AS IEC 60601.1.11:2017
IEC 60601-1-11:2015 (ED.2)

AS IEC 60601.1.11:2017

Australian STANDARD

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

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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
- College of Biomedical Engineering Engineers Australia
- Department of Defence (Australian Government)
- Engineers Australia
- Testing Interests (Australia)
- Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS IEC 60601.1.11:2017.

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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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

First published as AS IEC 60601.1.11:2017.

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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 822 8

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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 requirements for the basic safety and essential performance of medical electrical (ME) equipment and ME systems for use in the home healthcare environment. It applies regardless of whether the ME equipment or ME system is intended for use by a lay operator or by trained healthcare personnel.

This Standard is identical with, and has been reproduced from IEC 60601-1-11:2015 (ED. 2), *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*.

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.

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CONTENTS

FOREWORD 5
INTRODUCTION 8
1 Scope, object and related standards 9
1.1 * Scope 9
1.2 Object 9
1.3 Related standards 9
1.3.1 IEC 60601-1 9
1.3.2 Particular standards 10
2 Normative references 10
3 Terms and definitions 11
4 General requirements 12
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS 12
4.2 * Environmental conditions for ME EQUIPMENT 12
4.2.1 General 12
4.2.2 * Environmental conditions of transport and storage between uses 13
4.2.3 * Environmental operating conditions 14
5 * General requirements for testing ME EQUIPMENT 16
6 * Classification of ME EQUIPMENT and ME SYSTEMS 17
7 ME EQUIPMENT identification, marking and documents 17
7.1 * USABILITY of the ACCOMPANYING DOCUMENT 17
7.2 * Additional requirements for marking of IP classification 18
7.3 ACCOMPANYING DOCUMENTS 18
7.3.1 Contact information 18
7.3.2 LAY OPERATOR briefing information 18
7.4 Instructions for use 19
7.4.1 Additional requirements for warning and safety notices 19
7.4.2 * Additional requirements for an electrical power source 19
7.4.3 Additional requirements for ME EQUIPMENT description 20
7.4.4 Additional requirements for ME EQUIPMENT start-up PROCEDURE 20
7.4.5 Additional requirements for operating instructions 20
7.4.6 Additional requirements for ME EQUIPMENT messages 21
7.4.7 * Additional requirements for cleaning, disinfection and sterilization 21
7.4.8 Additional requirements for maintenance 21
7.4.9 Additional requirements for environmental protection 21
7.4.10 Additional requirements for ME EQUIPMENT and ME SYSTEMS 22
7.5 Technical description 22
7.5.1 PERMANENTLY INSTALLED CLASS I ME EQUIPMENT 22
7.5.2 Additional requirements for professional hygienic maintenance 22
8 Protection against excessive temperatures and other HAZARDS 22
8.1 * Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS 22
8.2 * Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS 23
8.3 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS 23
8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT 23

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Page

8.3.2 * Ingress of water or particulate matter into ME SYSTEMS 23
8.4 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM 23
8.5 Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE 24
8.5.1 * Indication of state 24
8.5.2 Accessibility of small INTERNAL ELECTRICAL POWER SOURCES 25
9 Accuracy of controls and instruments and protection against hazardous outputs 25
10 Construction of ME EQUIPMENT 25
10.1 * Additional requirements for mechanical strength 25
10.1.1 General requirements for mechanical strength 25
10.1.2 * Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT 27
10.1.3 * Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT 28
10.2 Additional requirements for actuating parts of controls of ME EQUIPMENT 29
11 * Protection against strangulation or asphyxiation 30
12 Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS 30
13 Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS 30
13.1 * Additional requirement for generation of ALARM SIGNALS 30
13.2 * Additional requirement for ALARM SIGNAL volume 30
Annex A (informative) General guidance and rationale 31
A.1 General guidance 31
A.2 Rationale for particular clauses and subclauses 32
Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 51
B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 51
B.2 ACCOMPANYING DOCUMENTS, general 51
B.3 ACCOMPANYING DOCUMENTS, instructions for use 51
B.4 ACCOMPANYING DOCUMENTS, technical description 53
Annex C (informative) Symbols on marking 54
Bibliography 56
Index of defined terms used in this collateral standard 58

Figure 1 – Small finger probe Ø 5,6 17
Figure A.1 – Saturation water vapour pressure as function of temperature 36

Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE 26
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE 27
Table A.1 – Saturation water vapour pressure as function of temperature 37
Table A.2 – Summary by use of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT ENCLOSURE ingress of water and particulate matter requirements 46
Table A.3 – Qualitative assessment of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT subjected to shock and vibration 47
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 51
Table B.2 – ACCOMPANYING DOCUMENTS, general 51
Table B.3 – ACCOMPANYING DOCUMENTS, instructions for use 52

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Page

Table B.4 – ACCOMPANYING DOCUMENTS, technical description 53
Table C.1 – General symbols 54

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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 60601-1-11 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.

It is published as a double logo standard.

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

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This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

– correction of test method for relative humidity control at temperatures above 35 °C;
– redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
– harmonizing with the changes to the amendments to the general standard and other collateral standards.

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

FDIS	Report on voting
62A/959/FDIS	62A/978/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, the standard has been approved by 17 P-members out of 17 having cast a vote.

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: 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 collateral 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;

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– “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 mandatory 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.

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INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

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.

AUSTRALIAN STANDARD

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

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 for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

The HOME HEALTHCARE ENVIRONMENT includes:

– the dwelling place in which a PATIENT lives;
– other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

NOTE HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

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 and ME SYSTEMS, 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 60601-1-11 alone;
– "this standard" designates the combination of the general standard and this collateral standard.

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