IEC 60601-1-6

Edition 3.0 2010-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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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

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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. 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.

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 IEC 62366: 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, 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. 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.

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.

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) 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.1 of IEC 62366:2007.

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 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 14155-1 and usability testing for verification or validation according to this standard are two fundamentally different activities and should not be confused.

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, 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).

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;
- "this collateral standard" designates IEC 60601-1-6 alone;
- "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*

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*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

ISO 14971:2007, *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, IEC 60601-1-8:2006, IEC 62366:2007 and the following definitions apply.

NOTE An index of defined terms used with this collateral standard is found beginning on page 24.

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.

3.2
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

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 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 62366 shall be performed.

In applying IEC 62366, the terms in this collateral standard and those in IEC 60601-1:2005 shall be used as follows:

- 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 INTERFACE” shall assume the same meaning as OPERATOR-EQUIPMENT 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:

– *established a USABILITY ENGINEERING PROCESS;*

– *established acceptance criteria for USABILITY; and*

– *demonstrated that the acceptance criteria for USABILITY have been met.*

5 * Replacement of requirements given in IEC 62366

In addition to requirements of IEC 62366 the following replacements shall apply:

Replace the first two paragraphs including NOTES 1 and 2 of Clause 6 of IEC 62366:2007 by:

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 USABILITY. 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.

The instructions for use shall contain a summary of the application specification.

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 OPERATOR-EQUIPMENT INTERFACE 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 – OPERATOR-EQUIPMENT INTERFACE

The OPERATOR-EQUIPMENT INTERFACE 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:

– markings and ACCOMPANYING DOCUMENTS;
– lights;
– video displays;
– push buttons;
– touch screens;
– auditory and visual INFORMATION SIGNALS;
– ALARM SIGNALS;
– vibratory signals;
– keyboard and mouse; and
– haptic controls.

Subclause 4.1 – Conditions for application to ME EQUIPMENT

This collateral standard specifies requirements addressing particular RISKS associated with USABILITY. When these requirements are complied with, the RESIDUAL RISKS associated with USABILITY 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."

The criteria for judging RISK acceptability are established by the USABILITY VALIDATION plan, which specifies the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS.

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.

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 involving the same elements.

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 IEC 60601-1:2005, persons performing those functions are described as SERVICE PERSONNEL. This subclause bridges between the general PROCESS requirement in IEC 62366 and the specific application to ME EQUIPMENT.

Clause 5 – Replacement of requirements given in IEC 62366

Clause 6 of IEC 62366:2007 specifies the general requirements for the material to be included in the ACCOMPANYING DOCUMENT, if such a document is provided. The ACCOMPANYING DOCUMENT is required to include a summary of the application specification (see 5.1 of IEC 62366). This replacement paragraph clarifies that for ME EQUIPMENT the summary is described in the same terms used in subclause 7.9.2.5 of IEC 60601-1:2005 to specify the ME EQUIPMENT description.

In IEC 60601-1, the ACCOMPANYING DOCUMENTS consist of the instructions for use and the technical description. IEC 62366, on the other hand, discusses the ACCOMPANYING DOCUMENT without specifically identifying any sub-parts. IEC 60601-1 anticipates that the instructions for use and the technical description can be provided as separate physical documents. If they are, then the summary of the application specification is required to appear in both documents.

Annex B
(informative)

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

This annex contains a mapping of the clauses and subclause of IEC 60601-1-6:2006 to the comparable clauses and subclauses in IEC 62366:2007. Table B.1 is intended to provide a tool to assist users of IEC 60601-1-6:2006 to trace requirements between that edition and their equivalent requirements in IEC 62366:2007.

