/FDIS	62A/988/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 26 P-members out of 26 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this International Standard, the following print types are used:

– Requirements and definitions: roman type.
– *Means to assess compliance: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type
– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

The requirements are followed by means to assess compliance.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses and subclauses for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 62366 series, published under the general title *Medical devices,* can be found on the IEC website.

The committee has decided that the contents of this 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 National Committees and Member Bodies 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.

The contents of the corrigendum of July 2016 have been included in this copy.

AMENDMENT A1 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.

INTRODUCTION

Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS are non-intuitive, difficult to learn and difficult to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. The design of the USER INTERFACE to achieve adequate USABILITY requires a different PROCESS and skill set than that of the technical implementation of the USER INTERFACE.

The USABILITY ENGINEERING PROCESS is intended to identify and minimise USE ERRORS and thereby reduce use-associated RISKS. Some, but not all, forms of incorrect use are suited to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in [A1] Figure A.5 [A1].

This International Standard describes a USABILITY ENGINEERING PROCESS to provide acceptable RISK related to USABILITY of a MEDICAL DEVICE. It is intended to be useful not only for MANUFACTURERS of MEDICAL DEVICES, but also for technical committees responsible for the preparation of particular MEDICAL DEVICE standards.

This International Standard strictly focuses on applying the USABILITY ENGINEERING PROCESS to optimize MEDICAL DEVICE USABILITY as it relates to SAFETY. The companion technical report (IEC 62366-2[1]) is comprehensive and has a broader focus. It focuses not only on USABILITY as it relates to SAFETY, but also on how USABILITY relates to attributes such as TASK accuracy, completeness and EFFICIENCY, and USER satisfaction.

NOTE SAFETY is freedom from unacceptable RISK. Unacceptable RISK can arise from USE ERROR, which can lead to exposure to direct physical HAZARDS or loss or degradation of clinical [A1] performance [A1].

MANUFACTURERS can choose to implement a USABILITY ENGINEERING program focused narrowly on SAFETY or more broadly on SAFETY and other attributes, such as those cited above. A broader focus might also be useful to address specific USABILITY ENGINEERING expectations, such as the need to confirm that USERS can successfully perform non-SAFETY-related TASKS. A MANUFACTURER might also implement a broader program to realize the commercial [A1] advantages [A1] of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

1 [A1] IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*. [A1]

⟨A1⟩ 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. ⟨A1⟩

MEDICAL DEVICES –

Part 1: Application of usability engineering to medical devices

1 * Scope

This part of IEC 62366 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated [A1] with NORMAL USE, i.e., CORRECT USE and USE ERROR [A1]. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

[A1] 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. [A1]

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2[2], which addresses not only SAFETY but also aspects of USABILITY not related to SAFETY.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with, then the USABILITY of a MEDICAL DEVICE as it relates to SAFETY is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE 3 Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance.

2 Normative references

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 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography beginning on page 51.

[A1] ISO 14971:2019 [A1], *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purpose of this document, the terms and definitions given in [A1] ISO 14971:2019 [A1] and the following apply.

NOTE An index of defined terms is found beginning on page 56.

3.1
*** ABNORMAL USE**
conscious, [A1] deliberate [A1] act or [A1] deliberate [A1] omission of an act that is counter to or violates NORMAL USE and is also beyond any further reasonable means of USER INTERFACE-related RISK CONTROL by the MANUFACTURER

EXAMPLES Reckless use or sabotage or [A1] deliberate [A1] disregard of information for SAFETY are such acts.

---

2 [A1] IEC TR 62366-2:2016, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*. [A1]