

**ELEKTRILISED MEDITSIINISEADMED. OSA 1-6:
ÜLDNÕUDED ESMASELE OHUTUSELE JA OLULISTELE
TOIMIMISNÄITAJATELE. KOLLATERAALSTANDARD:
KASUTUSSOBIVUS**

**Medical electrical equipment - Part 1-6: General
requirements for basic safety and essential performance
- Collateral standard: Usability (IEC 60601-1-6:2010 +
IEC 60601-1-6:2010/A1:2013)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN 60601-1-6:2010+A1:2015 sisaldab Euroopa standardi EN 60601-1-6:2010 ingliskeelset teksti ja selle muudatuse A1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-6:2010+A1:2015 consists of the English text of the European standard EN 60601-1-6:2010 and its amendment A1:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.04.2010, muudatus A1 22.05.2015.	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 16.04.2010, for A1 22.05.2015.
Sellesse standardisse on muudatus A1 sisse viidud ja tehtud muudatused tähistatud topeltpüst- kriipsuga lehe välisveerisel. Selles standardis on rahvusvahelise standardi ühismuudatused tähistatud püstkriipsuga teksti välimisel veerisel. Standard on kättesaadav Eesti Standardi- keskusest.	The amendment A1 has been incorporated into this standard and changes have been marked by a double vertical line on the outer row of the page. Common modifications has been incorporated into this international standard and changes have been marked by a vertical line on the outer row of the page. The standard is available from the Estonian Centre for Standardisation.

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English Version

**Medical electrical equipment - Part 1-6: General requirements for
basic safety and essential performance - Collateral standard:
Usability
(IEC 60601-1-6:2010 + IEC 60601-1-6:2010/A1:2013)**

Appareils électromédicaux - Partie 1-6: Exigences
générales pour la sécurité de base et les performances
essentiels - Norme collatérale: Aptitude à l'utilisation
(IEC 60601-1-6:2010 + IEC 60601-1-6:2010/A1:2013)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale
(IEC 60601-1-6:2010 + IEC 60601-1-6:2010/A1:2013)

This European Standard was approved by CENELEC on 2010-04-01. Amendment A1 was approved by CENELEC on 2015-04-14. 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.

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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/682/FDIS, future edition 3 of IEC 60601-1-6, 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 was approved by CENELEC as EN 60601-1-6 on 2010-04-01.

This standard supersedes EN 60601-1-6:2007.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- | | | |
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| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-01-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-04-01 |

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 93/42/EEC and 90/385/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010 was approved by CENELEC as a European Standard without any modification.

EN 60601-1-6:2010/A1 foreword

The text of document 62A/890/FDIS, future IEC 60601-1-6:2010/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 60601-1-6:2010/A1:2015.

The following dates are fixed:

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| • latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2016-01-14 |
| • latest date by which the national standards conflicting with the document have to be withdrawn | (dow) | 2018-12-31 |

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 90/385/EEC, see informative Annex ZZ, which is an integral part of this document.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-1-6:2010.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A1:2013 was approved by CENELEC as a European Standard without any modification.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 1-6: General requirements for basic safety
and essential performance –
Collateral standard: Usability**

FOREWORD

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International Standard IEC 60601-1-6 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.

This third edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

This document cancels and replaces the second edition of IEC 60601-1-6 which has been technically revised. *Deleted text*

This edition of IEC 60601-1-6 was revised to align with the USABILITY ENGINEERING PROCESS in IEC 62366.

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

FDIS	Report on voting
62A/682/FDIS	62A/689/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.

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

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications or instructions to modify requirements in IEC 62366: 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 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes subclauses 4.1, 4.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 4.1 and 4.2 are all subclauses of Clause 4).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

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

To assist the user of this collateral standard in migrating from IEC 60601-1-6:2006 to IEC 62366:2007+A1—¹⁾, Table B.1 has been developed. This table maps the clauses and subclause of IEC 60601-1-6:2006 to the comparable clauses and subclauses in IEC 62366:2007+A1—¹⁾. To further assist the user of this collateral standard, Table C.1 relates certain elements of IEC 62366 to other standards, such as parts of the ISO 9241 series, which might be useful in meeting the requirements of IEC 62366.

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

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.

NOTE The attention of National Committees 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.

IEC 60601-1-6/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.

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

FDIS	Report on voting
62A/890/FDIS	62A/898/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.

¹⁾ To be published.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL ELECTRICAL EQUIPMENT USABILITY have become an increasing cause for concern. Much of ME EQUIPMENT developed without applying a USABILITY ENGINEERING PROCESS are non-intuitive, difficult to learn and to use. As healthcare evolves, less skilled OPERATORS including PATIENTS themselves are now using MEDICAL ELECTRICAL EQUIPMENT while the MEDICAL ELECTRICAL EQUIPMENT itself is becoming more complicated. In simpler times, the OPERATOR of the MEDICAL ELECTRICAL EQUIPMENT might be able to cope with an ambiguous, difficult-to-use OPERATOR-EQUIPMENT INTERFACE. The design of usable MEDICAL ELECTRICAL EQUIPMENT is a challenging endeavour. The design of the OPERATOR-EQUIPMENT 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 be controlled by the MANUFACTURER. The relationship of the USABILITY ENGINEERING PROCESS to the RISK MANAGEMENT PROCESS is described in Figure A.1 of IEC 62366:2007.

