



Medical electrical equipment

Part 2.10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10:2016 (ED. 2.1), MOD)



AS 60601.2.10:2018

This Australian Standard® was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 11 September 2018.

This Standard was published on 27 September 2018.

The following are represented on Committee HE-003:

- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian College of Perioperative Nurses
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Certification Body Australia (Certification Interests Australia)
- College of Biomedical Engineering, Engineers Australia
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This Standard was issued in draft form for comment as DR AS/NZS 60601.2.10:2018.

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ISBN 978 1 76072 181 7



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First published as AS 60601.2.10:2018.

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Preface

This Standard was prepared by the Australian members of the 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 safety and essential performance of nerve and muscle stimulators, for use in the practice of physical medicine. This includes transcutaneous electrical nerve stimulators (TENS) and electrical muscle stimulators (EMS).

This Standard amends and supplements the general Standard IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-10:2016 (ED. 2.1), *Medical electrical equipment — Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*. Appendix ZZ lists the variations for the application of this Standard in Australia.

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(a) In the source text “this particular Standard” should read “this Australian Standard”.

(b) A full point substitutes for a comma when referring to a decimal marker.

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.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-10: Particular requirements for the basic safety
and essential performance of nerve and muscle stimulators**

FOREWORD

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This Consolidated version of IEC 60601-2-10 bears the edition number 2.1. It consists of the second edition (2012-06) [documents 62D/1003/FDIS and 62D/1015/RVD] and its amendment 1 (2016-04) [documents 62D/1332/FDIS and 62D/1352/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 60601-2-10 has been prepared by IEC subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition, published in 1987 and its Amendment 1 (2001). This edition constitutes a technical revision and is 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

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