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

IEC 60601-2-4:2010-12/AMD1:2018-02(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.10

ISBN 978-2-8322-5376-2

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- withdrawn,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".

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Add, after 201.8.3, the following new subclause:

201.8.5.3 * MAXIMUM MAINS VOLTAGE

Addition:

Where the MAXIMUM MAINS VOLTAGE has been assigned the value of 250 V, and the derivation of test voltage from the value of the MAXIMUM MAINS VOLTAGE includes a 110 % multiplier, that multiplier shall not apply.

201.8.7.1 General requirements

Replace the existing instruction by the following new instruction:

Replacement of b) dash 4 with:

201.8.8.3 * Dielectric strength

Replace, in the "Addition" section, the first existing paragraph by the following new paragraph:

For the DEFIBRILLATOR and PACER high-voltage circuits, between high-voltage parts of opposite polarity and high-voltage to low-voltage circuits, the following tests shall replace those of the general standard.

Delete, in the second paragraph in the "Addition" section, the words "during discharging".

Replace, in the fifth paragraph of Test 1, the term "DEFIBRILLATOR" by "DEFIBRILLATOR or PACER".

Replace, in the seventh paragraph of Test 1, the term "DEFIBRILLATORS" by "DEFIBRILLATORS or PACERS".

Add, after the last paragraph of the Subclause, the following new paragraph:

For the dielectric tests of the general standard, the WORKING VOLTAGE is determined without regard to the presence of defibrillation or pacing voltages.

201.8.9.1.5 * ME EQUIPMENT RATED for high altitudes

Replace the existing paragraph by the following new paragraph:

General standard subclause 8.9.1.5 does not apply to DEFIBRILLATORS rated for use at altitudes up to 5 000 m.

201.8.9.1.101 * DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

Delete, in the note, the words "but is under consideration for future application".

Replace the existing item b), excluding the compliance statement, by the following new paragraphs:

b) * Except for components where the adequacy of ratings can be demonstrated (e.g. by component manufacturers' ratings or by the dielectric strength tests of 201.8.8.3 of this standard) the CREEPAGE DISTANCES and AIR CLEARANCES of insulation between the DEFIBRILLATOR or PACER high-voltage circuits and other parts, and between different parts of the high-voltage circuits, shall be at least 3 mm/kV.

This requirement shall also apply to the isolating means between the high-voltage circuit of the DEFIBRILLATOR or PACER and other PATIENT circuits.

201.12.3 ALARM SYSTEMS

Delete the entire subclause, including 201.12.3.101.

201.12.4 Protection against hazardous output

Add, after 201.12.4.103, the following new subclause:

201.12.4.104 * Audible warnings prior to energy delivery

The DEFIBRILLATOR shall include an audible warning signal that indicates the DEFIBRILLATOR is preparing to or is about to deliver energy to the PATIENT. The preparing-to or about-to-deliver-energy-to-the-patient warning shall not be capable of being inhibited by the OPERATOR or RESPONSIBLE ORGANIZATION. The warning shall occur:

a) for manual DEFIBRILLATORS and AEDs with OPERATOR activated discharge control, when the discharge control is active;

b) for AEDs with automatic discharge control, at least 5 s prior to energy delivery.

The effectiveness of the audible warnings to mitigate the risk of unintentional energy delivery to the OPERATOR or bystander shall be included in the RISK MANAGEMENT FILE.

201.15.4.3.101 * Non-rechargeable battery replacement

Replace the existing title by the following new title:

201.15.4.3.101 * Battery replacement

201.101.1 Requirements for FREQUENT USE, MANUAL DEFIBRILLATORS

Replace, in the third paragraph, "201.7.2.101" *by* "201.7.2.102"*.*

201.101.4 * Requirements for INFREQUENT USE, AUTOMATED EXTERNAL DEFIBRILLATORS

Replace the existing paragraph before the last by the following new paragraph:

In case of a DEFIBRILLATOR *with non-rechargeable batteries, the test is to start with a battery depleted by the delivery of the number of charge/discharge cycles after which it is specified as still useable by the MANUFACTURER, or when the ME EQUIPMENT indicates that the battery needs replacement, whichever comes first.*

201.102.3.1 FREQUENT USE AED

Add, after the first paragraph, the following new paragraphs:

If the AED is incapable of meeting one of the above criteria due to the implementation of a fixed protocol which does not meet the above criteria, select and use the available protocol that most closely matches one of the provided criteria.

