

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE



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

**Appareils électromédicaux –**  
**Partie 2-10: Exigences particulières pour la sécurité de base et les performances**  
**essentiels des stimulateurs de nerfs et de muscles**

<https://standards.iteh.ai/catalog/standards/iec/a12a2c76-e26c-4589-a184-6b0a7f8c769d/iec-60601-2-10-2012>





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IEC 60601-2-10

Edition 2.1 2016-04  
CONSOLIDATED VERSION

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INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-3374-0

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**MEDICAL ELECTRICAL EQUIPMENT –**

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

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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**This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.**

**IEC 60601-2-10 edition 2.1 contains 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].**

**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted 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:~~2005+A1:2012~~.

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.

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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,
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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 ~~(third edition, 2005 plus Amendment 1, 2012)~~, *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<sup>1)</sup> 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:~~2007~~ 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.

<sup>1)</sup> The general standard is IEC 60601-1:~~2005+A1:2012~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

#### 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.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

<https://standards.iteh.ai/> Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

#### 201.2 Normative references

Clause 2 of the general standard applies with the following exception:

*Replacement:*

IEC 60601-1-2:~~2007~~, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

*Addition:*

IEC 60601-1:~~2005~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*  
~~Amendment 1:2012~~

### 201.3 Terms and definitions

*Replacement:*

For the purposes of this document, the terms and definitions given in IEC 60601-1:~~2005~~+A1:2012 apply, except as follows:

NOTE 1 Where values of “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

#### 201.3.8 APPLIED PART

*Addition:*

the STIMULATOR electrodes and all parts conductively connected to them

*Addition:*

#### 201.3.201 LEAD

insulated conductor having a means of connecting to a STIMULATOR at one end and a means of connecting to an electrode at the other end, and intended for conducting output signals from a STIMULATOR to an electrode

#### 201.3.202 PULSE

portion of WAVEFORM between two zero voltage levels

#### 201.3.203 PULSE DURATION

duration of the output PULSE at 50 % of the maximum amplitude

#### 201.3.204 STIMULATOR

ME EQUIPMENT for the application of electric currents via electrodes in direct contact with the PATIENT for the diagnosis and/or therapy of neuromuscular disorders.

#### 201.3.205 WAVEFORM

variations in amplitude of an electrical signal which is output from the APPLIED PART (in either voltage or current) as a function of time .

### 201.4 General requirements

Clause 4 of the general standard applies, except as follows:

#### **201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS**

*Additional subclause:*

##### **201.4.1.101 Additional conditions for application to ME EQUIPMENT or ME SYSTEMS**

In the case of combined ME EQUIPMENT (e.g. a STIMULATOR provided with a function or an APPLIED PART for ultrasonic therapy), the additional part shall comply with any relevant particular standard.

#### **201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS**

*Addition:*

MANUFACTURERS shall include, within their RISK ANALYSIS, the risk associated with the potential use of their STIMULATORS and accessories to deliver current exceeding 10 mA or current densities for any electrode exceeding 2 mA/cm<sup>2</sup>.

##### **201.4.11 Power input**

*Addition:*

The EQUIPMENT shall be operated in the output mode and using the load which creates the highest amplitude steady state current.

#### **201.5 General requirements for testing of ME EQUIPMENT**

Clause 5 of the general standard applies.

#### **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

[IEC 60601-2-10:2012](https://standards.iteh.ai/IEC/60601-2-10:2012)

<https://standards.iteh.ai/IEC/60601-2-10:2012> Clause 6 of the general standard applies, except as follows: [84-6b0a7f8c769d/iec-60601-2-10-2012](https://standards.iteh.ai/IEC/60601-2-10:2012)

##### **201.6.2 \* Protection against electric shock**

*Amendment:*

Delete TYPE B APPLIED PART.

##### **201.6.6 \* Mode of operation**

*Amendment:*

Delete all except CONTINUOUS OPERATION.

#### **201.7 ME EQUIPMENT identification, marking and documents**

Clause 7 of the general standard applies, except as follows:

##### **201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**

###### **201.7.2.7 Electrical input power from the SUPPLY MAINS**

*Replacement of the fourth paragraph:*