

**ELEKTRILISED MEDITSIINISEADMED.  
OSA 2-10: ERINÕUDED NÄRVI- JA  
LIHASSTIMULAATORITE ESMASELE OHUTUSELE JA  
OLULISTELE TOIMIMISNÄITAJATELE**

**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 + IEC 60601-2-10:2012/A1:2016 + IEC 60601-2-10:2012/AMD2:2023)**

**EESTI STANDARDI EESSÕNA****NATIONAL FOREWORD**

|  |  |
|--|--|
| See Eesti standard EVS-EN 60601-2-10:2015+A1+A2:2024 sisaldab Euroopa standardi EN 60601-2-10:2015 ja selle muudatuste A1:2016 ja A2:2024, ingliskeelset teksti.   | This Estonian EVS-EN 60601-2-10:2015+A1+A2:2024 consists of the English text of the European standard EN 60601-2-10:2015 and its amendments A1:2016 and A2:2024.   |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.<br><br>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015, muudatused A1 16.12.2016 ja A2 20.09.2024.                                 | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.<br><br>Date of Availability of the European standard is 22.05.2015, for A1 16.12.2016 and A2 20.09.2024.                              |
| Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega $\boxed{A_1}$ $\langle A_1 \rangle$ .<br><br>Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega $\boxed{A_2}$ $\langle A_2 \rangle$ . | The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags $\boxed{A_1}$ $\langle A_1 \rangle$ .<br><br>The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags $\boxed{A_2}$ $\langle A_2 \rangle$ . |
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ICS 11.040.60

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EUROPEAN STANDARD

**EN 60601-2-10 + A1 +A2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015, December 2016, September 2024

ICS 11.040.60

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 + IEC 60601-2-10:2012/A1:2016 + IEC  
60601-2-10:2012/AMD2:2023)**

Appareils électromédicaux - Partie 2-10: Exigences  
particulières pour la sécurité de base et les performances  
essentielle des stimulateurs de nerfs et de muscles  
(IEC 60601-2-10:2012 + IEC 60601-2-10:2012/A1:2016 +  
IEC 60601-2-10:2012/AMD2:2023)

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 + IEC 60601-2-10:2012/A1:2016 +  
IEC 60601-2-10:2012/AMD2:2023)

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Comité Européen de Normalisation Electrotechnique  
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Ref. No. EN 60601-2-10:2015 E  
+ EN 60601-2-10:2015/A1:2016 E  
+ EN 60601-2-10:2015/A2:2024 E

## 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

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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.

## **A1** Amendment A1 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.

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For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-10:2015.

### **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. **A1**

## **A<sub>2</sub>** Amendment A2 European foreword

The text of document 62D/2004/FDIS, future edition 2 of IEC 60601-2-10/AMD2, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-10:2015/A2:2024.

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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**



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IEC 60601-2-10

Edition 2.1 2023-01  
CONSOLIDATED VERSION

# 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**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT –**

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

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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 **A1** IEC 60601-1 **A1**.

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.
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- “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.

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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.

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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     |

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Amendment 2 to IEC 60601-2-10:2012 has been prepared by subcommittee 62D: Particular medical equipment, software and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

|               |                  |
|---------------|------------------|
| Draft         | Report on voting |
| 62D/2004/FDIS | 62D/2015/RVD     |

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications/](http://www.iec.ch/standardsdev/publications/).

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- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication. 

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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 <sup>A1</sup> IEC 60601-1 <sup>A1</sup>: *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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## **A2** INTRODUCTION to Amendment 2

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1831/RR. **A2**

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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.

**A1**) IEC 60601-1-2 **A1**) 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) **A2**) The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* **A2**)

#### **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

☐<sup>A2</sup> Clause 2 of the general standard applies, except as follows:

*Replacement:*

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*  
Amendment 1:2020

*Addition:*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*  
Amendment 1:2012  
Amendment 2:2020 ☐<sup>A2</sup>

## 201.3 Terms and definitions

*Replacement:*

For the purposes of this document, the terms and definitions given in ☐<sup>A2</sup> IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ☐<sup>A2</sup> 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.