SS IEC 60601-1-6:2018+A1:2020

IEC 60601-1-6:2010+AMD2:2020, IDT

(ICS 11.040)

SINGAPORE STANDARD

Medical electrical equipment

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

Incorporating Amendment No. 1

Singapore Standards Council

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– Collateral standard: Usability

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The content of this Singapore Standard was approved on 19 October 2018 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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BHSC consists of the following members:

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Secretary	:	Ms Iris Peng	*Singapore Manufacturing Federation – Standards Development Organisation*
Members	:	Ms Chua Chui Khim	*Becton Dickinson Medical (S) Pte Ltd*
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The Technical Committee set up the National Mirror Working Group on IEC SC62D MT20 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

		Name
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Members	:	Mr Peter Haywood
		Dr Ho Teck Tuak
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		Prof Tong Yen Wah

The organisations in which the experts of the Working Group are involved are:

Advent Access Pte Ltd
AWAK Technologies Pte Ltd
Kidney Dialysis Foundation
National University of Singapore
Temasek Polytechnic
The Institution of Engineers, Singapore

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National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on IEC SC62D MT20 set up by the Technical Committee on Medical Devices under the purview of BHSC.

This standard is identical with IEC 60601-1-6:2010, “Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability”, including the amendments to this edition, published by the International Electrotechnical Commission.

NOTE 1 – Where appropriate, the words “International Standard” are read as “Singapore Standard”.

NOTE 2 – Reference to International Standards are replaced by applicable Singapore Standards.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as “Mature Standards”. Mature Standards will not be subject to further review, unless there are requests to review such standards.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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].

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted 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.

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 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.

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.

1) 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 INTERFACE. The design of usable MEDICAL ELECTRICAL EQUIPMENT is a challenging endeavour. 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.

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 62366-1:2015.

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. 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 [2] and 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.

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, 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, 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, including any amendments;
- "this collateral standard" designates IEC 60601-1-6 alone, 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 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*