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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 essentielles des stimulateurs de nerfs et de muscles

IEC 60601-2-10:2012

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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CONTENTS

FOREWORD 3
INTRODUCTION 5
201.1 Scope, object and related standards 6
201.2 Normative references 7
201.3 Terms and definitions 8
201.4 General requirements 8
201.5 General requirements for testing of ME EQUIPMENT 9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 9
201.7 ME EQUIPMENT identification, marking and documents 9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 11
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 11
201.10 Protection against unwanted and excessive radiation HAZARDS 11
201.11 Protection against excessive temperatures and other HAZARDS 11
201.12 Accuracy of controls and instruments and protection against hazardous outputs 11
201.13 HAZARDOUS SITUATIONS and fault conditions 13
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 13
201.15 Construction of ME EQUIPMENT 13
201.16 ME SYSTEMS 13
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 13
202 Electromagnetic compatibility – Requirements and tests 14
Annexes 15
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 16
Annex AA (informative) Particular guidance and rationale 17
Index of defined terms used in this particular standard 20

Figure 202.101 – Testing layout 15

Table 201.101 – Pulse frequency versus applied current limits 13
Table 201.C.101 – Marking on the outside of STIMULATORS or their parts 16

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Full document details: IEC 60601-2-10 2012

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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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.

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

FDIS	Report on voting
62D/1003/FDIS	62D/1015/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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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 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.

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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[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 60601-1-2:2007 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.

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

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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.

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:

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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:

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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^2.

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

Clause 6 of the general standard applies, except as follows:

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:

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The RATED input power of a mains powered STIMULATOR shall be the maximum power averaged over any period of 5 s under the specified operating conditions set out by the manufacturer.

Additional subclause:

201.7.2.101 * Output

ME EQUIPMENT capable of delivering outputs in excess of 10 mA or 10 V averaged over any period of 1 s shall be marked near the electrode connections with symbol No. 10 of Table D.2 of the general standard.

201.7.9 Accompanying documents

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional information in instructions for use

The instructions for use shall contain additionally:

a) * Information on the output WAVEFORM(S), including any d.c. component, PULSE DURATIONS, PULSE repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on these parameters.

b) * Advice on the size and type of electrodes to be used and the method of application for each particular type of treatment for which the STIMULATOR is intended.

c) Advice on any necessary precautions to be taken when the output contains a d.c. component.

d) * Advice that a PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.

e) A warning on the following potential hazards:

– Simultaneous connection of a PATIENT to a high frequency surgical ME EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.

– Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.

– Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

f) * For ME EQUIPMENT capable of delivering output values in excess of 10 mA or 10 V:

– Information on maximum output values available at the electrodes recommended by the manufacturer for use with the STIMULATOR.

g) Advice that any electrodes that have current densities exceeding 2 mA/cm^2 may require the special attention of the OPERATOR.

h) Advice that stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

– The technical description shall specify the parameters mentioned in item a) of 201.7.9.2.101 along with the range of load impedances for which these parameters are valid.

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201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

201.8.3 * Classification of APPLIED PARTS

Amendment:

The APPLIED PARTS of STIMULATORS shall be TYPE BF or TYPE CF APPLIED PARTS.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies except as follows.

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 * Output amplitude

A means shall be provided to control the STIMULATOR output from minimum to maximum continuously, or in discrete increments of not more than 1 mA or 1 V per increment. At its minimum setting, the output shall not exceed 2 % of that available at the maximum setting of the control.

Compliance is checked by inspection and measurement using the load impedance which is the least favourable within the load impedance range specified in the ACCOMPANYING DOCUMENTS.

201.12.1.102 * PULSE parameters

The values of PULSE DURATIONS, PULSE repetition frequencies and amplitudes, including any d.c. component, whether caused by an offset or by an unsymmetrical waveform, as described in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2), shall not deviate by more than ± 20 % when measured with a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see 201.7.9.3).

Compliance is checked by measurement with an error not exceeding ± 10 %.

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201.12.2 USABILITY

Additional subclause:

201.12.2.101 * Electrodes

The STIMULATOR shall comply with this standard when operated with either open-circuited or short-circuited electrodes.

Compliance is checked by the following test:

Operate the STIMULATOR with all output controls set to the maximum position and each pair of output terminals left open-circuited for a period of 10 min and then short-circuited for a further period of 5 min. After this test the ME EQUIPMENT shall comply with all the requirements of this standard.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 * Supply voltage fluctuations

Supply voltage fluctuations of ± 10 % shall not affect the STIMULATOR output amplitude, PULSE DURATION or PULSE repetition frequency by more than ± 10 %.

Compliance is checked by measurement.

201.12.4.102 * Output interlock

A stimulator that is capable of delivering an output in excess of 10 mA or 10 V shall not be energizeable unless the output amplitude control(s) is (are) first set to its (their) minimum position.

This requirement shall also apply upon the restoration of the SUPPLY MAINS following a temporary interruption or following replacement of the INTERNAL ELECTRICAL POWER SOURCE.

This requirement shall not apply when a stimulator is released from a pause mode, having been operating prior to being paused.

Compliance is checked by functional check.

201.12.4.103 * Output indicator

In NORMAL CONDITION and SINGLE FAULT CONDITION, ME EQUIPMENT shall indicate when it can deliver an output of more than 10 mA or 10 V, or can deliver PULSES having an energy exceeding 10 mJ per PULSE, into a load resistance of 1 000 Ω. If the indication is by means of a signal lamp, its colour shall be yellow.

Compliance is checked by inspection and functional test.

201.12.4.104 * Limitation of output parameters

a) ME EQUIPMENT intended for therapeutic applications:

With a load resistance of 500 Ω the output current shall not exceed the limits in Table 201.101:

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