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REDLINE VERSION

colour inside

Medical electrical equipment –
Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

FOREWORD 4
INTRODUCTION 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 * Terms and definitions 10
201.4 General requirements 12
201.5 General requirements for testing ME EQUIPMENT 13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 13
201.7 ME EQUIPMENT identification, marking and documents 14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 17
201.9 Protection against MECHANICAL 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 25
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 30
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 30
201.15 Construction of ME EQUIPMENT 30
201.16 ME SYSTEMS 30
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 30
202 * ELECTROMAGNETIC ~~compatibility~~ DISTURBANCES – Requirements and tests 30
Annexes 33
Annex I Identification of IMMUNITY pass/fail criteria 33
Annex AA (informative) Particular guidance and rationale 34
Bibliography 55
Index of defined terms used in this particular standard 56

Figure 201.101 – Test waveform V_{test} implemented by example RCL circuit using C = 120 µF, L = 25 µH, $RL + R$ = 1 Ω 18
Figure 201.102 – Example circuit of defibrillation test voltage generator for generating a decaying exponential waveform 19
Figure 201.103 – Test setup for a SINGLE CHAMBER external CARDIAC PACEMAKER 20
Figure 201.104 – Test setup for a DUAL CHAMBER external CARDIAC PACEMAKER 20
Figure 201.105 – Test setup for a triple chamber external CARDIAC PACEMAKER, e.g. bi-ventricular external CARDIAC PACEMAKER 21
Figure 201.106 – Timing sequence 21
Figure 201.~~101~~107 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE 23
Figure 201.~~102~~108 – Measuring circuit for the MAXIMUM TRACKING RATE 27
Figure 201.~~103~~109 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE 28
Figure AA.1 – Simple model of a SINGLE CHAMBER EXTERNAL PACEMAKER during defibrillation 41

Figure AA.2 – First proposal for a defib-protection test of SINGLE CHAMBER EXTERNAL PACEMAKER 44
Figure AA.3 – Circuit for a defibrillation test generator for defibrillation test according to conditions during open heart surgery 45
Figure AA.4 – Defibrillation PULSE generated by the defibrillation test generator from Figure AA.3 46
Figure AA.5 – Rise times of a defibrillation PULSE according to the circuit proposed in Figure AA.3 50

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements 13
Table 201.102 – DUAL CHAMBER connector terminal marking 14
Table 201.103 – ~~Measurement method accuracy~~ ME EQUIPMENT parameters 25
Table 202.101 – Static discharge requirements 31
Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory 35
Table AA.2 – PULSE energies calculated for *C* = 120 µF ± 5 % 47
Table AA.3 – PULSE energies calculated for *C* = 122 µF ± 5 % 48
Table AA.4 – PULSE energies calculated for *C* = 126,32 µF ± 5 % 49

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

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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This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International standard IEC 60601-2-31 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC6: Active implants, of ISO technical committee 150: Implants for surgery.

This publication is published as a double logo standard.

This third edition cancels and replaces the second edition published in 2008 and Amendment 1:2011. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) The requirement for testing for energy reduction has been removed;
b) The test for exposure to external defibrillation has been completely revised;
c) The exclusion for testing ESD immunity only with respect to air discharges has been removed;
d) Alignment with the latest edition of ISO 14708-2 for pacemakers, as well as the associated EMC standard ISO 14117;
e) Additional rationale for all changes.

The text of this International Standard is based on the following documents of IEC:

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– 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.

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– "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.);
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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.

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

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of EXTERNAL ~~cardiac~~ PACEMAKERS with an internal power source.

Basically, CARDIAC PACEMAKERS treat cardiac arrhythmias. Such arrhythmias reduce cardiac output and can lead to confusion, dizziness, loss of consciousness and death. The objective of pacing is to restore cardiac rhythm and output appropriate to the PATIENT's physiological needs.

There are two distinct families of CARDIAC PACEMAKERS, implantable PACEMAKERS and EXTERNAL PACEMAKERS. EXTERNAL PACEMAKERS are used to pace PATIENTS temporarily prior to implanting an implantable PACEMAKER as well as for temporary pacing related to other medical PROCEDURES, e.g. open heart surgery.

CARDIAC PACEMAKERS differ in the various ways in which they maintain and monitor cardiac activity in different circumstances. The simplest model stimulates the atrium or ventricle independently of the cardiac activity; others detect atrial or ventricular activity and stimulate the atrium or ventricle as and when this is necessary; others, more complex, detect the spontaneous heart activity and stimulate appropriately the atrium and/or the ventricle. Certain PACEMAKERS work on preset frequency values, amplitudes and impulse duration. Others can have several values for parameters.

