



SLOVENSKI STANDARD
SIST EN 60601-2-10:2015/A1:2017
01-februar-2017

Medicinska električna oprema - 2-10. del: Posebne zahteve za osnovno varnost in bistvene lastnosti živčnih in mišičnih stimulatorjev - Dopolnilo A1 (IEC 60601-2-10:2012/A1:2016)

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/A1:2016)

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

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

Ta slovenski standard je istoveten z: EN 60601-2-10:2015/A1:2016

ICS:

11.040.60 Terapevtska oprema Therapy equipment

SIST EN 60601-2-10:2015/A1:2017 en

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EUROPEAN STANDARD

EN 60601-2-10:2015/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2016

ICS 11.040.60

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/A1:2016)

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/A1:2016)

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/A1:2016)

This amendment A1 modifies the European Standard EN 60601-2-10:2015; it was approved by CENELEC on 2016-06-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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

EN 60601-2-10:2015/A1:2016**European foreword**

The text of document 62D/1332/FDIS, future IEC 60601-2-10:2012/A1, prepared by SC 62D "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/A1:2016.

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) 2017-06-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-12-16

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 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-10:2015.

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Endorsement notice

The text of the International Standard IEC 60601-2-10:2012/A1:2016 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>In Annex ZA of EN 60601-2-10:2015, replace the existing references to IEC 60601-1-2:2007 and IEC 60601-1:2005 as follows:</i>				
IEC 60601-1-2	-	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1	-	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. Mar. + A1 + A12	2006 2010 2013 2014

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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
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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/1332/FDIS	62D/1352/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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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FOREWORD

In the eleventh paragraph, replace “IEC 60601-1:2005+A1:2012” by “IEC 60601-1”.

INTRODUCTION

In the second paragraph, replace “IEC 60601-1 (third edition, 2005 plus Amendment 1, 2012)” by “IEC 60601-1”.

201.1 Scope, object and related standards

In footnote 1), replace “IEC 60601-1:2005+A1:2012” by “IEC 60601-1”.

201.1.3 Collateral standards

In the second paragraph, replace “IEC 60601-1-2:2007” by “IEC 60601-1-2”.

IEC 60601-2-10:2012/AMD1:2016
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201.2 Normative references

In the third line, replace “IEC 60601-1-2:2007” by “IEC 60601-1-2”.

In the seventh line, replace “IEC 60601-1:2005” by “IEC 60601-1”.

In the eighth line, delete “Amendment 1:2012”.

201.3 Terms and definitions

In the third line, replace “IEC 60601-1:2005+A1:2012” by “IEC 60601-1”.

201.12.2 USABILITY

Replace the subclause title with the following new title:

201.12.2 Usability of ME EQUIPMENT

201.13 Hazardous situations and fault conditions

Replace the subclause title by the following new title:

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

202 Electromagnetic compatibility – Requirements and tests

Replace the clause title by the following new title:

202 Electromagnetic disturbances – requirements and tests

In the first line, replace “IEC 60601-1-2:2007” by “IEC 60601-1-2”.

Replace:

“202.6.1 Emissions

202.6.1.1.2 Tests

a) Patient cables”

by:

“202.7.1.11 PATIENT-coupled cables”