

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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

AMENDMENT 2

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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
62D/2317/FDIS	62D/2327/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. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION to Amendment 2

Amendment 2 to the International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems in medical practice. Amendment 2 changes is to align to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

201.1 Scope, object and related standards

Replace the existing footnote 1 with the following new text:

¹ 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*.

201.2 Normative references

Replace the existing reference to IEC 60601-1-2, modified by Amendment 1, with 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*
IEC 60601-1-2:2014/AMD1:2020

Replace the existing reference to IEC 60601-1, modified by Amendment 1, with 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
IEC 60601-1:2005/AMD2:2020

Replace the existing reference to ISO 15223-1, modified by Amendment 1, with the following new reference:

ISO 15223-1:2021, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*

Add the following normative references:

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

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*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test*

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test*

IEC 61000-4-8, *Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test*

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/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

201.7.2.103 Disposable defibrillator electrodes

Replace, in the existing item a), modified by Amendment 1, "ISO 15223-1:2007" with "ISO 15223-1:2021".

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Replace, in the existing last paragraph, modified by Amendment 1, "250 V" with "240 V".

201.8.5.5.1 * Defibrillation protection

Replace the existing second sentence that reads "Replacement of the third paragraph ("After the operation of S, the peak...") by the following:" with the following:

Replacement of the second-to-last paragraph ("After the operation of S, the peak....") by the following:

Add, at the end of the existing Subclause 201.12.2.102, the following new Subclause 201.12.3 and text:

201.12.3 * ALARM SYSTEMS

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/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 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**

Replace the entire existing text of this subclause, including items a) and b), modified by Amendment 1, with the following new 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:
 - 1) when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE;
 - 2) when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:
 - i) the delivery of charge and discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging;
 - ii) the delivery of the maximum number of charge and discharge cycles after which the battery is specified as still useable by the MANUFACTURER.
- 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:
 - 1) when the MANUAL DEFIBRILLATOR is operated on 90 % of the RATED MAINS VOLTAGE;
 - 2) when the MANUAL DEFIBRILLATOR is operated with batteries depleted by whichever of the following conditions comes last:

- i) the delivery of charge and discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging;
- ii) the delivery of the maximum number of charge and discharge cycles after which the battery is specified as still useable by the MANUFACTURER.

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

Replace the entire existing text of this subclause, including items a) and b), with the following new 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:
 - 1) 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;
 - 2) 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:
 - i) the delivery of charge and discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging;
 - ii) the delivery of the maximum number of charge and discharge cycles after which is specified as still useable by the MANUFACTURER.
- 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:
 - 1) 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;
 - 2) 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:
 - i) the delivery of charge and discharge cycles until the MANUAL DEFIBRILLATOR indicates when non-rechargeable batteries require replacement or rechargeable batteries require recharging;
 - ii) the delivery of the maximum number of charge and discharge cycles after which is specified as still useable by the MANUFACTURER.