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in ~~selecting~~ developing and applying these devices. It is through these aspects of standardization that the central role of clinical experience should be, or has been, acknowledged. The ability to predict how a PACEMAKER will perform in a specific PATIENT based on testing of a device to a set of technical criteria is limited.

This particular standard does not take into consideration the specific safety aspects of EXTERNAL PACEMAKERS that are connected to a SUPPLY MAINS while simultaneously connected to the PATIENT.

This particular standard amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard ~~(see 1.4)~~.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

An inventory of the PATIENT's safety posed by EXTERNAL PACEMAKERS and a rationale for the safety requirements contained in this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of ~~the~~ this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of EXTERNAL PACEMAKERS powered by an INTERNAL ELECTRICAL POWER SOURCE, hereafter referred to as ME EQUIPMENT.

This document applies to PATIENT CABLES as defined in 201.3.~~109~~209, but does not apply to LEADS as defined in 201.3.206.

~~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 within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document does not apply to the implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES covered by ISO 14708-1. This document does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This document does not apply to transthoracic and oesophageal pacing ME EQUIPMENT and antitachycardia ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS as defined in ~~201.3.103~~ 201.3.205.

201.1.3 Collateral standards

Addition:

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[1] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 60601-1-2:2014 applies as modified in Clause 202. IEC 60601-1-3 does not apply. 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 and applicable collateral standards 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 3.147, additional definitions in this document 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 document" 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.

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

Replacement:

IEC 60601-1-2:~~2007~~2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

Addition:

~~ANSI/AAMI PC69:2007, *Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*~~

~~NOTE Informative references are listed in the bibliography on page 34.~~

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

ISO 14117:2019, *Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

ISO 14708-2:~~2005~~2019, *Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers*

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INTERNATIONAL STANDARD

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Medical electrical equipment –
Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

Appareils électromédicaux –
Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne



IEC 60601-2-31:2020-01(en-fr)

CONTENTS

FOREWORD 4
INTRODUCTION 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 * Terms and definitions 10
201.4 General requirements 12
201.5 General requirements for testing ME EQUIPMENT 13
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
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201.11 Protection against excessive temperatures and other HAZARDS 23
201.12 Accuracy of controls and instruments and protection against hazardous outputs 24
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 29
201.15 Construction of ME EQUIPMENT 29
201.16 ME SYSTEMS 29
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 29
202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests 29
Annexes 31
Annex I Identification of IMMUNITY pass/fail criteria 31
Annex AA (informative) Particular guidance and rationale 32
Bibliography 52
Index of defined terms used in this particular standard 53

Figure 201.101 – Test waveform V_{test} implemented by example RCL circuit using C = 120 µF, L = 25 µH, $RL + R$ = 1 Ω 18
Figure 201.102 – Example circuit of defibrillation test voltage generator for generating a decaying exponential waveform 19
Figure 201.103 – Test setup for a SINGLE CHAMBER external CARDIAC PACEMAKER 20
Figure 201.104 – Test setup for a DUAL CHAMBER external CARDIAC PACEMAKER 20
Figure 201.105 – Test setup for a triple chamber external CARDIAC PACEMAKER, e.g. bi-ventricular external CARDIAC PACEMAKER 21
Figure 201.106 – Timing sequence 21
Figure 201.107 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE 23
Figure 201.108 – Measuring circuit for the MAXIMUM TRACKING RATE 26
Figure 201.109 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE 27
Figure AA.1 – Simple model of a SINGLE CHAMBER EXTERNAL PACEMAKER during defibrillation 39

Figure AA.2 – First proposal for a defib-protection test of SINGLE CHAMBER EXTERNAL PACEMAKER 41
Figure AA.3 – Circuit for a defibrillation test generator for defibrillation test according to conditions during open heart surgery 42
Figure AA.4 – Defibrillation PULSE generated by the defibrillation test generator from Figure AA.3 43
Figure AA.5 – Rise times of a defibrillation PULSE according to the circuit proposed in Figure AA.3 47

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements 12
Table 201.102 – DUAL CHAMBER connector terminal marking 14
Table 201.103 – ME EQUIPMENT parameters 25
Table 202.101 – Static discharge requirements 30
Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory 33
Table AA.2 – PULSE energies calculated for *C* = 120 µF ± 5 % 44
Table AA.3 – PULSE energies calculated for *C* = 122 µF ± 5 % 45
Table AA.4 – PULSE energies calculated for *C* = 126,32 µF ± 5 % 46

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Basically, CARDIAC PACEMAKERS treat cardiac arrhythmias. Such arrhythmias reduce cardiac output and can lead to confusion, dizziness, loss of consciousness and death. The objective of pacing is to restore cardiac rhythm and output appropriate to the PATIENT's physiological needs.

