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 + IEC 60601-1-6:2010/A2:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-6:2010 +A1+A2:2021 sisaldab Euroopa standardi EN 60601-1-6:2010 ja selle muudatuste A1:2015 ja A2:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-6:2010 +A1+A2:2021 consists of the English text of the European standard EN 60601-1-6:2010 and its amendments A1:2015 and A2:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 16.04.2010, muudatused A1 22.05.2015 ja A2 16.07.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 16.04.2010, for A1 22.05.2015 and A2 16.07.2021.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tähistatud püstkriipsuga teksti vasakul veerisel. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2] ⟨A2⟩. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated by a vertical line in the left margin of the text. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags [A2] ⟨A2⟩. The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-6 + A1 + A2

April 2010, May 2015, July 2021

ICS 11.040

Supersedes EN 60601-1-6:2007

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 + IEC 60601-1-6:2010/A2:2020)

Appareils électromédicaux - Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Aptitude à l'utilisation (IEC 60601-1-6:2010 + IEC 60601-1-6:2010/A1:2013 + IEC 60601-1-6:2010/A2:2020)

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 + IEC 60601-1-6:2010/A2:2020)

This European Standard was approved by CENELEC on 2010-04-01. Amendment A1 was approved by CENELEC on 2015-04-14. Amendment A2 was approved by CENELEC on 2020-08-26. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendments 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 This European Standard and its Amendments A1 and A2 exist 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.

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

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-1-6:2010 E + IEC 60601-1-6:2010/A1:2015 E
+ EN 60601-1-6:2010/A2:2021 E

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:

– 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.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[1] ISO 9241-2:1992	NOTE	Harmonized as EN 29241:1993 (not modified).
[2] ISO 9241-11:1998	NOTE	Harmonized as EN ISO 9241-11:1998 (not modified).
[3] ISO 9241-20:2008	NOTE	Harmonized as EN ISO 9241-20:2009 (not modified).
[4] ISO 9241-110:2006	NOTE	Harmonized as EN ISO 9241-110:2006 (not modified).
[5] ISO 9241-171:2008	NOTE	Harmonized as EN ISO 9241-171:2008 (not modified).
[7] ISO 9241-300:2008	NOTE	Harmonized as EN ISO 9241-300:2008 (not modified).
[8] ISO 9241-302:2008	NOTE	Harmonized as EN ISO 9241-302:2008 (not modified).
[9] ISO 9241-303:2008	NOTE	Harmonized as EN ISO 9241-303:2008 (not modified).
[10] ISO 9241-304:2008	NOTE	Harmonized as EN ISO 9241-304:2008 (not modified).
[11] ISO 9241-305:2008	NOTE	Harmonized as EN ISO 9241-305:2008 (not modified).
[12] ISO 9241-307:2008	NOTE	Harmonized as EN ISO 9241-307:2008 (not modified).
[13] ISO 9241-400:2007	NOTE	Harmonized as EN ISO 9241-400:2007 (not modified).

[14] ISO 9241-410:2008 NOTE Harmonized as EN ISO 9241-410:2008 (not modified).

[16] ISO 13407:1999 NOTE Harmonized as EN ISO 13407:1999 (not modified).

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:

• 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

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.

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.

A2 Amendment A2 European foreword

The text of document 62A/1391/FDIS, future IEC 60601-1-6/A2, 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/A2:2021.

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) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14155	NOTE	Harmonized as EN ISO 14155

A2

IEC 60601-1-6

Edition 3.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux –
Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation

IEC 60601-1-6:2010-01+AMD1:2013-10+AMD2:2020-07 CSV(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,…). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et définitions des publications IEC parues entre 2002 et 2015. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

IEC 60601-1-6

Edition 3.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux – Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8706-4

[Blank page]

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

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

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 ▌A2⟩ IEC 62366-1 ⟨A2▐.

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* ⟨A2⟩ *IEC 62366-1* ⟨A2⟩*: 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 (*).

