SLOVENSKI STANDARD
SIST EN 60601-2-4:2011/oprA2:2025

01-februar-2025

Medicinska električna oprema - 2-4. del: Posebne zahteve za osnovno varnost in bistvene lastnosti srčnih defibrilatorjev - Dopolnilo A2

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

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Defibrillatoren

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

Ta slovenski standard je istoveten z: **EN 60601-2-4:2011/prA2:2024**

ICS:

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

SIST EN 60601-2-4:2011/oprA2:2025 **en**

62D/2185/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-4/AMD2 ED3**	
DATE OF CIRCULATION: **2024-12-13**	CLOSING DATE FOR VOTING: **2025-03-07**
SUPERSEDES DOCUMENTS: **62D/2129/CD, 62D/2147A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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Amendment 2 to IEC 60601-2-4:2010 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
XX/XX/FDIS	XX/XX/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 [change language if necessary].

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, [and the ISO/IEC Directives, JTC 1 Supplement] available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

68 # INTRODUCTION to Amendment 2

69 Amendment 2 to the International standard IEC 60601-2-4 has been prepared by IEC
70 subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical
71 committee 62: Medical equipment, software, and systems in medical practice. Amendment 2
72 changes is to align to IEC 60601-1:2005+A1:2012+A2:2020 and IEC 60601-1-2:2014+A1:2020.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object, and related standards

Updated footer 1 with the following text:

[1] The general standard is IEC 60601-1:2005+A1:2012+A2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

201.2 Normative references

Replace the existing fourth paragraph with the following:

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*
IEC 60601-1-2:2014+A1:2020

Add the following paragraph under Addition:

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015+A1:2020

Replace the existing seventh paragraph with the following:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005+A1:2012+A2:2020

Replace the existing eighth paragraph with the following:

ISO 15223-1:2021 *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.*

201.3 Terms and definitions

Replace the existing text in the first paragraph with the following updated text:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014, and IEC 60601-1-2:2014+A1:2020 apply, except as follows:

201.7.2.103 Disposable defibrillator electrodes

Replace the existing text with the following updated text for reference to ISO 15223-1:

a) symbols (in accordance with ISO 15223-1:2021) or a statement indicating the date the electrodes will expire (e.g., "use before ____") and the lot number or the date of manufacture;

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Replace the existing text with the following updated text:

Where the MAXIMUM MAINS VOLTAGE has been assigned the value of 240 V, and the derivation of test voltage from the value of the MAXIMUM MAINS VOLTAGE includes a 110 % multiplier, that multiplier shall not apply.

201.8.5.5.1 * Defibrillation protection

Replace the existing text with the following updated text:

- Differential-mode test

Replacement of the fourth paragraph (“After the operation of S, the peak….”) by the following*:*

201.12.3 ALARM SYSTEMS

New clause for ALARM SYSTEMS with the following text:

Replacement:

RISK MANAGEMENT is used to determine RISK CONTROL measures required for reducing the RISK(S) due to unsatisfactory PATIENT physiological states or unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM, to an acceptable level.

Requirements of IEC 60601-1-8:2006, IEC 60601-1-8:2006+A1:2012 and IEC 60601-1-8:2006+A2:2020 apply when RISK MANAGEMENT has determined a requirement to indicate to the OPERATOR of unsatisfactory physiological PATIENT states or unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM, or to warn the OPERATOR of HAZARDS to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM.

RISK CONTROL measures shall be appropriate for the environment of use and level of OPERATOR training.

Deviations from the alarm standard shall be validated (e.g. usability).

201.101 * Charging time

201.101.1 Requirements for FREQUENT USE, MANUAL DEFIBRILLATORS

Replaced the text in a) with the following text:

a) The time from the MANUAL DEFIBRILLATOR discharging or disarming its ENERGY STORAGE DEVICE to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 15 s under the following conditions:

– when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE.

– when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:

  – the delivery of charge/discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging.

  – the delivery of the maximum number of charge/discharge cycles after which the battery is specified as still useable by the MANUFACTURER.

Replaced the text in b) with the following text:

b) The time from initially switching power on, or from within any OPERATOR programming mode, to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 25 s under the following conditions:

– when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE.

– when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:

  – the delivery of charge/discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging.

  – the delivery of the maximum number of charge/discharge cycles after which the battery is specified as still useable by the MANUFACTURER.

Replaced the text in the last 2 paragraphs with the following single paragraph:

Check compliance with a) and b) above by measurement. In the case of INTERNALLY POWERED ME EQUIPMENT, the test is to start with a new and fully charged battery. In the case of such ME EQUIPMENT also capable of charging the ENERGY STORAGE DEVICE when connected to the SUPPLY MAINS or to a separate battery charger, compliance is also checked when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. In cases with a discharged or missing battery, verify performance is consistent with the markings provided as required by 201.7.2.102.

201.101.2 Requirements for infrequent use, MANUAL DEFIBRILLATORS

Replaced the text in a) with the following text:

a) For the time from the MANUAL DEFIBRILLATOR discharging or disarming its ENERGY STORAGE DEVICE to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy, the following charge time requirements apply:

– the time from the MANUAL DEFIBRILLATOR discharging or disarming its ENERGY STORAGE DEVICE to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 20 s when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE.

– the time from the MANUAL DEFIBRILLATOR discharging or disarming its ENERGY STORAGE DEVICE to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 25 s when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:

  – the delivery of charge/discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging.

  – the delivery of the maximum number of charge/discharge cycles after which is specified as still useable by the MANUFACTURER.

Replaced the text in b) with the following text:

b) For the time from initially switching power on, or from within any OPERATOR programming mode, to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy, the following charge time requirements apply:

– the time from switching power on, or from within any OPERATOR programming mode, to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 30 s when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE.

– the time from switching power on, or from within any OPERATOR programming mode, to the MANUAL DEFIBRILLATOR being ready for discharge at maximum energy shall not exceed 35 s when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:

  – the delivery of charge/discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging.

  – the delivery of the maximum number of charge/discharge cycles after which is specified as still useable by the MANUFACTURER.

Removed the last paragraph.

201.101.3 * Requirements for frequent use, AUTOMATED EXTERNAL DEFIBRILLATORS (AED)

Replaced the text in a) with the following text:

a) The time from activation of the RHYTHM RECOGNITION DETECTOR to the AED being ready for discharge at maximum energy shall not exceed 30 s under the following conditions:

– when the AED is operated on 90 % of the RATED MAINS VOLTAGE;

– when the AED is operated with batteries depleted by whichever of the following conditions comes last:

  – the delivery of charge/discharge cycles until the AED indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging.

  – the delivery of the maximum number of charge/discharge cycles after which is specified as still useable by the MANUFACTURER.