

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

Appareils électromédicaux – [IEC 60601-1-6:2010](#)
Partie 1-6: Exigences générales pour la sécurité de base et les performances
essentiels – Norme collatérale: Aptitude à l'utilisation



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IEC 60601-1-6

Edition 3.2 2020-07
CONSOLIDATED VERSION

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8706-4

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VERSION REDLINE



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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
INTRODUCTION to Amendment 1	7
INTRODUCTION to Amendment 2	7
1 Scope, object and related standards.....	9
1.1 * Scope	9
1.2 Object	9
1.3 Related standards	9
1.3.1 IEC 60601-1	9
1.3.2 Particular standards	10
2 Normative references	10
3 Terms and definitions	10
4 General requirements.....	11
4.1 * Conditions for application to ME EQUIPMENT	11
4.2 * USABILITY ENGINEERING PROCESS for ME EQUIPMENT.....	11
5 * Replacement of requirements given in IEC 62366 ME EQUIPMENT ACCOMPANYING DOCUMENTS.....	12
Annex A (informative) General guidance and rationale.....	14
Annex B (informative) Mapping between the elements of IEC 60601-1-6:2006 and the related elements in IEC 62366:2007	14
Annex C (informative) References to items of USABILITY provided in IEC 62366:2007 and their use in other standards.....	14
Bibliography.....	28
Index of defined terms used with this collateral standard	30

~~Table B.1 — Mapping between the elements of IEC 60601-1-6:2006 and the related
elements in IEC 62366:2007+A1—4).....~~

~~Table C.1 — References to items of USABILITY in IEC 62366 and their use in other
standards.....~~

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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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-6 edition 3.2 contains the third edition (2010-01) [documents 62A/682/FDIS and 62A/689/RVD], its amendment 1 (2013-10) [documents 62A/890/FDIS and 62A/898/RVD] and its amendment 2 (2020-07) [documents 62A/1391/FDIS and 62A/1406/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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. ~~To allow for equipment manufacturers and testing organizations to make products and to equip themselves for conducting revised tests in accordance with this third edition, it is recommended by SC 62A that the content of this document not be adopted for mandatory implementation earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.~~

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

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 62366-1: 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+A1¹⁾, 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+A1¹⁾. 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.~~

To assist the user to implement the USABILITY ENGINEERING PROCESS, the Technical Report IEC TR 62366-2 [1]²⁾ 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.

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 the base publication and its amendments 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 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.

IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

¹⁾ To be published

²⁾ Figures in square brackets refer to the Bibliography.

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)~~ safe use (adequate 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.4 of IEC 62366:2007~~ Figure A.4 of IEC 62366-1:2015.

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 62366:2007. 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 14155-4 [2] and ~~usability testing for verification or validation~~ USABILITY TESTS for FORMATIVE EVALUATION or SUMMATIVE EVALUATION 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.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[IEC 60601-1-6:2010](https://standards.iteh.ai/catalog/standards/sist/691e96f7-0193-48b9-b530-3c00bfd0ea61/iec-60601-1-6-2010)

<https://standards.iteh.ai/catalog/standards/sist/691e96f7-0193-48b9-b530-3c00bfd0ea61/iec-60601-1-6-2010>

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~~ develop and evaluate the 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).~~

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.

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)~~, including any amendments;
- "this collateral standard" designates IEC 60601-1-6 alone ~~(IEC 60601-1-6:2010+A1:2013)~~, including any amendments;
- "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 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:–³⁾~~

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

[IEC 60601-1-6:2010](https://standards.iteh.ai/catalog/standards/sist/691e96f7-0193-48b9-b530-3c00bfd0ea61/iec-60601-1-6:2010)
<https://standards.iteh.ai/catalog/standards/sist/691e96f7-0193-48b9-b530-3c00bfd0ea61/iec-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, IEC 60601-1-8:2006+A1:2012, IEC 62366:2007+A1:–³⁾ and the following definitions apply.~~

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 30.

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⁾-To be published

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 intended OPERATOR population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements~~

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".]

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~~ NORMAL USE, i.e. CORRECT 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 62366A1:—⁴⁾ 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.~~

⁴⁾ To be published