

FINAL VERSION

VERSION FINALE

**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**

CONTENTS

FOREWORD.....	4
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions.....	9
201.4 General requirements.....	12
201.5 General requirements for testing of ME EQUIPMENT.....	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	13
201.7 ME EQUIPMENT identification, marking and documents.....	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	17
201.9 Protection against MECAHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	24
201.10 Protection against unwanted and excessive radiation HAZARDS.....	24
201.11 Protection against excessive temperatures and other HAZARDS.....	24
201.12 * Accuracy of controls and instruments and protection against hazardous outputs	26
201.13 HAZARDOUS SITUATIONS and fault conditions	28
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	28
201.15 Construction of ME EQUIPMENT	28
201.16 ME SYSTEMS.....	32
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	32
201.101 * Charging time	32
201.102 INTERNAL ELECTRICAL POWER SOURCE.....	35
201.103 * Endurance	37
201.104 * SYNCHRONIZER	37
201.105 * Recovery of the MONITOR and/or ECG input after defibrillation.....	38
201.106 * Disturbance to the MONITOR from charging or internal discharging.....	42
201.107 * Requirements for RHYTHM RECOGNITION DETECTOR	43
201.108 DEFIBRILLATOR ELECTRODES.....	44
201.109 * External pacing.....	46
202 * Electromagnetic compatibility – Requirements and tests.....	50
Annexes	53
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	54
Annex A (informative) Particular guidance and rationale.....	56
Annex B (informative) Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010	71
Bibliography.....	76
Index of defined terms used in this particular standard.....	77
Figure 201.101 – Dynamic test for limitation of energy from different parts of the ME EQUIPMENT	19
Figure 201.102 – Allowed current versus applied test voltage	23
Figure 201.103 – Examples of cord anchorages that require testing	31
Figure 201.104 – Test apparatus for flexible cords and their anchorages.....	32

Figure 201.105 – Arrangement for test of recovery after defibrillation	40
Figure 201.106 – Arrangement of monitoring electrodes on sponge	41
Figure 201.107 – Arrangement for recovery test after defibrillation	41
Figure 201.108 – Arrangement for test of disturbance from charging and internal discharging	43
Figure 201.110 – Test circuit for DEFIBRILLATOR overload test of pacing output circuitry	50
Figure AA.1 – Simulated PATIENT Load	70
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	12
Table 201.102 – RHYTHM RECOGNITION DETECTOR CATEGORIES	43
Table 201.C.101 – Marking on the outside of a CARDIAC DEFIBRILLATOR or its parts.....	54
Table 201.C.102 – Marking of controls and instruments of a CARDIAC DEFIBRILLATOR	54
Table 201.C.103 – ACCOMPANYING DOCUMENTS, general	54
Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use	55
Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description	55
Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010	71

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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This Consolidated version of IEC 60601-2-4 bears the edition number 3.1. It consists of the third edition (2010-12) [documents 62D/857/FDIS and 62D/878/RVD] and its amendment 1 (2018-02) [documents 62D/1549/FDIS and 62D/1555/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

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 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 50 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.

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 the base publication and its amendment 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 standard¹ 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, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [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 heart detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.10.8 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.

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, efficiency, 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.

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.