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

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	**Title**	**Clause**	**Title**
1	Scope, object and related standards	1	Scope NOTE IEC 62366:2007 applies to MEDICAL DEVICES as defined in 3.11. That definition is identical to that in ISO 13485:2003.
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
3.1	ABNORMAL USE	3.1	ABNORMAL USE
IEC 60601-1: 2005, 3.4	ACCOMPANYING DOCUMENT	3.2	ACCOMPANYING DOCUMENT
IEC 60601-1-8: 2006, 3.3	ALARM LIMIT	3.3	ALARM LIMIT
IEC 60601-1-8: 2006, 3.4	ALARM OFF	3.4	ALARM OFF
IEC 60601-1-8: 2006, 3.9	ALARM SIGNAL	3.5	ALARM SIGNAL
IEC 60601-1-8: 2006, 3.11	ALARM SYSTEM	3.6	ALARM SYSTEM
IEC 60601-1: 2005, 3.10	BASIC SAFETY	ISO 14971: 2007, 2.24	SAFETY NOTE SAFETY is used as defined term in IEC 62366.
IEC 60601-1: 2005, 3.27	ESSENTIAL PERFORMANCE		
		3.7	CORRECT USE NOTE This is a new term in IEC 62366, and is defined as "NORMAL USE without USE ERROR."
3.2	EFFECTIVENESS	3.8	EFFECTIVENESS
3.3	EFFICIENCY	3.9	EFFICIENCY
IEC 60601-1: 2005, 3.37	HAND-HELD		NOTE Not a defined term in IEC 62366.
IEC 60601-1: 2005, 3.38	HARM	ISO 14971: 2007, 2.2	HARM
IEC 60601-1: 2005, 3.39	HAZARD	ISO 14971: 2007, 2.3	HAZARD
IEC 60601-1: 2005, 3.40	HAZARDOUS SITUATION	ISO 14971: 2007, 2.4	HAZARDOUS SITUATION

Table B.1 *(continued)*

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	**Title**	**Clause**	**Title**
IEC 60601-1-8: 2006, 3.23	INFORMATION SIGNAL	3.10	INFORMATION SIGNAL
IEC 60601-1: 2005, 3.44	INTENDED USE	ISO 14971: 2007, 2.5	INTENDED USE
IEC 60601-1: 2005, 3.55	MANUFACTURER	ISO 14971: 2007, 2.8	MANUFACTURER
IEC 60601-1: 2005, 3.63	MEDICAL ELECTRICAL EQUIPMENT	3.11	MEDICAL DEVICE
IEC 60601-1: 2005, 3.71	NORMAL USE	3.12	NORMAL USE NOTE The phrase, "or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use" has been added to deal with MEDICAL DEVICES, such as simple surgical instruments, that are not accompanied by instructions for use.
IEC 60601-1: 2005, 3.72	OBJECTIVE EVIDENCE	ISO 14971: 2007, 2.10	OBJECTIVE EVIDENCE
IEC 60601-1: 2005, 3.73	OPERATOR	3.23	USER NOTE In IEC 62366, the USER includes but is not limited to cleaners, maintainers and installers. In IEC 60601-1:2005, individuals who install, assemble, maintain or repair ME EQUIPMENT are described as "SERVICE PERSONNEL."
3.4	OPERATOR-EQUIPMENT INTERFACE	3.24	USER INTERFACE NOTE The word "communicate" was replaced by "interact".
3.5	OPERATOR PROFILE	3.25	USER PROFILE
IEC 60601-1: 2005, 3.76	PATIENT	3.13	PATIENT NOTE "Animal" has been deleted from the IEC 60601-1 definition.
3.6	PRIMARY OPERATING FUNCTION	3.14	PRIMARY OPERATING FUNCTION
IEC 60601-1: 2005, 3.89	PROCESS	ISO 14971: 2007, 2.13	PROCESS
3.7	REASONABLY FORESEEABLE MISUSE		NOTE Not a defined term in IEC 62366.
IEC 60601-1-8:2006, 3.34	REMINDER SIGNAL	3.15	REMINDER SIGNAL
IEC 60601-1: 2005, 3.100	RESIDUAL RISK	ISO 14971: 2007, 2.15	RESIDUAL RISK
IEC 60601-1: 2005, 3.101	RESPONSIBLE ORGANIZATION	3.16	RESPONSIBLE ORGANIZATION
IEC 60601-1: 2005, 3.102	RISK	ISO 14971: 2007, 2.16	RISK
IEC 60601-1: 2005, 3.103	RISK ANALYSIS	ISO 14971: 2007, 2.17	RISK ANALYSIS
IEC 60601-1: 2005, 3.105	RISK CONTROL	ISO 14971: 2007, 2.19	RISK CONTROL
IEC 60601-1: 2005, 3.106	RISK EVALUATION	ISO 14971: 2007, 2.21	RISK EVALUATION
IEC 60601-1: 2005, 3.107	RISK MANAGEMENT	ISO 14971: 2007, 2.22	RISK MANAGEMENT