IEC 60601-2-31

Edition 3.0 2020-01
REDLINE VERSION

INTERNATIONAL STANDARD

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

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

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-7781-2

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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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the 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:

FDIS	Report on voting
62D/1719/FDIS	62D/1732A/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 10 P members out of 10 having cast a vote.

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

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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- withdrawn,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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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:

[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*

201.3 * Terms and definitions

~~For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and ISO 14708-2:2005 apply, except as follows:~~

For the purposes of this document, the terms and definitions specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, ISO 14117:2019, and ISO 14708-2:2019 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 56.

Addition:

201.3.~~101~~201
ACTIVE IMPLANTABLE MEDICAL DEVICE

active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in place after the procedure

[SOURCE: ISO 14708-1:~~2000~~2014, 3.2, modified – The words "in place" have been added to the definition, and the note to entry has been deleted.]

201.3.~~102~~202
BATTERY DEPLETION INDICATOR
means of indicating when the battery should be replaced

201.3.~~103~~203
CARDIAC PACEMAKER
ME EQUIPMENT intended to treat bradyarrhythmias

201.3.~~104~~204
DUAL CHAMBER
relating to both atrium and ventricle

201.3.~~105~~205
EXTERNAL PACEMAKER
CARDIAC PACEMAKER ~~with~~ consisting of a NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE(S) (if used)

201.3.~~106~~206
LEAD
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length between the EXTERNAL PACEMAKER and the PATIENT'S heart

[SOURCE: ISO 14708-1:~~2000~~2014, ~~definition 3.5 modified~~ 3.13, modified – The words "between the EXTERNAL PACEMAKER and the PATIENT'S heart" have been added to the definition, and the note to entry has been deleted.]

201.3.~~107~~207
MAXIMUM TRACKING RATE
maximum PULSE RATE at which the multi-chamber NON-IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a ~~triggering~~ sensed atrial signal

[SOURCE: ISO 14708-2:~~2005~~2019, ~~definition 3.3.18~~ 3.30, modified – The word " IMPLANTABLE " has been replaced by "multi-chamber NON-IMPLANTABLE" and the word "triggering" by "sensed atrial".]

201.3.~~108~~208
NON-IMPLANTABLE PULSE GENERATOR
ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE which is intended for use outside the body and which produces a periodic electrical PULSE intended to stimulate the heart through a LEAD (or combination of a LEAD and PATIENT CABLE)

201.3.~~109~~209
PATIENT CABLE
cable used to extend the distance between the NON-IMPLANTABLE PULSE GENERATOR and the pacing LEAD

201.3.~~110~~210
POST-VENTRICULAR ATRIAL REFRACTORY PERIOD
PVARP
~~atrial refractory period minus the AV delay~~

refractory period in atrial channel after paced or sensed event in ventricular channel, used in DUAL CHAMBER modes

Note 1 to entry: This note applies to the French language only.

201.3.~~111~~211
PRIMARY BATTERY
one or more cells, which are not designed to be electrically recharged, that are fitted with devices necessary for use, for example case, terminals, marking and protective devices

[SOURCE: IEC 60050-482:2004, 482-01-04, modified – The word "primary" has been added to the term, and the words "which are not designed to be electrically recharged" have been added to the definition.]

201.3.~~112~~212
SINGLE CHAMBER
relating to either atrium or ventricle

201.3.213
BASIC RATE
PULSE RATE of a NON-IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

[SOURCE: ISO 14708-2:2019, 3.26, modified – The words "an implantable" have been replaced by "a NON-IMPLANTABLE".]

201.3.214
ESCAPE INTERVAL
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of a NON-IMPLANTABLE PULSE GENERATOR

[SOURCE: ISO 14117:2019, 3.128, modified – The words "an implantable" have been replaced by "a NON-IMPLANTABLE".]

201.3.215
INTERFERENCE PULSE RATE
PULSE RATE with which the NON-IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity that it recognizes as interference

[SOURCE: ISO 14117:2019, 3.129, modified – The words "an implantable" have been replaced by "NON-IMPLANTABLE".]

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
BATTERY DEPLETION INDICATOR	201.11.8
ME EQUIPMENT parameter stability	201.12.1.101
PULSE AMPLITUDE stability	201.12.1.102
~~Disarming~~ Disabling runaway rate protection	201.12.4.1
Deliberate action required to change settings	201.12.4.101
Parameter stability at onset of the BATTERY DEPLETION INDICATOR	201.12.4.102
Runaway protection	201.12.4.103
Interference reversion in the presence of sensed ELECTROMAGNETIC DISTURBANCE or electrical ~~interference~~ energy sources	201.12.4.104
Limit at which the ventricle is paced in response to sensed atrial activity	201.12.4.105

201.4.10.1 Source of power for ME EQUIPMENT

Replacement:

ME EQUIPMENT shall be powered by a PRIMARY BATTERY.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

This subclause of the general standard does not apply.

201.4.11 * Power input

This subclause of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

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

Replacement:

ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

ME EQUIPMENT shall be recognized as INTERNALLY POWERED only if no external connections to an electrical power source are provided.

APPLIED PARTS shall be classified as TYPE CF APPLIED PARTS. APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS.

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

Additional subclauses:

201.7.2.101 ME EQUIPMENT intended for SINGLE CHAMBER application

If the ME EQUIPMENT is intended for SINGLE CHAMBER applications, the connector terminals (if used) shall be conspicuously marked positive (+) and negative (–).

201.7.2.102 * ME EQUIPMENT intended for DUAL CHAMBER application

If the ME EQUIPMENT is intended for DUAL CHAMBER application, the connector terminals (if used) shall be marked according to Table 201.102. If colour is used to differentiate between channels in a DUAL CHAMBER application, then the ventricular channel should be marked with the colour white and the atrial channel should be marked with a contrasting colour.

Table 201.102 – DUAL CHAMBER connector terminal marking

Channel	Symbol		Terminal label
	Positive terminal	Negative terminal	
Atrial channel	A+	A–	ATRIUM
Ventricular channel	V+	V–	VENTRICLE

201.7.2.103 Bipolar connectors

When bipolar connectors are used, they shall have keyways that prevent inadvertent polarity reversal.

201.7.2.104 * Battery compartment

The means of access to the battery compartment shall be easily identifiable. The battery compartment shall be clearly and permanently marked with the IEC battery nomenclature, the voltage and type. The battery compartment shall be clearly and permanently marked to show the correct orientation of the battery or batteries.

201.7.4 Marking of controls and instruments

Additional subclauses:

201.7.4.101 * Control or indicator for pacing output

If constant current output is used, the control for selecting pacing output or the relevant indicating means shall be marked in terms of current in milliamperes (mA) through a resistive load of 500 Ω ± 1 %. If a constant voltage output is used, the pacing output or the relevant indicating means shall be marked in terms of volts (V) across a resistive load of 500 Ω ± 1 %.

201.7.4.102 * Control or indicator for PULSE RATE

The control for selecting PULSE RATE or the relevant indicating means shall be marked in terms of reciprocal minutes.

201.7.4.103 * Control for selecting pacing mode

If a means of selecting the pacing mode is provided, the ME EQUIPMENT shall indicate, as well as the mode selected, the possible pacing modes using the codes described in Annex ~~DD~~ C of ISO 14708-2:~~2005~~2019.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2.2 * Warning and safety notices

Replacement:

The instructions for use shall include all warning and safety notices.

~~NOTE~~ General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments.

The instructions for use shall include the following.

~~aa~~a) * Warnings regarding potential changes in the behaviour of the NON-IMPLANTABLE PULSE GENERATOR caused by ELECTROMAGNETIC ~~or other interference~~ DISTURBANCE sources (e.g. communication transmitters in hospitals, emergency transport vehicles, cellular telephones, etc.) and the effects of therapeutic and diagnostic energy sources (e.g. external cardioversion, diathermy, transcutaneous electrical nerve stimulators [TENS] devices, high-frequency surgical equipment, magnetic resonance imaging or similar sources) on the NON-IMPLANTABLE PULSE GENERATOR. This shall include advice on recognizing when the behaviour of the NON-IMPLANTABLE PULSE GENERATOR is being influenced by external ~~interference~~ ELECTROMAGNETIC DISTURBANCE or electrical energy sources and steps to be taken to avoid ~~such~~ interference.

~~bb~~b) * A warning about the danger of inadvertently introducing LEAKAGE CURRENT into the heart if SUPPLY MAINS-operated equipment is connected to the LEAD system.

~~cc~~c) * A warning that the PATIENT CABLE shall be connected to the NON-IMPLANTABLE PULSE GENERATOR before the pacing LEADS are connected to the PATIENT CABLE.

~~dd~~d) * A warning that when handling indwelling LEADS, the terminal pins or exposed metal are not to be touched nor be allowed to contact electrically conductive or wet surfaces.

~~ee~~e) * A warning regarding the HAZARDS of using PRIMARY BATTERIES other than those recommended by the MANUFACTURER (for example, short BATTERY life after the indication of low BATTERY condition, degraded ME EQUIPMENT performance, overall reduced BATTERY life, and erratic or no pacing).

~~ff~~f) * A warning that, before handling the ~~external~~ NON-IMPLANTABLE PULSE GENERATOR, the PATIENT CABLE or indwelling LEADS, steps shall be taken to equalize the electrostatic potential between the user and the PATIENT, for example by touching the PATIENT at a site remote from the pacing ~~lead~~ LEADS.

~~gg~~g) * A caution that, when clinically indicated, supplemental monitoring of the PATIENT should be considered.

201.7.9.2.4 * Electrical power source

Replacement:

The instructions for use shall contain advice on removal of the PRIMARY BATTERY if the ME EQUIPMENT is to be stored or when a long period of disuse is anticipated.

The instructions for use shall state the recommended PRIMARY BATTERY specification.

The instructions for use shall contain the estimated service time from a fully charged BATTERY at 20 °C ambient temperature when operating under specified conditions.

The instructions for use shall contain the estimated service time following activation of the BATTERY DEPLETION INDICATOR when operating under specified conditions.

The instructions for use shall contain the information (including a reference to the appropriate PRIMARY BATTERY specified in IEC 60086-2 [1] [2] giving the identity of the PRIMARY BATTERIES to be used ~~so that they may be obtained from local sources~~.

201.7.9.2.5 * ME EQUIPMENT description

Addition:

The instructions for use shall include the following.

~~aa~~a) * A general description, explanation of function available, and a description of each heart/PULSE GENERATOR interaction for each available pacing mode. See ~~Annex DD~~ Clause C.3 of ISO 14708-2:~~2005~~2019 for a description of pacing modes.

~~bb~~b) * The connector configuration, the geometry and/or dimensions of the receiving connectors and instructions for connecting the LEAD(S) or PATIENT CABLE(S) to the NON-IMPLANTABLE PULSE GENERATOR.

~~cc~~c) * The electrical characteristics (including tolerances where applicable) ~~at 20 °C ± 2 °C~~ with 500 Ω ± 1 % load, unless otherwise stated, as follows:

- ranges of BASIC RATE, ESCAPE INTERVAL, MAXIMUM TRACKING RATE and INTERFERENCE PULSE RATES (as applicable);
- PULSE AMPLITUDE(S);
- PULSE DURATION(S);
- the SENSITIVITY range for both positive and negative polarities (if a sensing function is provided);
- sensing amplifier blanking period(s) (if a sensing function is provided);
- the REFRACTORY PERIOD(S) (pacing and sensing) and A-V INTERVAL(S) (as applicable);
- mode of operation in the presence of sensed ~~interference~~ ELECTROMAGNETIC DISTURBANCE or electrical energy sources;
- the rate limit (runaway protection), in reciprocal minutes.

~~dd~~d) * The electrical characteristics listed below and as reported in 201.7.9.2.5 c) upon activation of the BATTERY DEPLETION INDICATOR ~~(including tolerances where applicable, and measured at 20 °C ± 2 °C with 500 Ω ± 1 % load), including as applicable~~, unless these are unchanged from the values ~~provided in 7.9.2.5 cc)~~ previously reported:

- BASIC RATE or equivalent PULSE INTERVAL;
- PULSE AMPLITUDES(s);
- PULSE DURATION(s);
- SENSITIVITY (if a sensing function is provided);
- mode change (if applicable).

[2] Numbers in square brackets refer to the Bibliography.

201.7.9.2.8 * Start-up PROCEDURE

Addition:

The instructions for use shall contain any environmental limitations regarding storing the ME EQUIPMENT immediately prior to use.

201.7.9.2.13 * Maintenance

Addition:

The instructions for use shall contain details for replacing the PRIMARY BATTERY and the means of ascertaining when replacement is required.

The instructions for use shall contain information calling the RESPONSIBLE ORGANIZATION'S attention to the need for periodic maintenance, as well as to the need for maintenance after any malfunction or accident of the ME EQUIPMENT irrespective of usage, especially:

– cleaning and disinfection of reusable PATIENT CABLES;
– cleaning and disinfection of the NON-IMPLANTABLE PULSE GENERATOR;
– inspection of cables and connections for possible defects, for example, loosening of connections and other wear and tear from such causes as PATIENT movement;
– inspection of the NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE for signs of physical damage or contamination, in particular damage or contamination that can have a detrimental effect on the electrical isolation properties of the ME EQUIPMENT;
– functional checks, calibration, activation of keys, switches, etc., especially if the ME EQUIPMENT has suffered severe shock, for example, by being dropped.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 * Defibrillation protection

Replacement:

~~The ME EQUIPMENT shall comply with 6.2.1 of ANSI/AAMI PC69:2007.~~

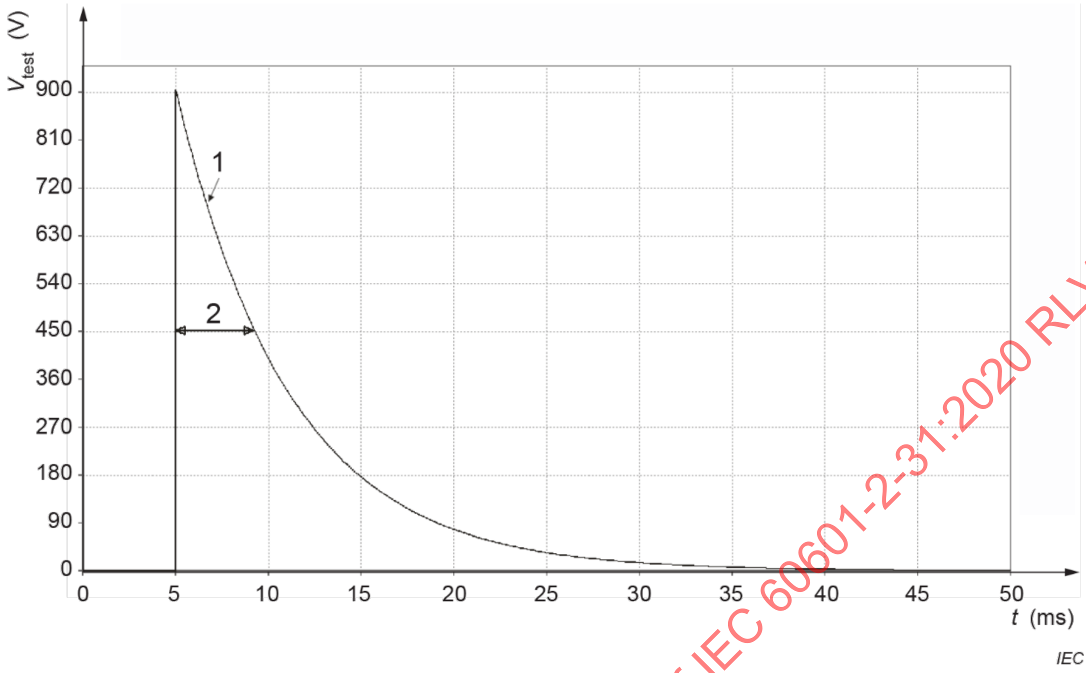
201.8.5.5.1.1 General requirements

The ME EQUIPMENT shall be designed so that defibrillation of the PATIENT using an internal defibrillator will not permanently affect the ME EQUIPMENT, provided that the internal defibrillator electrodes (e.g. paddles) are placed according to the ME EQUIPMENT MANUFACTURER's recommendations.

201.8.5.5.1.2 Test of defibrillation protection

Test equipment: Use a defibrillation test voltage generator providing a decaying exponential waveform presented in Figure 201.101 with the following characteristics: a maximum voltage V_{test} of 900 V $^{+2,5}_{-0}$ % and an energy of 50 J to 55 J, having T_{w50} = 4,05 ms to 4,6 ms, where T_{w50} is the time interval during which the test voltage is above 50 % of the maximum value V_{test}, if discharged into a load resistance R_{heart} = 50 Ω ± 1 %.

NOTE 1 The resistance R_{heart} = 50 Ω ± 1 % simulates the resistance of the heart seen by a defibrillator during open heart surgery.



