IEC 60601-2-4

Edition 3.0 2010-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2002. This edition constitutes a technical revision, revised to structurally align it with IEC 60601-1:2005 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;

- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match IEC 60601-1-2, third edition.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/857/FDIS	62D/878/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site 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.

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

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27 [2][2]). 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.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for cardiac defibrillators as defined in 201.3.202.

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1 The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

2 Numbers in square brackets refer to the bibliography.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general

standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 73.

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

ISO 15223-1:2007, *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

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

Addition:

NOTE An index of defined terms is found beginning on page 74.

201.3.201
AUTOMATED EXTERNAL DEFIBRILLATOR
AED
DEFIBRILLATOR that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the patient's skin identifies shockable cardiac rhythms, and automatically operates the DEFIBRILLATOR when a shockable rhythm is detected, hereinafter referred to as an AED

NOTE AEDs may provide varying levels of automation and be referred to by various terms. A semi-automatic DEFIBRILLATOR requires manual shock activation. A fully automatic DEFIBRILLATOR will provide shock without OPERATOR intervention.

201.3.202
CARDIAC DEFIBRILLATOR
MEDICAL ELECTRICAL EQUIPMENT intended to normalize the rhythm of the heart by an electrical pulse via electrodes applied either to the PATIENT's skin with external electrodes or to the exposed heart with internal electrodes

NOTE 1 A CARDIAC DEFIBRILLATOR can be referred to in this standard as a DEFIBRILLATOR or as ME EQUIPMENT.

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions.

201.3.203
CHARGING CIRCUIT
circuit within the DEFIBRILLATOR intended for charging the ENERGY STORAGE DEVICE. This circuit includes all parts conductively connected to the ENERGY STORAGE DEVICE during the charging period

201.3.204
DEFIBRILLATOR ELECTRODE
electrode intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation

NOTE DEFIBRILLATOR ELECTRODES may also provide other monitoring (e.g. ECG acquisition) or therapeutic (e.g. transcutaneous pacing) functions and may be disposable or reusable.

201.3.205
DELIVERED ENERGY
energy which is delivered through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value

201.3.206
DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which connects the ENERGY STORAGE DEVICE to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

201.3.207
DUMMY COMPONENT
test replacement for moulded components like transformers, resistors, semiconductors etc.

NOTE The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test, but provides dielectric isolation. The volume may lack parts of the original components (for example: semiconductor die, transformer cores and windings). The DUMMY COMPONENT makes it possible to test creepage, clearance and dielectric strength with the correct geometry without exceeding the internal maximum voltage of the part being replaced. The DUMMY COMPONENT shall be identical to the component replaced with respect to conductive external details such as metal legs, pins etc.

201.3.208
DEFIBRILLATOR TESTER

instrument capable of measuring the energy output from a CARDIAC DEFIBRILLATOR while generating a simulated ECG output to the CARDIAC DEFIBRILLATOR

201.3.209
ENERGY STORAGE DEVICE
component that is charged with the energy necessary to deliver an electrical defibrillation pulse to the PATIENT

NOTE A capacitor is a typical example of the component.

201.3.210
FREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure more than 2 500 discharges (see 201.103)

201.3.211
INFREQUENT USE
term used to describe a DEFIBRILLATOR designed to endure less than 2 500 discharges (see 201.103)

201.3.212
INTERNAL DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

201.3.213
MANUAL DEFIBRILLATOR
DEFIBRILLATOR capable of being manually operated by the OPERATOR for selection of energy, charging and discharging

201.3.214
MONITOR
part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this particular standard to distinguish such a MONITOR from one which forms a separate ME EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

201.3.215
RHYTHM RECOGNITION DETECTOR
RRD
a system that analyzes the ECG and identifies whether a cardiac rhythm is shockable

NOTE The algorithm in an AED is designed for sensitivity and specificity for the detection of arrhythmias for which a defibrillation shock is clinically indicated. May be referred to as RRD.

