AS 60601.2.10:2018

Australian STANDARD

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)

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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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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.

As this document has been reproduced from an International Standard, the following applies:

(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.

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

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.

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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.

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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 nerve and muscle stimulators.

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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard specifies the requirements for the safety of nerve and muscle STIMULATORS, defined in subclause 201.3.204, for use in the practice of physical medicine, hereinafter referred to as ME EQUIPMENT. This includes transcutaneous electrical nerve STIMULATORS (TENS) and electrical muscle STIMULATORS (EMS).

NOTE A muscle STIMULATOR may also be known as a neuromuscular STIMULATOR.

The following ME EQUIPMENT is excluded:

– ME EQUIPMENT intended to be implanted or to be connected to implanted electrodes;
– ME EQUIPMENT intended for the stimulation of the brain (e.g. electroconvulsive therapy ME EQUIPMENT);
– ME EQUIPMENT intended for neurological research;
– external cardiac pacemakers (see IEC 60601-2-31);
– ME EQUIPMENT intended for averaged evoked potential diagnosis (see IEC 60601-2-40);
– ME EQUIPMENT intended for electromyography (see IEC 60601-2-40);
– ME EQUIPMENT intended for cardiac defibrillation (see IEC 60601-2-4).

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for nerve and muscle STIMULATORS as defined in 201.3.204.

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 and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

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