For a FREQUENT USE AED with a pre-programmed energy setting sequence, not changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the pre-programmed setting. In case of pre-programmed energy setting sequence being changeable by the OPERATOR or RESPONSIBLE ORGANIZATION, the AED shall be able to deliver 20 defibrillation discharges at the maximum energy setting sequence selectable.

201.102.3.2 INFREQUENT USE AED

Add, after the first paragraph, the following new paragraph:

If the AED is incapable of meeting one of the above criteria due to the implementation of a fixed protocol which does not meet the above criteria, select and use the available protocol that most closely matches one of the provided criteria.

201.105.1 ECG signal derived via DEFIBRILLATOR ELECTRODES

Add, after the second paragraph, the following new paragraph:

If the AED incorporates a CPR interval after a shock within the pre-programmed defibrillation sequence, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s after the minimum CPR interval setting.

201.105.3 ECG signal derived via non-reusable DEFIBRILLATOR ELECTRODES

Add, after the last paragraph, the following new paragraph:

If the AED incorporates a CPR interval after a shock within the pre-programmed defibrillation sequence, the ECG shall be correctly interpreted by the ECG RHYTHM RECOGNITION DETECTOR 20 s after the minimum CPR interval setting.

201.106 * Disturbance to the MONITOR from charging or internal discharging

Add, after item c) of the third paragraph, the following new paragraph:

If necessary, a capacitor may be added in parallel with the 5 kΩ impedance for tests b) and c) above such that the device operates within its valid patient impedance range. If used, the capacitor shall be the minimum value required to achieve a valid patient impedance. The value of the capacitor and the rationale for the selected value shall be disclosed in the test report.

201.108.1.1 * AC small signal impedance

Replace the first two existing paragraphs by the following new paragraphs:

The 10 Hz impedance for any of at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak, shall not exceed 3 kΩ. The impedance at 30 kHz shall be less than 10 Ω.

Reference: ANSI/AAMI EC12, Section 4.2.2.1 on sample size and failure rate.

Compliance is checked by connecting a pair of electrodes, gel-to-gel, applying a 10 Hz sinusoidal current of known amplitude not exceeding 100 μA p-p and observing the amplitude of the resulting voltage across the electrodes. The magnitude of the impedance is the ratio of the voltage to that of the current. An adequate current generator can be assembled utilizing a sinusoidal signal (voltage) generator with a resistor in series with the electrode pair. The value of the resistor should be at least 10 times the value of the electrode impedance.

201.108.1.2 * AC large signal impedance

Replace, in the first paragraph, "3 Ω" *by* "5 Ω".

Replace, in the second paragraph, "3:50" *by* "5:50".

201.108.1.3 * Combined offset instability and internal noise

Delete the entire subclause.

201.108.1.4 * Defibrillation recovery

Replace the existing paragraph by the following new paragraphs:

The potential of a pair of gel-to-gel electrodes in series with a 50 Ω resistor and subjected to three shocks at 360 J or maximum energy at 1 min intervals shall not exceed 500 mV at 4 s and 400 mV at 60 s after the last shock delivery.

When this test is executed after pacing according to 201.108.1.10 c) the potential shall not exceed 1 000 mV at 4 s and 750 mV at 60 s.

