IEC 60601-1-6

Edition 3.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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/AMD2:2020-07(en-fr)

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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- withdrawn,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 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.

FOREWORD

Replace, in the existing fourth paragraph beginning with " This edition of IEC 60601-1-6 was revised…", *the reference to* "IEC 62366" *with* "IEC 62366-1*".*

Replace, in the second dash of the existing ninth paragraph beginning with "In this collateral standard, the following print types…"*, the reference to* "IEC 62366" *with* "IEC 62366-1"*.*

Replace the existing second paragraph before the last (including the footnote), beginning with "To assist the user of this collateral standard*…" and modified by Amendment 1, with the following new paragraph and footnote:*

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.

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

INTRODUCTION

Replace, in the second sentence before the last of the existing first paragraph, the term "OPERATOR-EQUIPMENT INTERFACE" *with* "OPERATOR INTERFACE"*.*

Replace the last sentence of the existing first paragraph with the following new sentence:

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.

Replace, in the second paragraph, the reference "Figure A.1 of IEC 62366:2007" *with* "Figure A.4 of IEC 62366-1:2015"*.*

Replace, in the existing paragraph before the last, the last sentence with:

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.

1.1 * Scope

Replace, in the existing first paragraph, the words "design, VERIFY and VALIDATE USABILITY" *with* "develop and evaluate the USABILITY"*.*

Replace the existing third paragraph with the following new paragraph and note:

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.

1.3.1 IEC 60601-1

Replace, in the first two bullet points of the existing second paragraph, the parentheses, added by Amendment 1, with the words ", including any amendments".

2 Normative references

Replace the existing references to IEC 60601-1 and IEC 62366, both modified by Amendment 1, with the following new references:

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

Delete the reference to IEC 60601-1-8.

Replace the existing reference to ISO 14971 by the following new reference:

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

Replace the existing first paragraph with:

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.

3.1
*** OPERATOR-EQUIPMENT INTERFACE**

Replace the existing term and definition with the following new term and definition:

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

Replace the existing term and definition with the following new term and definition:

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".]

Add the following new definition:

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".]

4.1 * Conditions for application to ME EQUIPMENT

Replace, in the existing first paragraph, "NORMAL USE and USE ERROR" *with* "NORMAL USE, i.e. CORRECT USE and USE ERROR,".

4.2 * USABILITY ENGINEERING PROCESS for ME EQUIPMENT

Replace the existing text of 4.2, modified by Amendment 1, including footnote 3), with:

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.

5 * Replacement of requirements given in IEC 62366

Delete the existing asterisk before the title of Clause 5.

Replace the existing title of Clause 5 with "ME EQUIPMENT ACCOMPANYING DOCUMENTS".

Delete the existing first paragraph, as well as the second paragraph (including footnote 3) modified by Amendment 1.

Replace, in the existing third paragraph, the word "USABILITY" *with* "use".

Replace the existing last paragraph with the following new paragraphs:

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.

A.2 Rationale for particular clauses and subclauses

Subclause 1.1 – Scope

Replace, in the first sentence of the existing paragraph, the word "OPERATOR-EQUIPMENT INTERFACE " *with* "OPERATOR INTERFACE".

Definition 3.1 – OPERATOR-EQUIPMENT INTERFACE

Replace, in the title and in the first sentence of the existing paragraph, the word "OPERATOR-EQUIPMENT INTERFACE " *with* "OPERATOR INTERFACE" *in two places.*

Replace the existing dash list with the following new list:

– 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.

Subclause 4.1 – Conditions for application to ME EQUIPMENT

Replace, in the existing first paragraph, the words "RISKS associated with USABILITY" *by* "use-related RISKS" *in two places*.

Replace the existing last paragraph with the following new paragraph:

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.

Subclause 4.2 – USABILITY ENGINEERING PROCESS for ME EQUIPMENT

Replace, in the existing fourth paragraph, added by Amendment 1, the reference "IEC 62366" *with* "IEC 62366-1".

Replace, in the existing last paragraph, modified by Amendment 1, the reference "IEC 60601-1:2005+A1:2012" *with* "IEC 60601-1:2005+A1:2012+A2:2020", *as well as the reference* "IEC 62366" *with* "IEC 62366-1".

Clause 5 – Replacement of requirements given in IEC 62366

Delete the existing rationale for Clause 5, including its title.

Annex B – Mapping between the elements of IEC 60601-1-6:2006 and the related elements in IEC 62366:2007

Delete the existing annex, modified by Amendment 1, including its title.

Annex C – References to items of USABILITY provided in IEC 62366:2007 and their use in other standards

Delete the existing annex, including its title.

Bibliography

Replace the existing references [1] to [27], including footnote [13], *with the following new references:*

[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*

Index of defined terms used with this collateral standard

Delete the following terms and their references from the index, modified by Amendment 1:

ALARM LIMIT

ALARM OFF

EFFECTIVENESS

HAND-HELD

HAZARD

HAZARDOUS SITUATION

INTENDED USE

PRIMARY OPERATING FUNCTION

RESPONSIBLE ORGANIZATION

RISK ANALYSIS

RISK ASSESSMENT

RISK CONTROL

RISK MANAGEMENT FILE

USABILITY SPECIFICATION

USE SCENARIO

VALIDATION

VERIFICATION

Replace the term "OPERATOR-EQUIPMENT INTERFACE" *with* " OPERATOR INTERFACE".

Replace the following terms of the index, modified by Amendment 1:

Add the following new terms:

_____