There are two distinct families of CARDIAC PACEMAKERS, implantable PACEMAKERS and EXTERNAL PACEMAKERS. EXTERNAL PACEMAKERS are used to pace PATIENTS temporarily prior to implanting an implantable PACEMAKER as well as for temporary pacing related to other medical PROCEDURES, e.g. open heart surgery.

CARDIAC PACEMAKERS differ in the various ways in which they maintain and monitor cardiac activity in different circumstances. The simplest model stimulates the atrium or ventricle independently of the cardiac activity; others detect atrial or ventricular activity and stimulate the atrium or ventricle as and when this is necessary; others, more complex, detect the spontaneous heart activity and stimulate appropriately the atrium and/or the ventricle. Certain PACEMAKERS work on preset frequency values, amplitudes and impulse duration. Others can have several values for parameters.

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in developing and applying these devices. It is through these aspects of standardization that the central role of clinical experience should be, or has been, acknowledged. The ability to predict how a PACEMAKER will perform in a specific PATIENT based on testing of a device to a set of technical criteria is limited.

This particular standard does not take into consideration the specific safety aspects of EXTERNAL PACEMAKERS that are connected to a SUPPLY MAINS while simultaneously connected to the PATIENT.

This particular standard amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

An inventory of the PATIENT's safety posed by EXTERNAL PACEMAKERS and a rationale for the safety requirements contained in this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of EXTERNAL PACEMAKERS powered by an INTERNAL ELECTRICAL POWER SOURCE, hereafter referred to as ME EQUIPMENT.

This document applies to PATIENT CABLES as defined in 201.3.209, but does not apply to LEADS as defined in 201.3.206.

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

NOTE See also 4.2 of the general standard.

This document does not apply to the implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES covered by ISO 14708-1. This document does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This document does not apply to transthoracic and oesophageal pacing ME EQUIPMENT and antitachycardia ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS as defined in 201.3.205.

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.

---

[1] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

IEC 60601-1-2:2014 applies as modified in Clause 202. IEC 60601-1-3 does not apply. 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 and applicable collateral standards 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 3.147, additional definitions in this document 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 document" 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.

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

Replacement:

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*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

ISO 14117:2019, *Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

ISO 14708-2:2019*, Implants for surgery – Active implantable medical devices – Part 2: Cardiac pacemakers*

SOMMAIRE

AVANT-PROPOS 58
INTRODUCTION 61
201.1 Domaine d'application, objet et normes connexes 62
201.2 Références normatives 64
201.3 * Termes et définitions 64
201.4 Exigences générales 66
201.5 Exigences générales relatives aux essais des APPAREILS EM 67
201.6 Classification des APPAREILS EM et des SYSTEMES EM 67
201.7 Identification, marquage et documentation des APPAREILS EM 67
201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM 71
201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM 78
201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs 78
201.11 Protection contre les températures excessives et les autres DANGERS 78
201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des RISQUES 79
201.13 SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM 84
201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP) 84
201.15 Construction de l'APPAREIL EM 84
201.16 SYSTÈMES EM 84
201.17 Compatibilité électromagnétique des APPAREILS EM et des SYSTEMES EM 84
202 * PERTURBATIONS ÉLECTROMAGNÉTIQUES – Exigences et essais 84
Annexes 86
Annexe I Identification des critères de réussite/échec à l'essai d'IMMUNITE 86
Annexe AA (informative) Guide particulier et justifications 87
Bibliographie 108
Index des termes définis utilisés dans la présente norme particulière 109

Figure 201.101 – Forme d'onde d'essai V_{test} mise en œuvre par un circuit RLC (exemple) avec C = 120 µF, L = 25 µH, $RL + R$ = 1 Ω 73
Figure 201.102– Exemple de circuit de générateur de tension d'essai de défibrillation pour la génération d'une forme d'onde exponentielle décroissante 74
Figure 201.103 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à CHAMBRE UNIQUE 75
Figure 201.104 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à DOUBLE CHAMBRE 75
Figure 201.105 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à triple chambre, par exemple un STIMULATEUR CARDIAQUE externe biventriculaire 76
Figure 201.106 – Séquences de synchronisation 76
Figure 201.107 – Circuit de mesure pour le COURANT AUXILIAIRE PATIENT pour les APPAREILS EM avec une SOURCE ELECTRIQUE INTERNE 78
Figure 201.108 – Circuit de mesure pour la FREQUENCE MAXIMALE DE REPONSE 81
Figure 201.109 – Affichage initial de l'oscilloscope lors d'une mesure de la FREQUENCE MAXIMALE DE REPONSE 82

