



SLOVENSKI STANDARD

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Medicinske naprave - 1. del: Izvedba tehnik uporabe pri medicinskih napravah

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

Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte

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

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

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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EUROPEAN STANDARD

EN 62366-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2015

ICS 11.040

English Version

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

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

Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte
(IEC 62366-1:2015)

This European Standard was approved by CENELEC on 2015-03-31. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 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: Avenue Marnix 17, B-1000 Brussels

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

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. https://standards.iteh.ai/catalog/standards/sist/4db73e47-947e-4b6b-bd5f-20d002f63802/iec-60601-1-2005
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.

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012

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IEC 62366-1

Edition 1.0 2015-02

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NORME INTERNATIONALE

Medical devices – iTeh STANDARD PREVIEW
Part 1: Application of usability engineering to medical devices
(standards.iteh.ai)

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Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs
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CONTENTS

FOREWORD	4
INTRODUCTION	6
1 * Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Principles	12
4.1 General requirements	12
4.1.1 * USABILITY ENGINEERING PROCESS	12
4.1.2 * RISK CONTROL as it relates to USER INTERFACE design	13
4.1.3 Information for SAFETY as it relates to USABILITY	13
4.2 * USABILITY ENGINEERING FILE	14
4.3 Tailoring of the USABILITY ENGINEERING effort	14
5 * USABILITY ENGINEERING PROCESS	14
5.1 * Prepare USE SPECIFICATION	14
5.2 * Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS	15
5.3 * Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS	15
5.4 * Identify and describe HAZARD-RELATED USE SCENARIOS	15
5.5 * Select the HAZARD-RELATED USE SCENARIOS for SUMMATIVE EVALUATION	16
5.6 * Establish USER INTERFACE SPECIFICATION	16
5.7 * Establish USER INTERFACE EVALUATION plan	16
5.7.1 General	16
5.7.2 * FORMATIVE EVALUATION planning	17
5.7.3 * SUMMATIVE EVALUATION planning	17
5.8 * Perform USER INTERFACE design, implementation and FORMATIVE EVALUATION	18
5.9 * Perform SUMMATIVE EVALUATION of the USABILITY of the USER INTERFACE	19
5.10 USER INTERFACE OF UNKNOWN PROVENANCE	19
Annex A (informative) General guidance and rationale	20
A.1 General guidance	20
A.2 Rationale for requirements in particular clauses and subclauses	20
ANNEX B (informative) Examples of possible HAZARDOUS SITUATIONS related to USABILITY	38
Annex C (normative) Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)	41
C.1 General	41
C.2 USABILITY ENGINEERING PROCESS for USER INTERFACE OF UNKNOWN PROVENANCE	41
C.2.1 * USE SPECIFICATION	41
C.2.2 * Review of POST-PRODUCTION information	42
C.2.3 HAZARDS and HAZARDOUS SITUATIONS related to USABILITY	42
C.2.4 RISK CONTROL	42
C.2.5 RESIDUAL RISK evaluation	42
Annex D (informative) Types of MEDICAL DEVICE use, with examples	43
Annex E (informative) Reference to the essential principles	45
Bibliography	46
Index of defined terms	49

Figure 1 – Relationship of the types of use	8
Figure A.1 – Model of USER-MEDICAL DEVICE interaction	24
Figure A.2 – Relationship of TASKS and functions within a USE SCENARIO	25
Figure A.3 – Relationship of TASKS and functions and USE ERROR within a HAZARD-RELATED USE SCENARIO	26
Figure A.4 – The relationship between the RISK MANAGEMENT PROCESS (ISO 14971:2007) and the USABILITY ENGINEERING PROCESS (IEC 62366-1)	32
Figure D.1 – Interrelationships between the different types of MEDICAL DEVICE use, with examples	44
Table B.1 – Glossary of relevant RISK MANAGEMENT terms	38
Table B.2 – Examples of HARM due to RISK caused by USE ERROR(S) or poor USABILITY (1 of 3)	38
Table E.1 – Correspondence between this document and the essential principles	45

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SIST EN 62366-1:2015

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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.
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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 ISO 14971:2007 and the related methods of RISK MANAGEMENT as applied to SAFETY related aspects of medical device user interfaces. Part 2 contains tutorial information to assist manufactures 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.

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 Figure A.4.

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 62366-2¹) 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 functionality.

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 benefits of a MEDICAL DEVICE that not only is safe to use but also offers superior USABILITY.

¹ IEC 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices* (in preparation).

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 with CORRECT USE and USE ERRORS, i.e., NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

NOTE 1 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 functionality.

NOTE 2 Guidance on the application of USABILITY ENGINEERING to MEDICAL DEVICES is available in IEC 62366-2², 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.

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2 Normative references

SIST EN 62366-1:2015

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 46.

ISO 14971:2007, *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 ISO 14971:2007 and the following apply.

