Singapore Standards Council

SS IEC 60601-1 : 2018
IEC 60601-1:2005+A1:2012, IDT
(ICS 11.040)

SINGAPORE STANDARD

Medical electrical equipment

– Part 1: General requirements for basic safety and essential performance

Published by

Enterprise Singapore

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– Part 1: General requirements for basic safety and essential performance

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This Singapore Standard was approved on 19 October 2018 by the Biomedical and Health Standards Committee under the purview of the Singapore Standards Council.

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The Biomedical and Health Standards Committee, appointed by the Standards Council, consists of the following members:

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The Technical Committee on Medical Devices, appointed by the Biomedical and Health Standards Committee, consists of representatives from the following organisations:

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The National Mirror Working Group on IEC SC62D MT20, appointed by the Technical Committee to assist in the preparation of this standard, comprises the following experts who contribute in their individual capacity:

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Secretary	:	Mr Kevin Tan
Members	:	Mr Peter Haywood
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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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CONTENTS

National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on IEC SC62D MT20 appointed by the Technical Committee on Medical Devices under the direction of the Biomedical and Health Standards Committee.

This standard is identical with IEC 60601-1:2005+A1:2012, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance", published by the International Electrotechnical Commission.

Attention is drawn to the following:

1. Where appropriate, the words "International Standard" shall be read as "Singapore Standard".

2. Where reference to a particular part of IEC 60601 is made, the appropriate Singapore Standard (which is an identical adoption of that part of IEC 60601) shall be referenced. The reference to other International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
ISO 11137-1:2006	SS ISO 11137-1 : 2018
ISO 13485	SS ISO 13485
ISO 14971	SS ISO 14971
ISO 14971:2007	SS ISO 14971 : 2017

3. The comma has been used throughout as a decimal marker whereas in Singapore Standards it is a practice to use a full point on the baseline as the decimal marker.

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.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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 IEC 60601-1 consists of the third edition (2005) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012) [documents 62A/805/FDIS and 62A/820/RVD], its corrigenda of December 2006 and 2007, the corrigendum of its amendment 1 of July 2014, and the interpretations sheets of April 2008, January 2009 and May 2013. It bears the edition number 3.1.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 60601-1 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 cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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 G 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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The committee has decided that the contents of the base publication and its amendment 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.

The content of the corrigendum of November 2012 have been included in this copy.

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.

INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);

– the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;

– the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and

– the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12][1)] in 1994. It was intended that the second edition of IEC/TR

1) Figures in square brackets refer to the Bibliography.

60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

– the first change is that the concept of "SAFETY" has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from "Medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance";

– the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those listed in 62A/593/DC and 62A/602/INF;
– the way in which risk management has been introduced into IEC 60601-1:2005; and
– the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];

– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or

– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.