201.108.1.9 * Packaging and shelf life

Replace the existing two paragraphs by the following new paragraphs:

The electrodes shall be manufactured and packaged in such a way that all requirements of this standard shall be met up to the expiration date and under the storage conditions specified by the MANUFACTURER. At a minimum, electrodes shall comply with all performance specifications after storage for 1 year at 35 °C. One-year storage may be simulated by accelerated testing at higher temperatures. Electrodes shall comply after storage for 24 h at −30 °C and for 24 h at +65 °C. Electrodes shall be returned to a temperature in the range of 15 °C to 35 °C before the test for compliance is performed. Electrodes shall be tested at both 15 °C and 35 °C.

Compliance is checked by conducting the tests of 201.108.1.1 through 201.108.1.8 at the end of the specified shelf life and at both 15 °C and 35 °C.

201.108.1.10 * Universal-function electrodes

Replace the last existing paragraph by the following new paragraph:

Compliance is checked by the electrodes meeting these requirements or shall be met by the disclosure of the performance to each specification: 201.108.1.1 to 201.108.1.4 following an hour of pacing. Tests shall be conducted immediately after the conclusion of pacing.

201.108.1.11 * Cable length

Replace the first sentence of the first existing paragraph by the following new sentence:

The electrode cables shall have an extended length of at least 2 m for monitor/DEFIBRILLATORs (e.g. hospital crash cart), and a length of at least 1 m for AEDs.

201.109 * External pacing (U.S.)

Delete, in the title, the words "(U.S.)".

201.109.2.1 Separate pacing pathway

Replace, in item (1) of the second existing paragraph, the reference "Figure US.2" *by* "Figure 201.109".

201.109.7 Demand pacing

Add, after the last paragraph of the subclause, the following new paragraphs:

Set the pacing rate to its maximum rate. Input ECG with maximum rate +10 %. The unit shall not have pacing activated. Change the ECG signal rate to maximum rate −10 %. The unit shall now have pacing activated.

Set the pacing rate to its minimum rate. Input ECG with minimum rate +10 %. The unit shall not have pacing activated. Change the ECG signal rate to minimum rate −10 %. The unit shall now have pacing activated.

201.109.8 Pacer lead-off indication

Delete Figure 201.109.

Figure 201.110 – Test circuit for DEFIBRILLATOR overload test of pacing output circuitry

Replace, in the key to the figure, the existing L and R + R_L values by the following new values:

L = 500 μH

R + R_L ≤ 10 Ω (R_L represents the d.c. resistance of inductor L)

202 * Electromagnetic compatibility – Requirements and tests

Replace, in the first sentence, the reference "IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014".

202.6.2.3.2 Tests

Add, in the title, an asterisk before the word "Tests".

Replace the first sentence of the existing paragraph before the last by the following new sentences:

** The DEFIBRILLATOR ELECTRODES are terminated in a simulated PATIENT load (1 kΩ resistor in parallel with a 1 μF capacitor) and, if necessary, an additional resistor and capacitor parallel combination in series such that the device operates within its valid patient impedance range. If used, the additional resistor and capacitor values shall be disclosed in the test report.*

Annex AA
(informative)

Particular guidance and rationale

Subclause 201.7.2.101 – Concise operating instructions

Add, after the existing paragraph, the following new paragraph:

The monitoring of a PATIENT's ECG is considered relevant where the ECG is needed to either deliver defibrillation therapy, or to make the determination that the delivery of defibrillation therapy is needed.

Add, after Subclause 201.8.3, the following new paragraph:

Subclause 201.8.5.3 – MAXIMUM MAINS VOLTAGE

This clarifies the definition in order to retain the test voltage of 250 V, which is considered to be sufficient for INTERNALLY POWERED ME EQUIPMENT with no means of connection to the SUPPLY MAINS, or ME EQUIPMENT with a connection to SUPPLY MAINS where the RATED supply voltage is less than 100 V.

Subclause 201.8.8.3 – Dielectric strength

Replace the first existing paragraph by the following new paragraphs:

Voltage spikes on the SUPPLY MAINS will not appreciably affect the voltage on the energy storage capacitor; therefore, a moderate test voltage relative to the PEAK WORKING VOLTAGE of the DEFIBRILLATOR or PACER high-voltage circuits was considered to be sufficient. The removal of defibrillation or pacing voltages from the calculation of WORKING VOLTAGE for the tests of the general standard ensure that all other tests (e.g. between APPLIED PARTS and MAINS PART) remain in effect, while the tests of this standard are appropriate to ensure the safety of the defibrillation and pacing circuits.

