

© Copyright SEK. Reproduction in any form without permission is prohibited.

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-10: Särskilda fordringar på nerv- och muskelstimulatorer

Medical electrical equipment –

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

Som svensk standard gäller europastandarden EN 60601-2-10:2015. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-10:2015.

Nationellt förord

Europastandarden EN 60601-2-10:2015

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-10, Second edition, 2012 - Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1.

Tidigare fastställd svensk standard SS-IEC 601-2-10, utgåva 1, 1988, SS-EN 60601-2-10, utgåva 1, 2001 och SS-EN 60601-2-10/A1, utgåva 1, 2001, gäller ej fr o m 2018-05-22.

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard

Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition:</i>				
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
<i>Replacement:</i>				
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

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

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 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 standard¹⁾ 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.

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