[A2] To assist the user to implement the USABILITY ENGINEERING PROCESS, the Technical Report IEC TR 62366-2 [1] [1] is available. IEC TR 62366-2 contains tutorial information to assist MANUFACTURERS in complying with this standard. The Technical Report also goes beyond safety-related aspects and offers more detailed descriptions of USABILITY ENGINEERING methods that can be applied to the development of ME EQUIPMENT. [A2]

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.

[A2] 1 Figures in square brackets refer to the Bibliography. [A2]

AMENDMENT 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.

AMENDMENT A2 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/1391/FDIS	62A/1406/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.

NOTE The attention of users of this document 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 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 ⟦A2⟩ OPERATOR INTERFACE ⟨A2⟧. The design of usable MEDICAL ELECTRICAL EQUIPMENT is a challenging endeavour. ⟦A2⟩ The design of the operator interface to achieve safe use (adequate usability) requires a very different skill set than that of the technical implementation of that interface. ⟨A2⟧

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 ⟦A2⟩ Figure A.4 of IEC 62366-1:2015 ⟨A2⟧.

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. ⟦A2⟩ It should be noted that clinical investigations conducted according to ISO 14155 [2] and usability tests for formative evaluation or summative evaluation according to this standard are two fundamentally different activities and should not be confused. ⟨A2⟧

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.

INTRODUCTION TO AMENDMENT 1

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.

[A2) INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1-6 was published in 2010 and amended in 2013. Since the publication of IEC 60601-1-6:2010+A1:2013, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fourth edition of IEC 60601-1-6, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, nine items were presented to the National Committees present. All nine items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1-6.

The "short list" of issues was documented in the design specification for Amendment 2. Because these issues are closely related to the application of IEC 62366-1 to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, the work was assigned to IEC/SC 62A-ISO/TC 210 Joint Working Group (JWG) 4. JWG 4 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the document was justified by the problem statement.

This amendment updates the references from the now obsolete IEC 62366:2007 to the current USABILITY ENGINEERING PROCESS standard, IEC 62366-1:2015+A1:2020.

Because this is an amendment to IEC 60601-1-6:2010, the style in force at the time of publication of IEC 60601-1-6 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, references to amendments take the following form: "IEC 60601-1:2005+A1:2012+A2:2020".

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference. (A2]

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, ▌A2⟩ develop and evaluate the USABILITY ⟨A2▐, 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.

▌A2⟩ If the USABILITY ENGINEERING PROCESS detailed in this collateral standard has been complied with, then the USABILITY of ME EQUIPMENT as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

NOTE Such OBJECTIVE EVIDENCE can subsequently originate from POST-PRODUCTION surveillance. ⟨A2▐

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 ▌A2⟩ , including any amendments ⟨A2▐;
- "this collateral standard" designates IEC 60601-1-6 alone ▌A2⟩ , including any amendments ⟨A2▐;
- "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
Amendment 2:2020

deleted text

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

ISO 14971:2019, *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+A2:2020, IEC 62366-1:2015+A1:2020, ISO 14971:2019 and the following definitions apply.

NOTE An index of defined terms used with this collateral standard is found beginning on page 23.

3.1
*** OPERATOR INTERFACE**
means by which the OPERATOR and the ME EQUIPMENT interact

Note 1 to entry: The ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and its OPERATOR INTERFACE.

Note 2 to entry: OPERATOR INTERFACE includes all the elements of the ME EQUIPMENT with which the OPERATOR interacts including the physical aspects of the ME EQUIPMENT as well as visual, auditory, tactile displays and is not limited to a software interface.

Note 3 to entry: For the purposes of this standard, the MANUFACTURER may treat the combination of ME EQUIPMENT and other equipment as a single OPERATOR INTERFACE.

Note 4 to entry: See IEC 62366-1:2015, 3.26.

3.2
OPERATOR PROFILE
summary of the mental, physical and demographic traits of the OPERATOR GROUP, as well as characteristics, such as knowledge, skills and abilities, which can have a bearing on design decisions

[SOURCE: IEC 62366-1:2015+A1:2020, definition 3.29, modified — Replaced "a USER GROUP" with "the OPERATOR GROUP".]

3.3
OPERATOR GROUP
subset of OPERATORS who are differentiated from other OPERATORS by factors that are likely to influence their interactions with the ME EQUIPMENT