BS EN 60601-2-10:2015

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-10:2015. It is identical to IEC 60601-2-10:2012. It supersedes BS EN 60601-2-10:2001, which will be withdrawn on 22 May 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-10

May 2015

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Supersedes EN 60601-2-10:2000

English Version

Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10:2012)

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)

Medizinische elektrische Geräte - Teil 2-10: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Geräten zur Stimulation von Nerven und Muskeln (IEC 60601-2-10:2012)

This European Standard was approved by CENELEC on 2012-07-09. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62D/1003/FDIS, future edition 2 of IEC 60601-2-10, prepared by IEC/SC 62 D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-10:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2015-11-22
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-05-22

This document supersedes EN 60601-2-10:2000.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-10:2012 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies with the following exceptions:

Publication	Year	Title	EN/HD	Year
Addition:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+corrigendum Mar	2010
			+AC	2014
			+A11	2011
+A1	2012		+A1	2013
			+A12	2014
Replacement:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
			+corrigendum Mar.	2010

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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.

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.

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*

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:

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^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:

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.

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 %.

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:

Table 201.101 – Pulse frequency versus applied current limits

Pulse Frequency	Current limit
d.c.	80 mA
≤ 400 Hz	50 mA
> 400 Hz to ≤ 1 500 Hz	80 mA
> 1 500 Hz	100 mA

If the output has a.c. and d.c. components, then these components shall be measured separately and compared with the allowable limits.

For PULSE DURATIONS of less than 0,1 s the PULSE energy with a load resistance of 500 Ω shall not exceed 300 mJ per PULSE. For longer PULSE DURATIONS, the above-mentioned current limit for d.c. applies.

Additionally, the output voltage shall not exceed a peak value of 500 V, when measured under open-circuit condition.

Where the APPLIED PART(S) is (are) energized by more than one patient circuit simultaneously (for example for interferential therapy), the above limits shall apply to each of these patient circuits.

b) ME EQUIPMENT intended for diagnostic applications:

For ME EQUIPMENT intended for dentistry and ophthalmology, the d.c. current with a load resistance of 2 000 Ω shall not exceed 10 mA.

Compliance is checked by measurement.

201.13 Hazardous situations and fault conditions

Clause13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause15 of the general standard applies

201.16 ME SYSTEMS

Clause16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC60601-1-2:2007 applies except as follows:

202.6.1 Emissions

202.6.1.1.2 Tests

a) Patient cables

Addition:

Connect all relevant electrodes to the contents of a 1 litre capacity phantom filled with 0,9 % saline. Position the phantom within 0,4 m of the ME EQUIPMENT as shown in Figure 202.101.

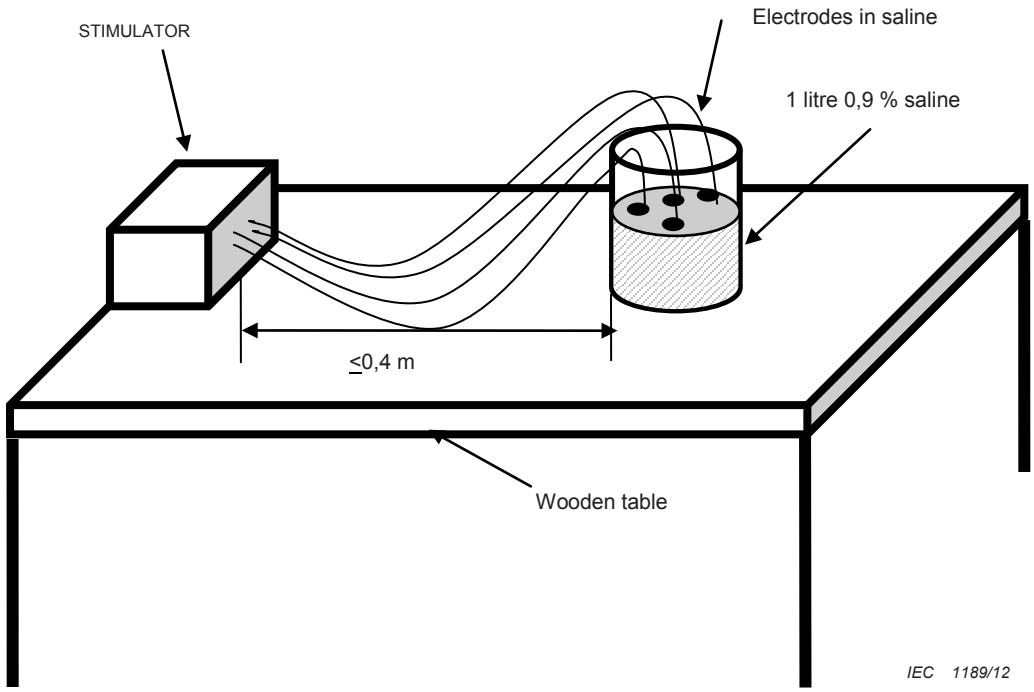

Figure 202.101 – Testing layout

202.6.2 * Immunity

202.6.2.1.5 PATIENT-COUPLED ME EQUIPMENT and ME SYSTEMS

Addition:

Connect all relevant electrodes and apply them to the contents of a 1 litre capacity phantom filled with 0,9 % saline. Position the phantom within 0,4 m of the ME EQUIPMENT as shown in Figure 202.101.

