SLOVENSKI STANDARD
SIST EN 60601-2-4:2011/A1:2019

01-december-2019

Medicinska električna oprema - 2-4. del: Posebne zahteve za osnovno varnost in bistvene lastnosti srčnih defibrilatorjev - Dopolnilo A1 (IEC 60601-2-4:2010/A1:2018)

Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010/A1:2018)

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Defibrillatoren (IEC 60601-2-4:2010/A1:2018)

Appareils électromédicaux - Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques (IEC 60601-2-4:2010/A1:2018)

Ta slovenski standard je istoveten z: **EN 60601-2-4:2011/A1:2019**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 60601-2-4:2011/A1:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-4:2011/A1

October 2019

ICS 11.040.10

English Version

Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010/A1:2018)

Appareils électromédicaux - Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques (IEC 60601-2-4:2010/A1:2018)

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Defibrillatoren (IEC 60601-2-4:2010/A1:2018)

This amendment A1 modifies the European Standard EN 60601-2-4:2011; it was approved by CENELEC on 2018-04-04. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1549/FDIS, future IEC 60601-2-4/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 60601-2-4:2011/A1:2019.

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) 2020-04-11
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-10-11

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

Endorsement notice

The text of the International Standard IEC 60601-2-4:2010/A1:2018 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.

The Annex ZA of EN 60601-1:2006 is applicable, except as follows:

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
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
IEC 61000-4-2	-	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	-
ISO 15223-1	2016		EN ISO 15223-1 +prA1	2016
Amendment				
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	EN 60601-1-2	2015

IEC 60601-2-4

Edition 3.0 2018-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

Appareils électromédicaux –
Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques

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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/1549/FDIS	62D/1555/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.

201.1.1 * Scope

Replace the fourth existing paragraph by the following new paragraph:

This particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2][1]). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

201.2 Normative references

Replace, in the "Amendment" section, the existing reference IEC 60601-1-2, including its title, by the following new reference:

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*

1 Numbers in square brackets refer to the bibliography.

Replace, in the "Addition" section, the existing reference "ISO 15223-1:2007" *by* "ISO 15223-1:2016"

Add, in the "Addition" section, the following new reference:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

201.3 Terms and definitions

Replace the first existing paragraph by the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 apply, except as follows:

201.3.202

Replace the existing Note 2 by the following new note:

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions (e.g. transcutaneous pacing).

201.3.203

Add, after the definition, the following new note:

NOTE The CHARGING CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.204

Replace the existing definition and note by the following new definition and note:

electrode intended to deliver an electrical pulse for the purpose of cardiac defibrillation and which may also be used to provide transcutaneous pacing and other monitoring functions

NOTE DEFIBRILLATOR ELECTRODES may be internal or external and disposable or reusable.

201.3.206

Add, after the definition, the following new note:

NOTE The DISCHARGE CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.209

Replace the existing note by the following new note:

NOTE The energy storage devices for defibrillation and pacing functions may be separate or combined.

Add, after 201.3.220, the following new term and definition:

201.3.221
PACER
EXTERNAL TRANSCUTANEOUS PACEMAKER
optional circuit within the DEFIBRILLATOR intended to stimulate the heart by a series of electrical pulses via electrodes applied to the PATIENT's skin

201.7.2.103 Disposable defibrillator electrodes

Replace, in item a) of the existing paragraph, the reference "ISO 15223-1:2007" *by* "ISO 15223-1:2016".