Figure AA.1 – Modèle simple d'un STIMULATEUR EXTERNE à CHAMBRE UNIQUE lors de la défibrillation 95
Figure AA.2 – Première proposition d'essai de protection contre la défibrillation d'un STIMULATEUR EXTERNE A CHAMBRE UNIQUE 97
Figure AA.3 – Circuit d'un générateur d'essai de défibrillation pour l'essai de défibrillation conformément aux conditions d'opération à cœur ouvert 98
Figure AA.4 – IMPULSION de défibrillation générée par le générateur d'essai de défibrillation de la Figure AA.3 99
Figure AA.5 – Temps de montée d'une IMPULSION de défibrillation selon le circuit proposé à la Figure AA.3 103

Tableau 201.101 – Répartition des exigences pour les PERFORMANCES ESSENTIELLES 66
Tableau 201.102 – Marquage des bornes de connecteur en DOUBLE CHAMBRE 68
Tableau 201.103 – Paramètres DES APPAREILS EM 80
Tableau 202.101 – Exigences pour les décharges d'électricité statique 85
Tableau AA.1 – Liste des DANGERS d'un STIMULATEUR EXTERNE 88
Tableau AA.2 – Énergies d'IMPULSION calculées pour *C* = 120 µF ± 5 % 100
Tableau AA.3 – Énergies d'IMPULSION calculées pour *C* = 122 µF ± 5 % 101
Tableau AA.4 – Énergies d'IMPULSION calculées pour *C* = 126,32 µF ± 5 % 102

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

_____

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne

AVANT-PROPOS

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La Norme internationale IEC 60601-2-31 a été établie par le groupe de travail commun du sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale, et du sous-comité SC6: Implants actifs, du comité technique 150 de l'ISO: Implants chirurgicaux.

La présente publication est une norme double logo.

Cette troisième édition annule et remplace la deuxième édition parue en 2008 et l'Amendement 1:2011. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) L’exigence concernant l’essai de réduction d’énergie a été supprimée;

b) L’essai d’exposition à la défibrillation externe a été entièrement révisé;

c) L’exclusion des essais d'immunité aux DES uniquement relatives aux décharges dans l’air a été supprimée;

d) Alignement sur la version la plus récente de l’ISO 14708-2 pour les stimulateurs cardiaques, ainsi que sur la norme ISO 14117 associée relative à la CEM;

e) Justifications supplémentaires pour toutes les modifications.

Le texte de cette Norme internationale est issu des documents suivants de l'IEC:

FDIS	Rapport de vote
62D/1719/FDIS	62D/1732A/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale. À l'ISO, la norme a été approuvée par 10 membres P sur un total de 10 votes exprimés.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2

Dans le présent document, les caractères d’imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– indications de nature informative figurant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l’intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS A L’ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES CAPITALES.

Concernant la structure du présent document, le terme:

– "article" désigne l’une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l’Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d’un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l’Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l’article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

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– "devoir" mis au présent de l’indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme;

– "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n’est pas obligatoire pour la conformité à la présente norme;

– "pouvoir" mis au présent de l’indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d’un alinéa ou d'un titre de tableau, il indique l'existence d'un guide ou d'une justification applicable à cet élément à consulter à l’Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

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- reconduit,
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- amendé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

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INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont considérées comme assurant un degré pratique de sécurité dans le fonctionnement des STIMULATEURS EXTERNES à source d'énergie interne.

Fondamentalement, les STIMULATEURS CARDIAQUES traitent les arythmies cardiaques. Celles-ci réduisent le débit cardiaque et peuvent entraîner des troubles, des étourdissements, des pertes de connaissance et la mort. Le but de la stimulation est de rétablir le rythme et le débit cardiaques qui sont appropriés aux besoins physiologiques du PATIENT.

Il existe deux familles distinctes de STIMULATEURS CARDIAQUES, les STIMULATEURS IMPLANTABLES et les STIMULATEURS EXTERNES. Les STIMULATEURS EXTERNES sont utilisés pour stimuler temporairement des PATIENTS avant d'implanter un STIMULATEUR implantable et aussi pour effectuer une stimulation temporaire en liaison avec d'autres actes médicaux, par exemple une opération à cœur ouvert.