The first and second editions of this collateral standard described a USABILITY ENGINEERING PROCESS that was tailored to the needs of MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT. They provided guidance on how to implement and execute the PROCESS to improve the safety of MEDICAL ELECTRICAL EQUIPMENT.

Subclause 1.3 of IEC 60601-1:2005+A1:2012 states that, “Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.” Consequently, the second edition of this collateral standard was developed specifically to align with IEC 60601-1:2005 and published in 2006. All other relevant collateral standards within the jurisdiction of IEC Subcommittee 62A also were updated and republished between 2006 and 2007 except for IEC 60601-1-1 and IEC 60601-1-4. These collateral standards were not revised because their requirements were integrated into IEC 60601-1:2005.

After the second edition of this collateral standard was published, IEC Subcommittee 62A, in partnership with ISO Technical Committee 210, developed and published a general usability engineering standard applicable to all MEDICAL DEVICES—IEC 62366:2007. IEC 62366 is based on IEC 60601-1-6, but was refined using the experience gained with applying the first edition of IEC 60601-1-6. Although the processes described in IEC 60601-1-6:2006 and IEC 62366:2007 are very similar, they are not identical.

At its Auckland meeting in 2008, IEC Technical Committee 62 approved a project to revise IEC 60601-1-6 so that it would reduce or eliminate duplication with IEC 62366 and also create a bridge between IEC 60601-1 and IEC 62366. This third edition of IEC 60601-1-6 creates that bridge and will enable a MANUFACTURER to conform to the requirements in IEC 60601-1:2005 that make normative reference to IEC 60601-1-6 by employing a USABILITY ENGINEERING PROCESS complying with IEC 62366. At a point in the future, that bridge can be eliminated by revising or amending IEC 60601-1 to include a direct reference to IEC 62366 and, as necessary, adding any additional requirements that are specific to medical electrical equipment, such as those contained in Clauses 4 and 5 of this collateral standard, to IEC 60601-1 or as a normative annex to IEC 62366.

This collateral standard is intended to be useful not only for MANUFACTURER(S) of MEDICAL ELECTRICAL EQUIPMENT, but also for technical committees responsible for the preparation of particular MEDICAL ELECTRICAL EQUIPMENT standards. It should be noted that clinical investigations conducted according to ISO 14155-1 and usability testing for verification or validation according to this standard are two fundamentally different activities and should not be confused.

Amendment 1 removes the reference to the complete life-cycle process (including post-production monitoring and surveillance). IEC 60601 (the series) is confined to performing a TYPE TEST of ME EQUIPMENT. It does not extend to the entire life cycle including post-production monitoring and periodic maintenance of the USABILITY ENGINEERING PROCESS.

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INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1-6 was published in 2010. The third edition created a bridge that enables a MANUFACTURER to conform to the requirements in IEC 60601-1 that make normative reference to IEC 60601-1-6 by employing a USABILITY ENGINEERING PROCESS complying with IEC 62366:2007. However, IEC 62366 contains certain life-cycle process elements that are inconsistent with a TYPE TEST.

This amendment is intended to clarify the elements of the USABILITY ENGINEERING PROCESS that are required for compliance with the IEC 60601 series.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

1 Scope, object and related standards

1.1 * Scope

This International Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

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.

If the USABILITY ENGINEERING PROCESS detailed in this collateral standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9 of IEC 62366:2007), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of ME EQUIPMENT are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2 of IEC 62366:2007).

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);
- "this collateral standard" designates IEC 60601-1-6 alone (IEC 60601-1-6:2010+A1:2013);
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
Amendment 1:—²⁾

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-8:2006+A1:2012, IEC 62366:2007+A1:—²⁾ and the following definitions apply.

NOTE An index of defined terms used with this collateral standard is found beginning on page 29.

3.1

* OPERATOR-EQUIPMENT INTERFACE

means by which the OPERATOR and the ME EQUIPMENT communicate

[ANSI/AAMI HE 74:2001, definition 3.24 modified]

NOTE The ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and the OPERATOR-EQUIPMENT INTERFACE.

3.2

OPERATOR PROFILE

summary of the mental, physical and demographic traits of the intended OPERATOR population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT

The ME EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERROR are acceptable. See also 7.1.1 and 12.2 of the general standard.

Compliance with this subclause is considered to exist when compliance with 4.2 and other clauses and subclauses of this collateral standard is demonstrated.

4.2 * USABILITY ENGINEERING PROCESS for ME EQUIPMENT

A USABILITY ENGINEERING PROCESS complying with IEC 62366:2007+A1: —³⁾ shall be performed except:

² To be published.