201.3.216
SELECTED ENERGY
energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an automatic protocol

201.3.217
SEPARATE MONITORING ELECTRODE
electrode applied to the PATIENT for the purpose of monitoring the PATIENT

NOTE These electrodes are not used to apply defibrillation pulses to the PATIENT.

201.3.218
STAND-BY
mode of operation in which the ME EQUIPMENT is operational except that the ENERGY STORAGE DEVICE is not yet charged

201.3.219
STORED ENERGY
energy which is stored in the DEFIBRILLATOR ENERGY STORAGE DEVICE

201.3.220
SYNCHRONIZER
device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

201.4.2.101 * Additional RISK MANAGEMENT requirements

MANUFACTURER shall address readiness for use in the RISK MANAGEMENT FILE.

Check compliance by inspection of RISK MANAGEMENT FILE.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Each of the three capabilities listed in Table 201.101, when included in a defibrillator, will be considered ESSENTIAL PERFORMANCE.

Where engineering judgement by the MANUFACTURER specifies performance in excess of ESSENTIAL PERFORMANCE, that performance may be degraded by external factors such as EMC, as long as the RISK MANAGEMENT FILE documents that ESSENTIAL PERFORMANCE is met.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	
Description	**(Sub)clause**
Deliver defibrillation therapy	201.12.1
Deliver synchronized defibrillation therapy	201.104
Accurately differentiate between shockable and nonshockable rhythms	201.107

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition:

aa) The test required in 201.102.2 and 201.102.3 shall be performed at an ambient temperature of 0 °C ± 2 °C.

201.5.4 Other conditions

Addition:

aa) Unless otherwise specified in this standard, all tests apply to all kinds of DEFIBRILLATOR types (manual, AEDs, INFREQUENT USE and FREQUENT USE DEFIBRILLATORS).

201.5.8 Sequence of tests

Addition:

The endurance test required in Clause 201.103 shall be performed after the test for excessive temperatures (see B.19 of the general standard).

The tests required in Clauses 201.101, 201.102, 201.104, 201.105 and 201.106 shall be performed after test B.35 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 * Electrical input power from the SUPPLY MAINS

Replacement of paragraph beginning "If the rating of ME EQUIPMENT includes ...":

The RATED power input of mains operated ME EQUIPMENT shall be the maximum value attained by averaging the power input over any period of 2 s.

Additional subclauses:

201.7.2.101 * Concise operating instructions

Instructions for defibrillating, and where relevant, monitoring a PATIENT'S ECG, shall be provided by means of either clearly legible markings, or clearly understandable auditory commands.

Check compliance of auditory commands by the following test:

Auditory commands shall be clearly understandable to a person of normal hearing from a distance of 1 m in an ambient white noise (defined as flat ±10 % over the range 100 Hz to 10 kHz) level of 65 dB, as measured with a Type 2 A-weighted sound level meter (see IEC 61672-1).

201.7.2.102 * INTERNALLY POWERED ME EQUIPMENT

INTERNALLY POWERED ME EQUIPMENT and any separate battery charger shall be marked with brief instructions for, as appropriate, the re-charging or replacement of the battery.

If a connection to the SUPPLY MAINS or to a separate battery charger is provided, the ME EQUIPMENT shall be marked to indicate any limitations of operation when the ME EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. Such marking shall include a description of the function as well as any limitations of operation of the ME EQUIPMENT with a discharged or missing battery.

201.7.2.103 Disposable defibrillator electrodes

The labelling accompanying the electrode package shall include, at a minimum, the following information:

a) symbols (in accordance with ISO 15223-1:2007) or a statement indicating the date the electrodes will expire (e.g., "use before ____") and the lot number or the date of manufacture;

b) appropriate cautions and warnings, including limits on duration of electrode application and a caution that the unit package shall not be opened until immediately prior to use, if applicable;

c) appropriate instructions for use, including procedures for skin preparation;

d) instructions describing storage requirements, if applicable.

201.7.4 Marking of controls and instruments

Additional subclause: