

SINGAPORE STANDARD

Medical electrical equipment

– Part 1-12 : General requirements for basic safety and essential performance – Collateral standard:
Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

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- Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

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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 60601-1-12:2014, “Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment”, 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.
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.

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 1-12: General requirements for basic
safety and essential performance –
Collateral Standard: Requirements for medical electrical
equipment and medical electrical systems intended for use
in the emergency medical services environment**

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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International standard IEC 60601-1-12 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition constitutes a collateral standard to IEC 60601-1 (third edition): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

The text of this collateral standard is based on the following documents:

| FDIS | Report on voting |
|--------------|------------------|
| 62A/932/FDIS | 62A/938/RVD |

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, this International Standard has been approved by 18 P-members out of 19 having cast a vote.

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

In the 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: 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 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.3.1 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 collateral 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 (*).

A list of all parts of the IEC 60601 series, published 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 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 Member Bodies and 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 ISO or IEC 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 implementation nationally not earlier than 3 years from the date of publication.

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 document using a colour printer.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the EMERGENCY MEDICAL SERVICES ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled, rough environment is a cause for concern.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

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, which are intended, as indicated in the instructions for use by their MANUFACTURER, for use in the EMS ENVIRONMENT (EMERGENCY MEDICAL SERVICES ENVIRONMENT), as defined in 3.1.

NOTE 1 For the purposes of this standard, the intent of the MANUFACTURER is indicated in the instructions for use. The RESPONSIBLE ORGANIZATION and the OPERATOR need to be aware that any other use outside the MANUFACTURER'S INTENDED USE can result in a HAZARDOUS SITUATION for the PATIENT.

The EMS ENVIRONMENT includes

- responding to and providing life support at the scene of an emergency to a PATIENT reported as experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care.
- providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the HOME HEALTHCARE ENVIRONMENT covered by IEC 60601-1-11 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-11 or this collateral standard. ME EQUIPMENT and ME SYSTEMS are often not solely intended for one environment. Such ME EQUIPMENT or ME SYSTEM can be intended for multiple use environments, and as such, if also intended for use in the EMS ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEM intended for both the EMS ENVIRONMENT and the professional healthcare facility environment.

NOTE 2 EMS ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can be used in locations with unreliable electrical sources and outdoor environmental conditions.

1.2 * Object

The object of this collateral standard is to provide general requirements for ME EQUIPMENT and ME SYSTEMS carried to the scene of an emergency and used there, as well as in transport, in situations where the ambient conditions differ from indoor conditions.

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 and ME SYSTEMS, this collateral standard complements IEC 60601-1, hereafter referred to as the general standard.

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 60601-1-12 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 51.

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60529:1989/AMD1:1999¹

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

IEC 60601-1:2005/AMD1:2012²

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

¹ There exists a consolidated edition 2.1(2001) including IEC 60529:1989 and its Amendment 1:1999.

² There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

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 60601-1-8:2006/AMD1:2012³

IEC 60601-1-11:—⁴, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

CISPR 11:2009, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

ISO 7000:2014, *Graphical symbols for use on equipment – Registered symbols*

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

Amendment 1:2012

Amendment 2:2012

Amendment 3:2012

Amendment 4:2013

Amendment 5:2014

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

EUROCAE⁵ ED-14G, *Environmental conditions and test procedures for airborne equipment*

RTCA⁶ DO-160G, *Environmental Conditions and Test Procedures for Airborne Equipment*