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MEDITSIINISEADMED. OSA 1: KASUTATAVUSPROJEKTEERIMISE RAKENDAMINE MEDITSIINISEADMETELE

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62366-1

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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)

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Comité Européen de Normalisation Electrotechnique
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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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-03-31

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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.

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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[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 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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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

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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 62366-2[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 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.

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