In the general standard, earthing of the PATIENT is not considered to be a fault condition; consequently, the situation where one side of the APPLIED PART is connected to earth had to be included.

*Replace, in the existing subclause, the eight occurrences of the term "*DEFIBRILLATOR*" by "*DEFIBRILLATOR or PACER*".*

Subclause 201.8.9.1.5 – ME EQUIPMENT RATED for high altitudes

Delete, in the existing paragraph, the last sentence.

Subclause 201.8.9.1.101 – DEFIBRILLATOR ELECTRODES, high-voltage circuits and cables

Add, in item b), the following new text:

The defibrillation and pacing circuits, typically both comprised of CHARGING CIRCUITS, DISCHARGING CIRCUITS, ENERGY STORAGE DEVICES, etc., may be combined or separate depending on the architecture of the DEFIBRILLATOR.

For those pacing circuits which utilize the same energy delivery circuits as the DEFIBRILLATOR, and where the DEFIBRILLATOR WORKING VOLTAGE used in calculating the CREEPAGE DISTANCES and AIR CLEARANCES is larger than the WORKING VOLTAGE for the PACER, there is no need to duplicate the testing at the lower voltage.

For those pacing circuits which have their own dedicated energy delivery circuits separate from the DEFIBRILLATOR, the maximum peak voltage present during pacing in NORMAL USE is used in calculating the CREEPAGE DISTANCES and AIR CLEARANCES. This should include the worst-case level of superimposed ripple and overshoot that can be present during NORMAL USE.

In those cases where a component or insulation which is a sub-part of a combined energy delivery circuit is only exposed to pacing voltages, only pacing voltages should be considered for that particular component or insulation.

Subclause 201.12.3.101 – Audible warnings prior to energy delivery

Delete the entire subclause.

Add, after Subclause 201.12.4.103, the following new paragraph:

Subclause 201.12.4.104 – Audible warnings prior to energy delivery

The term "warning" was chosen to differentiate from an alarm associated with patient monitoring.

Adequate OPERATOR warning prior to discharge is important. However, it is possible to charge safely even though discharge may not be imminent. Because charging may be an internal "background" function of the device, it is more important to the OPERATOR to be warned of impending external events, such as energy delivery. Of more relevance to the OPERATOR is the following.

a) If the DEFIBRILLATOR is manual or semi-automatic, audible warnings are needed when the DEFIBRILLATOR becomes fully armed and ready to shock. This allows the OPERATOR and any bystanders to prepare for the shock.

b) If the DEFIBRILLATOR is fully automatic, audible warnings at least 5 s prior to discharge are needed to allow time to cease touching the PATIENT.

Audible warnings can be provided as voice prompts, audible tones, or both.

It is highly recommended that the audible warnings prior to energy delivery also be accompanied by a visual indication.

Subclause 201.15.4.3.101 – Non-rechargeable battery replacement

Replace the existing title by the following new title:

Subclause 201.15.4.3.101 – Battery replacement

Subclause 201.108.1.3 – Combined offset instability and internal noise

Delete the entire subclause.

Subclause 201.108.1.9 – Packaging and shelf life

Add, after the last existing paragraph, the following new paragraph:

The operating temperature range for AEDs is typically 0 °C to 50 °C. Near freezing, a pair of hydrogel electrodes placed gel-to-gel exhibit very high impedances due to their water content. However, when placed on the chest, they readily equilibrate with body skin temperature (~33 °C). At the higher temperatures, there is less resistance to ionic flow and the gel-to-gel hydrogel electrode pair exhibit lower impedances than at room temperature. Again, when placed on skin, the electrodes' temperature will approach skin temperature. Thus,