Key

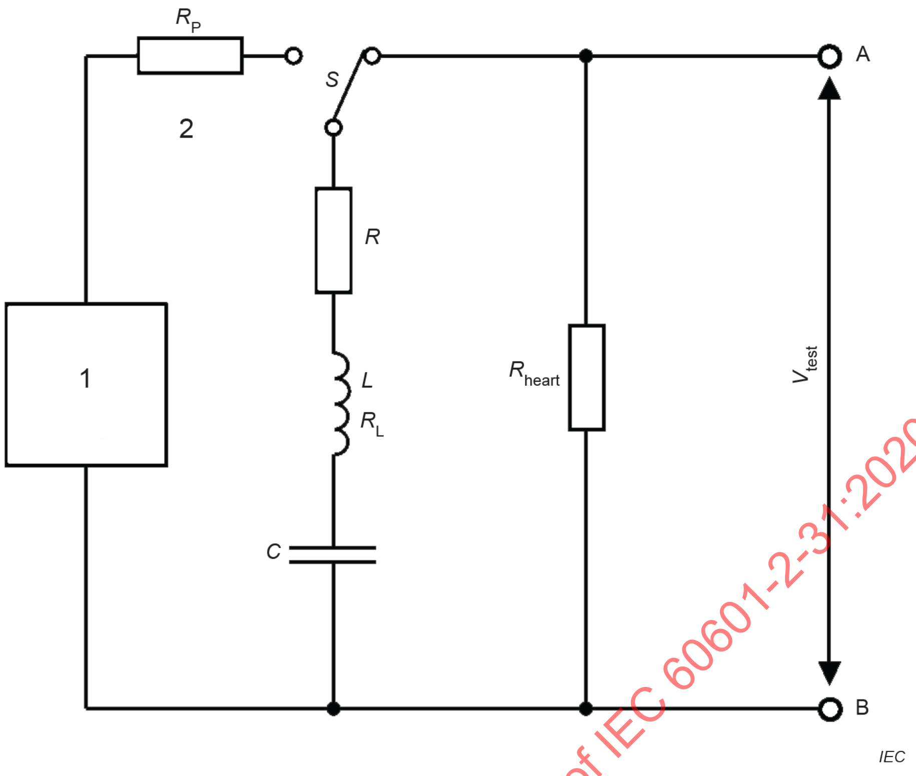
1 decaying exponential test waveform

2 T_{w50} = 4,05 ms to 4,6 ms: time interval during which the test voltage is above 50 % of the maximum value V_{test}

Figure 201.101 – Test waveform V_{test} implemented by example RCL circuit using C = 120 µF, L = 25 µH, RL + R = 1 Ω

Figure 201.102 illustrates an example schematic of such a defibrillation test generator with C = 120 µF ± 5% , L = 25 µH ± 5 %, R_L + R = 1 Ω ± 5 %, where R_L is the resistance of the inductance L, and R is the output resistance of the defibrillation test voltage generator.

NOTE 2 The current limiting resistor R_P can be used to protect the voltage generator during capacitor charging.



Key

1	voltage generator
2	current limiting resistor
S	switch for applying the test voltage
L	25 µh ± 5 % inductance
R_L	resistance of inductor
R	resistor in series with L and C
C	120 µF ± 5 % capacitor
R_{heart}	50 Ω ± 1 % load resistance, which simulates the resistance of the heart seen by a defibrillator during open heart surgery
V_{test}	test voltage
A,B	output terminals of the defibrillation test voltage generator

Figure 201.102 – Example circuit of defibrillation test voltage generator for generating a decaying exponential waveform

Test PROCEDURE: Connect the output V_{test} with its terminals A and B to the EXTERNAL PACEMAKER as described below.

The ME EQUIPMENT shall be categorized into one or more of two groups of EXTERNAL PACEMAKERS as appropriate and connected as indicated:

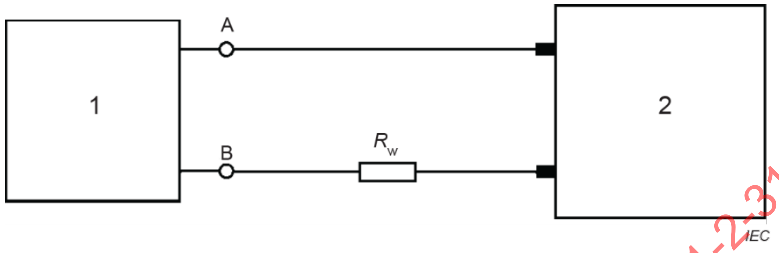
– SINGLE CHAMBER EXTERNAL PACEMAKER:

  The test voltage V_{test} is applied between one EXTERNAL PACEMAKER PATIENT CONNECTION connected to the terminal A of the defibrillation test voltage generator and the second EXTERNAL PACEMAKER PATIENT CONNECTION connected via an 80 Ω resistor to the terminal B of the defibrillation test voltage generator. The test setup is shown in Figure 201.103.

– Multi-chamber EXTERNAL PACEMAKER:

The test voltage V_{test} is applied to each EXTERNAL PACEMAKER PATIENT CONNECTION, being connected to the terminal A of the defibrillation test voltage generator, in turn with all the remaining EXTERNAL PACEMAKER PATIENT CONNECTIONS being connected together via 80 Ω resistors to the terminal B of the defibrillation test voltage generator. Figure 201.104 provides the test setup for a DUAL CHAMBER EXTERNAL PACEMAKER, whereas Figure 201.105 shows the test setup for a triple chamber EXTERNAL PACEMAKER (e.g. bi-ventricular).

NOTE 3 The 80 Ω resistors shown in the test setups below simulate the impedance of applied heart wires and the tissue between the internal defibrillator and the EXTERNAL PACEMAKER terminals.



Key

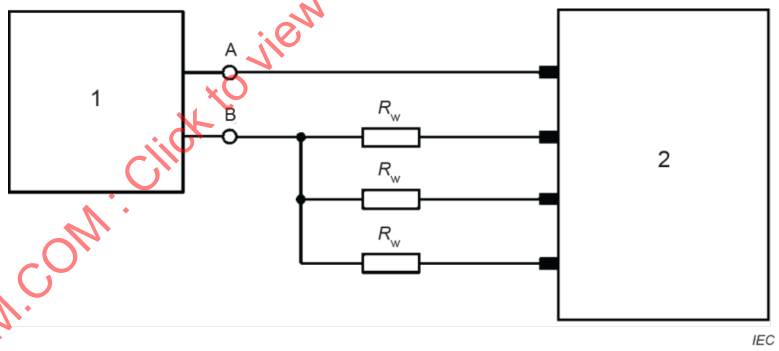
1 defibrillation test voltage generator

2 SINGLE CHAMBER EXTERNAL PACEMAKER

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.103 – Test setup for a SINGLE CHAMBER external CARDIAC PACEMAKER



Key

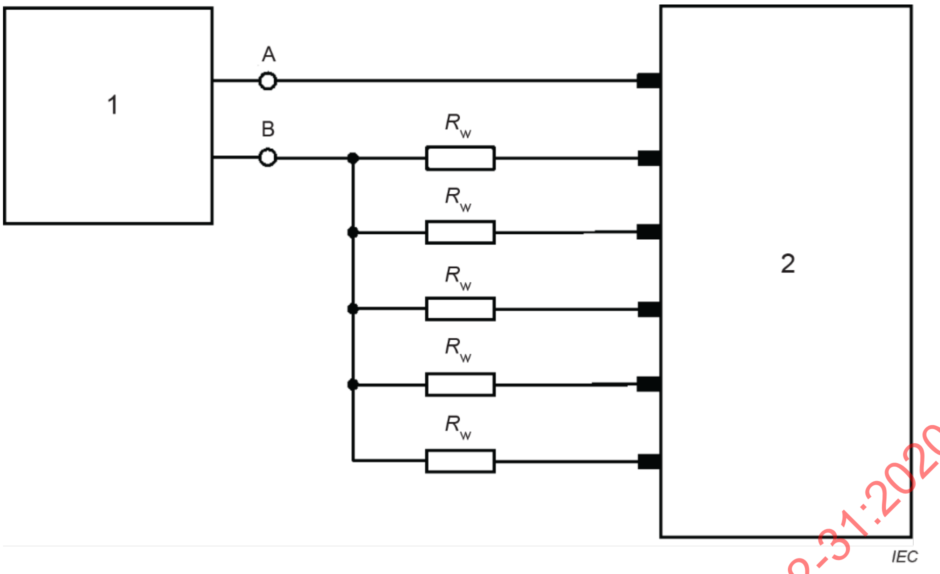
1 defibrillation test voltage generator

2 DUAL CHAMBER EXTERNAL PACEMAKER

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.104 – Test setup for a DUAL CHAMBER external CARDIAC PACEMAKER



Key

1 defibrillation test voltage generator

2 multi CHAMBER EXTERNAL PACEMAKER, e.g. bi-ventricular EXTERNAL PACEMAKER providing three pacing CHAMBERS

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.105 – Test setup for a triple chamber external CARDIAC PACEMAKER, e.g. bi-ventricular external CARDIAC PACEMAKER

Test by applying a sequence of three voltage PULSES of positive polarity at intervals of 20 s to 25 s. Then, after an interval of 60 s (minimum), repeat the test with PULSES of negative polarity (see Figure 201.106).

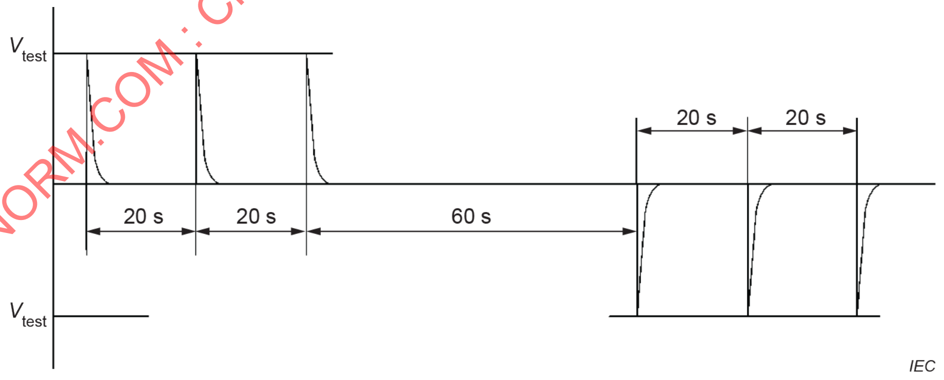


Figure 201.106 – Timing sequence

Compliance shall be confirmed if, after completing the test PROCEDURE, the ME EQUIPMENT continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

201.8.5.5.2 * Energy reduction test

This subclause of the general standard does not apply.

201.8.7.3 * Allowable values

Amendment:

In Table 3 of IEC 60601-1:2005, replace the values for PATIENT AUXILIARY CURRENT for TYPE CF APPLIED PARTS for ~~both d.c. and a.c. with~~ DC by 1 μA in NORMAL CONDITION (NC) and 5 μA in SINGLE FAULT CONDITION (SFC).

201.8.7.4 Measurements

201.8.7.4.1 * General

Addition:

aa) * The NON-IMPLANTABLE PULSE GENERATOR output should be disabled during LEAKAGE CURRENT testing if possible. If the output is to be active, its contribution should not be considered part of the LEAKAGE CURRENT.

201.8.7.4.8 * Measurement of the PATIENT AUXILIARY CURRENT

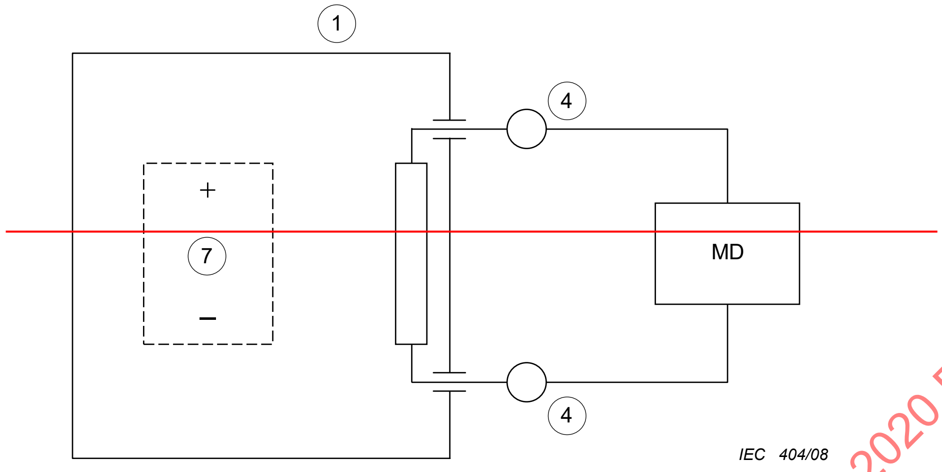
Replacement:

~~*For measurement of PATIENT AUXILIARY CURRENT, the ME EQUIPMENT is connected as shown in Figure 201.101 to a d.c. measuring device with an input resistance of 100 kΩ. The ME EQUIPMENT shall be connected to the measuring device for a minimum of 5 min before making the PATIENT AUXILIARY CURRENT measurement. When measured just before the pacing pulse, the measured voltage shall not exceed 100 mV for NORMAL CONDITIONS and shall not exceed 500 mV for SINGLE FAULT CONDITION.*~~

For measurement of the PATIENT AUXILIARY CURRENT, the ME EQUIPMENT is connected as shown in Figure 201.107. Each PATIENT CONNECTION is connected to a common bus through a 500 Ω ± 1 % load resistor (R_L). Using a measuring device (MD) consisting of a DC voltmeter, resolution better than 2 μV, fed through a low pass filter with a time constant of at least 10 s, measure the average direct voltage across each load resistor. Steady state condition shall be reached before the measurement is made.

