# SLOVENSKI STANDARD
# SIST EN 60601-2-4:2011/A2:2027

**01-januar-2027**

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**Medicinska električna oprema - 2-4. del: Posebne zahteve za osnovno varnost in bistvene lastnosti srčnih defibrilatorjev - Dopolnilo A2 (IEC 60601-2-4:2010/AMD2:2026)**

Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010/AMD2:2026)

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Defibrillatoren (IEC 60601-2-4:2010/AMD2:2026)

Appareils électromédicaux - Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques (IEC 60601-2-4:2010/AMD2:2026)

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**Ta slovenski standard je istoveten z:** **EN 60601-2-4:2011/A2:2026**

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**ICS:**

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

**SIST EN 60601-2-4:2011/A2:2027** **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 60601-2-4:2011/A2

November 2026

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/AMD2:2026)

Appareils électromédicaux - Partie 2-4: Exigences particulières pour la sécurité de base et les performances essentielles des défibrillateurs cardiaques (IEC 60601-2-4:2010/AMD2:2026)

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Defibrillatoren (IEC 60601-2-4:2010/AMD2:2026)

This amendment A2 modifies the European Standard EN 60601-2-4:2011; it was approved by CENELEC on 2026-11-02. 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.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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# European foreword

The text of document 62D/2317/FDIS, future edition 3 of IEC 60601-2-4/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 60601-2-4:2011/A2:2026.

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) 2027-11-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2029-11-30

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The text of the International Standard IEC 60601-2-4:2010/AMD2:2026 was approved by CENELEC as a European Standard without any modification.

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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

| | | |
|---|---|---|
| IEC 60601-1-11:2015 | NOTE | Approved as EN 60601-1-11:2015 (not modified) |
| CISPR 16-2-3 | NOTE | Approved as EN 55016-2-3 |



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# 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.cencenelec.eu.

*Replace IEC 60601-1-2 and its amendment with:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| 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 |
| + A1 | 2020 | | + A1 | 2021 |
| - | - | | + prAA | |

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*Replace IEC 60601-1 and its amendment with:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| IEC 60601-1 | 2005 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | EN 60601-1 | 2006 |
| - | - | | + corrigendum Mar. | 2010 |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + A12 | 2014 |
| + A2 | 2020 | | + A2 | 2021 |
| - | - | | + A13 | 2024 |

*Replace ISO 15223-1 and its amendment with:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| ISO 15223-1 | 2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements | EN ISO 15223-1 | 2021 |

*Add:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|



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|---|---|---|---|---|
| IEC 60601-1-8 | 2006 | Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | - | - |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + AC | 2014 |
| + A2 | 2020 | | - | - |
| IEC/TR 61000-2-5 | - | Electromagnetic compatibility (EMC) - Part 2-5: Environment - Description and classification of electromagnetic environments | - | - |
| IEC 61000-4-3 | - | Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test | EN IEC 61000-4-3 | - |
| IEC 61000-4-4 | - | Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test | EN 61000-4-4 | - |
| IEC 61000-4-5 | 2014 | Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test | EN 61000-4-5 | 2014 |
| IEC 61000-4-8 | - | Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test | EN 61000-4-8 | - |

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# IEC 60601-2-4

Edition 3.0 2026-09

# INTERNATIONAL STANDARD

AMENDMENT 2

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

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