

**MEDITSIINISEADMED. OSA 1:  
KASUTATAVUSPROJEKTEERIMISE RAKENDAMINE  
MEDITSIINISEADMETELE**

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

## EESTI STANDARDI EESSÕNA

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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)

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-03-31

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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.

**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](http://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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## 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 62366-2<sup>1</sup>) 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.

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