



SLOVENSKI STANDARD
SIST EN 62366:2008
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**Medicinske naprave - Uporaba inženirstva uporabljivosti pri medicinskih napravah
(IEC 62366:2007)**

Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)

Medizinprodukte - Anwendung der Ergonomie auf Medizinprodukte (IEC 62366:2007)

Dispositifs médicaux - Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux (CEI 62366:2007) **(standards.iteh.ai)**

Ta slovenski standard je istoveten z: EN 62366:2008
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**Medical devices -
Application of usability engineering to medical devices
(IEC 62366:2007)**

Dispositifs médicaux -
Application de l'ingénierie de l'aptitude
à l'utilisation aux dispositifs médicaux
(CEI 62366:2007)

Medizinprodukte -
Anwendung der Gebrauchstauglichkeit
auf Medizinprodukte
(IEC 62366:2007)

This European Standard was approved by CENELEC on 2007-12-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/574/FDIS, future edition 1 of IEC 62366, prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice and ISO/TC 210, Quality management and corresponding general aspects for medical devices, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 62366 on 2007-12-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2008-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2010-12-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives MDD (93/42/EEC) and IVD (98/79/EC). See Annex ZZ.

In this 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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 62366:2007 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	NOTE Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-1-8	NOTE Harmonized as EN 60601-1-8:2007 (not modified).
ISO 9000	NOTE Harmonized as EN ISO 9000:2005 (not modified).
ISO 9001	NOTE Harmonized as EN ISO 9001:2000 (not modified).
ISO 9241-11	NOTE Harmonized as EN ISO 9241-11:1998 (not modified).
ISO 13485	NOTE Harmonized as EN ISO 13485:2003 (not modified).

Annex ZA
(normative)

**Normative references to international publications
with their corresponding European publications**

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<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	2007

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Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directives 93/42/EEC and 98/79/EC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices – Application of usability engineering to medical devices

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

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**MEDICAL DEVICES –
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 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 technical committee ISO/TC 210: Quality management and corresponding general aspects for medical devices.

It is published as double logo standard.

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

FDIS	Report of voting
62A/574/FDIS	62A/579/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 20 P-members out of 20 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.

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

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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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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 PROCESS are non-intuitive, difficult to learn and to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. In simpler times, the USER of a MEDICAL DEVICE might be able to cope with an ambiguous, difficult-to-use USER INTERFACE. The design of a usable MEDICAL DEVICE is a challenging endeavour, yet many organizations treat it as if it were just “common sense”. The design of the USER INTERFACE to achieve adequate (safe) USABILITY requires a very different skill set than that of the technical implementation of that interface.

The USABILITY ENGINEERING PROCESS is intended to achieve reasonable USABILITY, which in turn is intended to minimise USE ERRORS and to minimise use-associated RISKS. Some, but not all, forms of incorrect use are amenable to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.1.

This International Standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide SAFETY in MEDICAL DEVICES. 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.

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MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

This International Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to SAFETY of a MEDICAL DEVICE. This USABILITY ENGINEERING PROCESS assesses and mitigates RISKS caused by USABILITY problems 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 For the purposes of this standard, USABILITY (see 3.17) is limited to characteristics of the USER INTERFACE.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of a MEDICAL DEVICE are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2).

This International Standard does not apply to clinical decision-making relating to the use of a MEDICAL DEVICE.

2 Normative references

[SIST EN 62366:2008](https://standards.iteh.ai/catalog/standards/sist/en-62366-2008)

The following referenced documents are indispensable for the application 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 Informative references are listed in the bibliography beginning on page 96.

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 98.

3.1

ABNORMAL USE

intentional act or intentional omission of an act by the RESPONSIBLE ORGANIZATION or USER of a MEDICAL DEVICE as a result of conduct that is beyond any further reasonable means of RISK CONTROL by the MANUFACTURER

NOTE 1 See also 4.1.3 and Annex B. Examples are given in Annex C.

NOTE 2 It is possible for the PATIENT to be the USER, e.g. when the MEDICAL DEVICE is used in the PATIENT'S home.

3.2

ACCOMPANYING DOCUMENT

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

[ISO 14971:2007, definition 2.1, modified]

3.3

ALARM LIMIT

threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.3]

NOTE This term is only used in notes and informative annexes.

3.4

ALARM OFF

state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.4]

NOTE This term is only used in notes and informative annexes.

3.5

ALARM SIGNAL

type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

NOTE This term is only used in notes and informative annexes.

3.6

ALARM SYSTEM

parts of the MEDICAL DEVICE that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11, modified]
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NOTE This term is only used in notes and informative annexes.

3.7

CORRECT USE

NORMAL USE without USE ERROR

3.8

EFFECTIVENESS

measure of accuracy and completeness with which USERS achieve specified goals

[ISO 9241-11:1998, definition 3.2, modified]

NOTE This is a different concept than the 'clinical effectiveness'.

3.9

EFFICIENCY

EFFECTIVENESS in relation to the resources expended

3.10

INFORMATION SIGNAL

any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

[IEC 60601-1-8:2006, definition 3.23]

NOTE This term is only used in notes and informative annexes.

3.11**MEDICAL DEVICE**

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological PROCESS,
- supporting or sustaining life,
- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its function by such means.

[ISO 13485:2003, definition 3.7]

3.12*** 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

[IEC 60601-1:2005, definition 3.71, modified]

NOTE 1 USE ERROR can occur in NORMAL USE.

NOTE 2 MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

3.13*** PATIENT**

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

[IEC 60601-1:2005, definition 3.76, modified]

3.14*** PRIMARY OPERATING FUNCTION**

function that involves USER interaction that is either frequently used or related to the SAFETY of the MEDICAL DEVICE

3.15**REMINDER SIGNAL**

periodic signal that reminds the USER that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

[IEC 60601-1-8:2006, definition 3.34, modified]

NOTE This term is only used in notes and informative annexes.