EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-6:2010+A2

July 2021

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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)

Appareils électromédicaux -
Partie 1-6: Exigences générales
pour la sécurité de base
et les performances essentielles -
Norme collatérale: Aptitude à l'utilisation
(CEI 60601-1-6:2010)

Medizinische elektrische Geräte -
Teil 1-6: Allgemeine Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale -
Ergänzungsnorm: Gebrauchstauglichkeit
(IEC 60601-1-6:2010)

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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.

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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/A2:2021 E

European 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.

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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– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01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).

Foreword to amendment A1

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

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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.

Foreword to amendment A2

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

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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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	2020
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

Annex ZZ
(informative)

Coverage of Essential Requirements of EU 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 given in Annex 1 of EU Directive 90/385/EEC of 20 June 1990 relating to active implantable medical devices.

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

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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

CONTENTS

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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

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 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. A1 *Text deleted* A1

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 (*).

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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.

A1 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. A1

1) Figures in square brackets refer to the Bibliography.

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

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 A1 IEC 60601-1:2005+A1:2012 A1 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 A1 IEC 62366 A1. 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

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〈A1〉 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. 〈A1〉

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.

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.

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

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:

[A1]
- "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]; [A1]
- "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

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 15.

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

Note 1 to entry: Attributes of OPERATOR GROUPS can include age, culture, expertise.

[SOURCE: IEC 62366-1:2015+A1:2020, 3.25, modified – Replaced "USER" with "OPERATOR" and "MEDICAL DEVICE" with "ME EQUIPMENT".]

IEC 60601-1-6:2010+A2:2020
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4 General requirements

4.1 * Conditions for application to ME EQUIPMENT

The ME EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from [A2] NORMAL USE, i.e. CORRECT USE and USE ERROR [A2], 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

[A2] A USABILITY ENGINEERING PROCESS complying with IEC 62366-1:2015+A1:2020 shall be performed except:

– the planning for and execution of production and POST-PRODUCTION monitoring in the context of applying the USABILITY ENGINEERING PROCESS within the framework of ISO 14971, and

– maintenance of the USABILITY ENGINEERING PROCESS.

In applying IEC 62366-1:2015+A1:2020, the terms in this collateral standard and those in IEC 60601-1:2005+A1:2012+A2:2020 shall be used as follows.

– The term "ACCOMPANYING DOCUMENTATION" shall assume the same meaning as ACCOMPANYING DOCUMENTS.

– The term "MEDICAL DEVICE" shall assume the same meaning as ME EQUIPMENT.

– The term "USER" shall assume the same meaning as OPERATOR.

– The term "PATIENT" shall include animals.

– The term "SAFETY" shall assume the same meaning as BASIC SAFETY and ESSENTIAL PERFORMANCE.

– The term "USER GROUP" shall assume the same meaning as OPERATOR GROUP.

– The term "USER INTERFACE" shall assume the same meaning as OPERATOR INTERFACE.

– The term "USER PROFILE" shall assume the same meaning as OPERATOR PROFILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE. Evidence of compliance with this clause and all requirements of this standard referring to inspection of the USABILITY ENGINEERING FILE are satisfied if the MANUFACTURER has demonstrated compliance with IEC 62366-1:2015+A1:2020. [A2]

[A2] 5 ME EQUIPMENT ACCOMPANYING DOCUMENTS [A2]

[A2] *Text deleted* [A2]

The instructions for use shall include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its [A2] use [A2]. The same information shall also be included in the technical description, if this is provided as a separate document.

NOTE An important purpose of this description is to help the OPERATOR to develop a correct mental model of the ME EQUIPMENT.

[A2] The instructions for use shall contain a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015+A1:2020, 5.1.

Compliance is checked by inspection. [A2]

Annex A
(informative)

General guidance and rationale

A.1 General guidance

This annex provides a concise rationale for the important requirements of this collateral standard. Its purpose is to promote effective application of the collateral standard by explaining the reasons for the requirements and provide additional guidance where appropriate.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 1.1 – Scope

This collateral standard focuses on the USABILITY of the A2 OPERATOR INTERFACE A2 of ME EQUIPMENT. USABILITY, in general, includes attributes such as OPERATOR satisfaction and EFFICIENCY. These attributes might be related to the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT. A degradation of these attributes can increase the probability of USE ERROR. Examples of attributes that are not considered could include the aesthetics of the ME EQUIPMENT or the amount of supplies consumed.

