



## **Medical electrical equipment**

**Part 2.3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment (IEC 60601-2-3:2016 (ED.3.1), MOD)**

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Australia



AS 60601.2.3:2018

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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
- Certification Body Australia (Certification Interests Australia)
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### **Part 2.3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment (IEC 60601-2-3:2010 (ED.3.1), MOD)**

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## Preface

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify the requirements for the basic safety and essential performance of short-wave therapy equipment. Short-wave therapy equipment are defined as medical equipment for the therapeutic treatment of a patient by exposure to electric or magnetic fields produced in the frequency range of more than 13 MHz but not exceeding 45 MHz. Equipment having a rated output power not exceeding 10 W are exempted from certain requirements of this Standard.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-3:2016 (ED. 3.1), *Medical electrical equipment — Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment*. Appendix ZZ lists the variations to IEC 60601-2-3:2016 (ED. 3.1) for the application of this Standard in Australia.

As this document has been 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 number.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms 'normative' and 'informative' are used in Standards to define the application of the appendices or annexes to which they apply. A 'normative' appendix or annex is an integral part of a Standard, whereas an 'informative' appendix or annex is only for information and guidance.

NOTES

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment**

## FOREWORD

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**This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) can be considered the official documents.**

This Consolidated version of IEC 60601-2-3 bears the edition number 3.1. It consists of the third edition (2012-04) [documents 62D/977/FDIS and 62D/993/RVD] and its amendment 1 (2016-04) [documents 62D/1330/FDIS and 62D/1350/RVD]. The technical content is identical to the base edition and its amendment.

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 60601-2-3 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-3 published in 1991 and its amendment 1 published in 1998. This edition constitutes a technical revision and has been aligned with IEC 60601-1.

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: 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 PARTICULAR STANDARD OR AS NOTED: 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 particular 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.

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 AA.

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 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.

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## INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of short-wave therapy equipment.

This particular standard amends and supplements IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (\*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

This particular standard specifies the requirements for the safety of SHORT-WAVE THERAPY EQUIPMENT, hereafter referred to as ME EQUIPMENT, as defined in subclause 201.3.206.

LOW POWER EQUIPMENT as defined in subclause 201.3.202 is exempted from certain requirements of this standard.

##### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SHORT-WAVE THERAPY EQUIPMENT as defined in 201.3.206.

##### 201.1.3 Collateral standards

*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard.

IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

##### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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<sup>1</sup> The general standard is IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*