Les différences entre STIMULATEURS CARDIAQUES concernent la manière dont ils maintiennent et surveillent l'activité cardiaque en différentes circonstances. Le modèle le plus simple stimule l'oreillette ou le ventricule indépendamment de l'activité cardiaque; d'autres détectent l'activité auriculaire ou ventriculaire et stimulent l'oreillette ou le ventricule comme il convient au moment nécessaire; d'autres, plus complexes, détectent l'activité spontanée du cœur et stimulent de manière appropriée l'oreillette et/ou le ventricule. Certains STIMULATEURS fonctionnent avec des fréquences, des amplitudes et des durées d'IMPULSION préréglées. D'autres appareils peuvent disposer de plusieurs valeurs pour ces paramètres.

Les normes concernant les STIMULATEURS EXTERNES spécifient des exigences portant sur les informations qui aideront à concevoir et à manipuler ces dispositifs. C'est au travers de ces aspects de la normalisation qu'il convient de prendre en compte ou qu'il a été pris en compte le rôle capital de l'expérience clinique. La possibilité de déterminer à l'avance les performances d'un STIMULATEUR pour un PATIENT spécifique, à partir de la mise à l'essai d'un dispositif selon un ensemble de critères techniques, est limitée.

La présente norme particulière ne prend pas en compte les aspects spécifiques de sécurité des STIMULATEURS EXTERNES qui sont reliés simultanément au RESEAU D'ALIMENTATION et au PATIENT.

La présente norme particulière modifie et complète l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles,* appelée norme générale dans la suite du texte.

Les exigences sont suivies de spécifications relatives aux essais correspondants.

Conformément à la décision prise par le sous-comité 62D lors de sa réunion à Washington en 1979, une section "Recommandations générales et justifications" contenant, le cas échéant, des notes explicatives concernant les exigences les plus importantes, figure dans l'Annexe AA.

Les articles ou paragraphes pour lesquels des notes explicatives sont données à l'Annexe AA sont marqués d'un astérisque (*).

Un inventaire des RISQUES pour la sécurité du PATIENT posés par les STIMULATEURS EXTERNES et des justifications pour les exigences de sécurité contenues dans cette norme particulière sont donnés dans Annexe AA. Il est considéré que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte de la présente norme particulière, mais accélère, en son temps, toute révision rendue nécessaire par suite de changements dans la pratique clinique ou en raison des évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des STIMULATEURS EXTERNES alimentés par une SOURCE D'ENERGIE ELECTRIQUE INTERNE désignés ci-après sous le terme APPAREILS EM.

Le présent document s'applique aux CABLES PATIENT tels qu'ils sont définis en 201.3.209, mais ne s'applique pas aux DERIVATIONS telles qu'elles sont définies en 201.3.206.

Les DANGERS inhérents à la fonction physiologique prévue de l'APPAREIL EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 7.2.13 et de 8.4.1 de la norme générale.

NOTE Voir aussi 4.2 de la norme générale.

Le présent document ne s'applique pas aux parties implantables des DISPOSITIFS MEDICAUX IMPLANTABLES ACTIFS traités par l'ISO 14708-1. Le présent document ne s'applique pas aux stimulateurs externes qui peuvent être connectés directement ou indirectement au RESEAU D'ALIMENTATION.

Le présent document ne s'applique pas aux APPAREILS EM de stimulation transthoracique et œsophagienne ni aux APPAREILS EM pour la tachycardie.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des STIMULATEURS EXTERNES tels qu'ils sont définis en 201.3.205.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

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[1] La norme générale est constituée de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

L'IEC 60601-1-2:2014 s'applique telle que modifiée dans l'Article 202 L'IEC 60601-1-3 ne s'applique pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM à l'étude et elles peuvent ajouter d'autres exigences pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012 sont désignées dans la présente norme comme la norme générale. Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple 201.1 dans le présent document couvre le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe "20x", où x est le dernier chiffre ou les derniers chiffres du numéro de document de la norme collatérale (par exemple 202.4 dans la présente norme particulière couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière couvre le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale et des normes collatérales applicables sont spécifiées par l'utilisation des termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"*Addition*" signifie que le texte de la présente norme particulière vient compléter les exigences de la norme générale ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, du fait que les définitions sont numérotées de 3.1 à 3.147 dans la norme générale, les définitions supplémentaires du présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires portent les lettres AA, BB, etc., et les éléments supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le numéro de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour faire référence à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que

pertinente, ne s’applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s’applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012

ISO 14117:2019, *Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices* (disponible en anglais seulement)

ISO 14708-2:2019*, Implants chirurgicaux – Dispositifs médicaux implantables actifs – Partie 2: Stimulateurs cardiaques*