Definition 3.1 – A2 OPERATOR INTERFACE A2

The A2 OPERATOR INTERFACE A2 includes all means of communication between the ME EQUIPMENT to the OPERATOR and the OPERATOR to the ME EQUIPMENT. These means include, but are not limited to:

A2
- elements that require manual manipulation;
- cables and tubing connections;
- accessories;
- handles;
- force required to move the weight;
- work surface height;
- dimensions that affect reach requirements;
- markings and ACCOMPANYING DOCUMENTS;
- video displays;
- push buttons;
- touch screens;
- auditory, vibratory, tactile, and visual signals to inform OPERATORS;
- voice recognition;
- keyboard and mouse; and
- haptic controls. A2

Subclause 4.1 – Conditions for application to ME EQUIPMENT

This collateral standard specifies requirements addressing particular ⟦A2⟧ use-related RISKS ⟨A2⟩. When these requirements are complied with, the RESIDUAL ⟦A2⟧ use-related RISKS ⟨A2⟩ are presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary. This follows from 4.2 of the general standard, which states "Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary."

⟦A2⟧ The criteria for judging RISK acceptability are described in the SUMMATIVE EVALUATION plan, which specifies the criteria for determining that the OPERATOR INTERFACE can be used safely. ⟨A2⟩

Subclause 4.2 – USABILITY ENGINEERING PROCESS for ME EQUIPMENT

The first edition of this collateral standard was published in 2004, and introduced a USABILITY ENGINEERING PROCESS tailored to ME EQUIPMENT. The second edition was published in 2006 and was intended to align the collateral standard with the third edition of IEC 60601-1 — principally the inclusion in IEC 60601-1:2005 of the requirement to conduct a RISK MANAGEMENT PROCESS following ISO 14971. The USABILITY ENGINEERING PROCESS described in the second edition of IEC 60601-1-6 was little altered from that in the first edition.

Shortly after the publication of the 2004 edition of IEC 60601-1-6, IEC Subcommittee 62A formed a joint project with ISO Technical Committee 210 to develop a general USABILITY ENGINEERING PROCESS standard applicable to all MEDICAL DEVICES as defined in the ISO quality system standard, ISO 13485:2003. This project was similar in scope to the effort that took the RISK MANAGEMENT PROCESS described in IEC 60601-1-4 and generalized it to produce ISO 14971. The result of the joint IEC/SC 62A – ISO/TC 210 USABILITY standard project was IEC 62366:2007.

⟦A1⟧ While the USABILITY ENGINEERING PROCESS described in IEC 62366 is more mature and refined than the PROCESS in the second edition of IEC 60601-1-6, it is fundamentally the same PROCESS.

The scope of IEC 60601-1 and of this collateral standard is confined to performing a TYPE TEST of ME EQUIPMENT; it does not extend to life-cycle monitoring. For this reason, the monitoring of production and post-production information and the planning thereof, as required by the ISO 14971 framework, is excluded from the USABILITY ENGINEERING PROCESS described in this standard. The requirement in ⟦A2⟧ IEC 62366-1 ⟨A2⟩ for periodic maintenance of the USABILITY ENGINEERING PROCESS is also excluded. ⟨A1⟩

As with the RISK MANAGEMENT PROCESS before it, the existence of a generalized standard for USABILITY ENGINEERING eliminates the need for much, but not all, of the content in the second edition of IEC 60601-1-6. For example, IEC 62366 defines the USER as the "person using, i.e. operating or handling, the MEDICAL DEVICE". This definition includes those who clean, maintain or install the MEDICAL DEVICE. In ⟦A2⟧ IEC 60601-1:2005+A1:2012+A2:2020 ⟨A2⟩, persons performing those functions are described as SERVICE PERSONNEL. This subclause bridges between the general PROCESS requirement in ⟦A2⟧ IEC 62366-1 ⟨A2⟩ and the specific application to ME EQUIPMENT.

⟦A2⟧ *Text deleted* ⟨A2⟩

Bibliography

[A2] [1] IEC TR 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

[2] ISO 14155, *Clinical investigation of medical devices for human subjects – Good clinical practice* [/A2]

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

Index of defined terms used with this collateral standard