Annexes

The annexes of the general standard apply except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of nerve and muscle STIMULATORS are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of STIMULATORS or their parts

Description of marking	Subclause
The RATED power input	201.7.2
Symbol No. 10 of Table D.2 in the general standard	201.7.2.101

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This appendix provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The types of ME EQUIPMENT which are excluded from the scope of this standard differ considerably with respect to technique and/or application from the ME EQUIPMENT normally used in physical medicine; therefore these types require different safety measures.

Subclause 201.6.2 – Protection against electric shock

The APPLIED PART needs to be isolated to avoid unwanted current paths through the PATIENT due to the capacitance or a possible conductive connection to earth.

Subclause 201.6.6 – Mode of operation

The ME EQUIPMENT is usually operated with one PATIENT for extended periods. It may also be used immediately with the next PATIENT. Therefore it needs to be suitable for CONTINUOUS OPERATION.

Subclause 201.7.2.101 – Output

The symbols alert the OPERATOR to consult the instructions for use because of the higher levels of output.

Subclause 201.7.9.2.101 a) – Additional instructions for use

Because of the electrolytic effects, any d.c. components of the PULSES needs to be declared.

Subclause 201.7.9.2.101 b) – Additional instructions for use

Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.

Subclause 201.7.9.2.101 d) – Additional instructions for use

A HAZARD could exist if the stimulating current interferes with the operation of the implanted devices

Subclause 201.7.9.2.101 f) – Additional instructions for use

Maximum output values are needed by OPERATORS and PATIENTS to make informed decisions. A HAZARD could exist if excessive current densities are present.

Subclause 201.8.3 – Classification of APPLIED PARTS

See rationale for subclause 201.6.2.

Subclause 201.12.1.101 – Output amplitude

A small increase in output amplitude may disproportionately stimulate the PATIENT. A control which allows the OPERATOR to adjust the output amplitude smoothly or in small steps is an important safety feature. Limitation of the output available at the minimum setting of the output control enables the OPERATOR to commence the treatment by increasing the output amplitude from an initial low (and therefore safe) level. As stated in Note 1 of 201.3, all values for voltage and current are r.m.s. unless specifically stated otherwise.

Subclause 201.12.1.102 – PULSE parameters

An accuracy of ± 20 % is adequately safe for therapeutic application, since the pulse parameters are set based upon the subjective reaction of the PATIENT. A considerably higher accuracy may be needed for diagnostic purposes.

Subclause 201.12.2.101 – Electrodes

The STIMULATOR should not become unsafe if the output is switched on inadvertently with open or short-circuited electrodes even if such operation is considered to be misuse.

Subclause 201.12.4.101 – Supply voltage fluctuations

Supply voltage fluctuations within the limits of the general standard should not affect the output parameters.

Subclause 201.12.4.102 – Output interlock

To avoid excessive stimulation of the PATIENT, sudden increases in the output current needs to be avoided in NORMAL USE and in the case of interruption and restoration of the SUPPLY MAINS or following replacement of the INTERNAL ELECTRICAL POWER SOURCE.

The exception for use of a pause mode is because many devices now have this mode so that electrodes can be repositioned,

Subclause 201.12.4.103 – Output indicator

An output indication is required for this single fault condition because a fault in the STIMULATOR could unintentionally make energization of the electrodes possible. The requirement may be met by a power on indicator with zero actual output or by an indicator activated by the STIMULATOR output.

Subclause 201.12.4.104 – Limitation of output parameters

For this standard, the pulse frequency is the inverse of the period of time for the pulse waveform to repeat itself. The specified current limits support all known therapeutic and/or diagnostic applications without greatly exceeding the values needed.

Subclause 202.6.2 – Immunity

The tests using the saline-filled phantom (see Figure 202.101) simulate NORMAL USE.

A STIMULATOR may be used in close proximity to ME EQUIPMENT that intentionally radiates radio frequency energy. STIMULATORS which are not adequately protected may produce considerable changes of output which could be hazardous to the PATIENT.

The test ensures that the STIMULATOR has been adequately protected against the effect of strong r.f. currents entering the STIMULATOR via the PATIENT LEADS and/or the mains cable. Simple filter networks in the PATIENT output and mains input circuits have proved effective.

Index of defined terms used in this particular standard

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