IEC 60601-1-6

Edition 3.0 2013-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

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

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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/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- withdrawn,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.

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INTRODUCTION TO THE AMENDMENT

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

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

FOREWORD

In the existing paragraph beginning "This document cancels and replaces…", delete the second sentence.

In the existing third paragraph from the end of the Foreword, beginning "To assist the user…", replace "IEC 62366:2007" *with* "IEC 62366:2007+A1—[1])" *in two places.*

Add the following note at the end of the Foreword:

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

[1]) To be published.

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

In the first sentence of the fourth paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012".

In the second sentence of the existing sixth paragraph, replace "IEC 62366:2007" *with* "IEC 62366".

Add, after the last paragraph of the introduction, the following new paragraph:

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.

1.3.1 IEC 60601-1

Replace the existing first bullet with:

– "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);

Replace the existing second bullet with:

– "this collateral standard" designates IEC 60601-1-6 alone (IEC 60601-1-6:2010+A1:2013).

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2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-8 and IEC 62366 by the following new references:

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

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

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

3 Terms and definitions

In the existing introductory paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012", "IEC 60601-1-8:2006" *with* "IEC 60601-1-8:2006+A1:2012" *and* "IEC 62366:2007" *with* "IEC 62366:2007+A1:—[2)]".

2) To be published.

4.2 * USABILITY ENGINEERING PROCESS for ME EQUIPMENT

Replace the existing first paragraph with following:

A USABILITY ENGINEERING PROCESS complying with IEC 62366:2007+A1: —[3] 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 the existing second paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012".

5 * Replacement of requirements given in IEC 62366

*In the existing second paragraph, replace "*IEC 62366:2007*" with "*IEC 62366:2007+A1—[3]).

Annex A –General guidance and rationale

A.2 Rationale for particular clauses and subclauses

Subclause 4.2 – USABILITY ENGINEERING PROCESS for ME EQUIPMENT

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Replace the existing third paragraph of the rationale with the following:

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.

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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 IEC 62366 for periodic maintenance of the USABILITY ENGINEERING PROCESS is also excluded.

In the existing fourth paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012".

Clause 5 – Replacement of requirements given in IEC 62366

In the existing first paragraph, replace "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012".

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

In the existing first paragraph, replace "IEC 62366:2007" *with* "IEC 62366:2007+A1—[3] *in two places.*

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

[3] To be published.

In the existing title of the table, replace "IEC 62366:2007" *with* "IEC 62366:2007+A1:[3]".

Throughout the existing table, replace all occurrences of "IEC 60601-1:2005" *with* "IEC 60601-1:2005+A1:2012", *all occurrences of* "IEC 60601-1-8:2006" *with* "IEC 60601-1-8:2006+A1:2012"*and all occurrences of* "IEC 62366:2007" *with* "IEC 62366:2007+A1—[4]".

Insert, immediately preceding the row on " 4 General requirements", the following new row:

		3.27	USER INTERFACE OF UNKNOWN PROVENANCE UOUP NOTE Amendment 1 to IEC 62366 added a new term that was not in IEC 60601-1.6:2006.

Insert, immediately following the row on "6.2.6 USABILITY VALIDATION", the following new row:

		5.10	USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) NOTE Amendment 1 to IEC 62366 added a set of requirements when dealing WITH USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available. These requirements are found in Annex K and replace those in subclauses 5.1 to 5.9 for UOUP.

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Insert, immediately following the row on "ANNEX J", the following new row:

		Annex K	Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) NOTE Amendment 1 to IEC 62366 added this annex. The annex provides a set of normative requirements when dealing WITH USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available.

Index of defined terms used with this collateral standard

Amend the references to the following defined terms as follows:

4 To be published.

NORMAL USE ..... IEC 60601-1:2005 + A1:2012, 3.71
OBJECTIVE EVIDENCE ..... IEC 60601-1:2005+A1:2012, 3.72
PATIENT ..... IEC 60601-1:2005 + A1:2012, 3.76
PROCESS ..... IEC 60601-1:2005 + A1: 2012, 3.89
RESIDUAL RISK ..... IEC 60601-1:2005+A1:2012, 3.100
RISK ..... IEC 60601-1:2005+ A1: 2012, 3.102
RISK ANALYSIS ..... IEC 60601-1:2005+ A1: 2012, 3.103
RISK CONTROL ..... IEC 60601-1:2005+ A1: 2012, 3.105
RISK MANAGEMENT ..... IEC 60601-1:2005+ A1: 2012, 3.107
RISK MANAGEMENT FILE ..... IEC 60601-1:2005+ A1: 2012, 3.108
VERIFICATION ..... IEC 60601-1:2005+A1:2012, 3.138

Add the following defined terms:

HAZARDOUS SITUATION ..... IEC 60601-1: 2005 + A1:2012, 3.40
RISK ASSESSMENT ..... IEC 60601-1:2005+ A1: 2012, 3.104
TYPE TEST ..... IEC 60601-1:2005, 3.135

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