



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



This Australian Standard® was prepared by Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 10 May 2017. This Standard was published on 23 June 2017.

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 - Australian and New Zealand College of Anaesthetists
 - Australian Chamber of Commerce and Industry
 - Australian Radiation Protection and Nuclear Safety Agency
 - Australian Society of Anaesthetists
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-

This Standard was issued in draft form for comment as DR AS IEC 60601.1.12:2017.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Australian Standard®

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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

First published as AS IEC 60601.1.12:2017.

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Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 76035 823 5

NOTES

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment.

The objective of this Standard is to specify the general requirements for medical electrical (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.

This Standard is identical with, and has been reproduced from 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*.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
1 Scope, object and related standards.....	8
1.1 * Scope.....	8
1.2 * Object.....	8
1.3 Related standards.....	9
1.3.1 IEC 60601-1.....	9
1.3.2 Particular standards.....	9
2 Normative references.....	9
3 Terms and definitions.....	10
4 General requirements.....	11
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS.....	11
4.2 * Environmental conditions for ME EQUIPMENT.....	11
4.2.1 * Environmental conditions of transport and storage between uses.....	12
4.2.2 * Environmental operating conditions.....	13
5 * Classification of ME EQUIPMENT and ME SYSTEMS.....	15
6 ME EQUIPMENT identification, marking and documents.....	16
6.1 * Additional requirements for legibility of markings.....	16
6.2 * Additional requirements for marking of IP classification.....	16
6.3 * Instructions for use.....	16
6.3.1 Additional general requirements.....	16
6.3.2 * Additional requirements for an electrical power source.....	17
6.3.3 Additional requirements for ME EQUIPMENT start-up PROCEDURE.....	17
6.3.4 * Additional requirements for operating instructions.....	18
6.3.5 Additional requirements for ME EQUIPMENT messages.....	18
6.4 Technical description – FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT.....	18
7 * Protection against electrical HAZARDS from ME EQUIPMENT.....	18
8 Protection against excessive temperatures and other HAZARDS.....	19
8.1 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS.....	19
8.1.1 * Ingress of water or particulate matter into ME EQUIPMENT.....	19
8.1.2 * Ingress of water or particulate matter into ME SYSTEMS.....	19
8.2 Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM.....	19
8.3 * Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT.....	20
9 * Accuracy of controls and instruments and protection against hazardous outputs.....	21
10 Construction of ME EQUIPMENT.....	21
10.1 * Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT.....	21
10.1.1 General requirements for mechanical strength.....	21
10.1.2 * Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance.....	22
10.1.3 * Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT.....	23

10.1.4	* Requirements for mechanical strength for ME EQUIPMENT intended for airborne use	24
10.2	Requirements for mounting of ME EQUIPMENT.....	25
11	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	25
Annex A (informative)	General guidance and rationale.....	26
A.1	General guidance.....	26
A.2	Rationale for particular clauses and subclauses.....	28
Annex B (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	42
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	42
B.2	ACCOMPANYING DOCUMENTS, instructions for use.....	42
B.3	ACCOMPANYING DOCUMENTS, technical description.....	43
Annex C (informative)	Symbols on marking.....	44
Bibliography	46
Index of defined terms used in this collateral standard	48
Figure A.1	– Saturation water vapour pressure as function of temperature.....	31
Table 1	– Mechanical strength test applicability	22
Table A.1	– Saturation water vapour pressure as function of temperature	32
Table B.1	– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	42
Table B.2	– ACCOMPANYING DOCUMENTS, instructions for use	42
Table B.3	– ACCOMPANYING DOCUMENTS, technical description.....	43
Table C.1	– General symbols	44

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.

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.

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