NOTE An index of defined terms is found beginning on page 49.

3.1

* ABNORMAL USE

conscious, intentional act or intentional 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 intentional disregard of information for SAFETY are such acts.

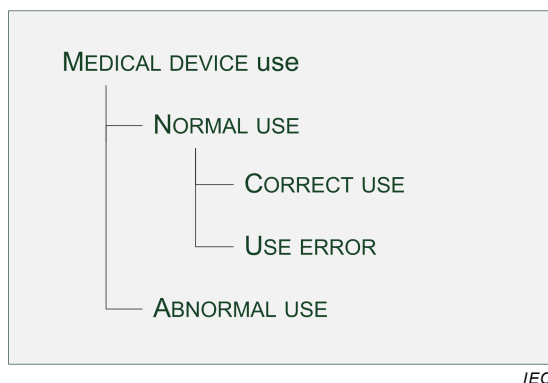
² IEC 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices* (in preparation).

Note 1 to entry See also 4.1.3.

Note 2 to entry: An intended but erroneous action that is not ABNORMAL USE is considered a type of USE ERROR.

Note 3 to entry: ABNORMAL USE does not relieve the MANUFACTURER from considering non-USER INTERFACE-related means of RISK CONTROL.

Note 4 to entry: Figure 1 shows the relationships of the types of use.



NOTE Figure D.1 contains additional detail

Figure 1 – Relationship of the types of use

3.2

ACCOMPANYING DOCUMENTATION

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

[SIST EN 62366-1:2015](https://standards.iteh.ai/catalog/standards/sist/4db73e47-947e-4b6b-bd5f-20182012888/sist-en-62366-1-2015)

[https://standards.iteh.ai/catalog/standards/sist/4db73e47-947e-4b6b-bd5f-](https://standards.iteh.ai/catalog/standards/sist/4db73e47-947e-4b6b-bd5f-20182012888/sist-en-62366-1-2015)

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 14971:2007, 2.1, modified – The term has been changed to refer to 'documentation' rather than 'document', and in the definition 'document' has been replaced by 'material', 'OPERATOR' has been deleted and notes to entry have been added.]

3.3

CORRECT USE

NORMAL USE without USE ERROR

Note 1 to entry: Deviation from instructions for use is only considered USE ERROR if it leads to a MEDICAL DEVICE response that is different than intended by the MANUFACTURER or expected by the USER.

Note 2 to entry: Figure 1 shows the relationships of the types of use.

3.4

EFFECTIVENESS

accuracy and completeness with which USERS achieve specified goals

Note 1 to entry: This is a different concept than 'clinical effectiveness'.

[SOURCE: ISO 9241-11:1998, 3.2, modified – Added the note to entry.]

3.5*** EFFICIENCY**

resources expended in relation to EFFECTIVENESS

[SOURCE: ISO 9241-11:1988, 3.3, modified – the term "EFFECTIVENESS" has replaced the original phrase, which here constitutes the definition of 3.4 EFFECTIVENESS.]

3.6**EXPECTED SERVICE LIFE**

time period specified by the MANUFACTURER during which the MEDICAL DEVICE is expected to remain safe for use (i.e. maintain basic SAFETY and essential performance)

Note 1 to entry: Maintenance can be necessary during the EXPECTED SERVICE LIFE.

[SOURCE: IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.28, modified – In the definition, 'ME EQUIPMENT and ME SYSTEM' have been replaced with 'MEDICAL DEVICE'.]

3.7**FORMATIVE EVALUATION**

USER INTERFACE EVALUATION conducted with the intent to explore USER INTERFACE design strengths, weaknesses, and unanticipated USE ERRORS

Note 1 to entry: FORMATIVE EVALUATION is generally performed iteratively throughout the design and development PROCESS, but prior to SUMMATIVE EVALUATION, to guide USER INTERFACE design as necessary.

3.8**HAZARD-RELATED USE SCENARIO**

USE SCENARIO that could lead to a HAZARDOUS SITUATION or HARM

Note 1 to entry: A HAZARD-RELATED USE SCENARIO can often be linked to a potential USE ERROR.

Note 2 to entry: A HAZARD-RELATED USE SCENARIO is not related to a failure of the MEDICAL DEVICE, unless the MEDICAL DEVICE failure was caused by a USE ERROR.

3.9*** NORMAL USE**

operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: USE ERROR can occur in NORMAL USE.

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.

Note 4 to entry: Figure 1 shows the relationships of the types of use.

[SOURCE: IEC 60601-1:2005, 3.71, modified – Notes 2, 3 and 4 to entry have been added, and in the definition 'OPERATOR' has been replaced with 'USER' and the entire phrase after "instructions for use" has been added.]

3.10*** PATIENT**

living being (person) undergoing a medical, surgical or dental PROCEDURE

Note 1 to entry: A PATIENT can be a USER.