The NON-IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the MANUFACTURER (i.e., the factory recommended settings) but with the PULSE AMPLITUDE and PULSE DURATION programmed to the highest available settings.

The low pass filter can be implemented by a four-element RC filter with elements built from 1 MΩ resistors and 10 μF metalized polypropylene capacitors. The input resistance of the DC voltmeter should be ≥ 400 MΩ.



~~Legend~~

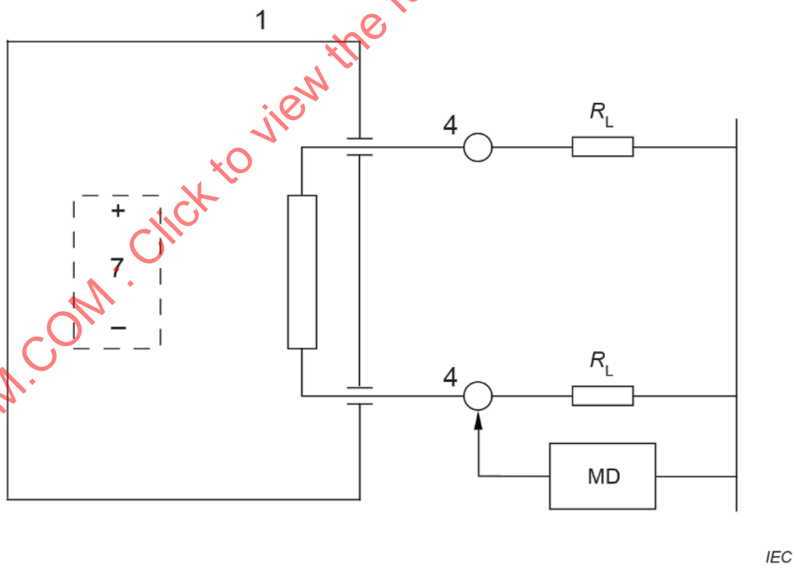
~~1 ME EQUIPMENT ENCLOSURE~~

~~4 PATIENT CONNECTIONS~~

~~7 INTERNAL ELECTRICAL POWER SOURCE~~

~~MD Measuring device (see Figure 12 of IEC 60601-1:2005)~~

~~See also Table 5 of IEC 60601-1:2005.~~



Key

1 ME EQUIPMENT ENCLOSURE

4 PATIENT CONNECTIONS

7 INTERNAL ELECTRICAL POWER SOURCE

R_L load resistor

MD measuring device (see 201.8.7.4.8)

Figure 201.~~101~~107 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE

Additional subclause:

201.8.101 High-frequency surgical ME EQUIPMENT protection

The ME EQUIPMENT shall comply with ~~6.1.1 of ANSI/AAMI PC69:2007~~ 6.1.2 of ISO 14117:2019.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replacement:

The ME EQUipment shall be so constructed that ~~in the event of spillage of liquids (accidental wetting), no HAZARDOUS SITUATION shall result~~ the ingress of liquids (accidental wetting), shall not result in an unacceptable RISK.

Compliance is checked by the following test.

The ME EQUIPMENT is placed in the least favourable position of NORMAL USE with the PATIENT CABLE attached. The ME EQUIPMENT is subjected to a spill of 400 ml of 9 g/l saline solution from a height of 30 cm. The entire 400 ml is poured over the ME EQUIPMENT in less than 5 s. Following the spill, the ME EQUIPMENT is not to be resting in a depth of more than 5 mm of saline solution.

Immediately after 30 s of exposure, the ME EQUIPMENT is removed from the saline solution and visible moisture on the outside of the ENCLOSURE is removed.

The ME EQUIPMENT is to operate within specification during and after the spill.

After at least 24 h have passed, the ME EQUIPMENT is to operate within specification. The ME EQUIPMENT is then disassembled and inspected. Any evidence that liquid has entered the electronic compartment constitutes a failure.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Replacement:

The ME EQUIPMENT shall be equipped with a BATTERY DEPLETION INDICATOR which clearly indicates when the power source is to be replaced.

Compliance is checked by inspection and by functional test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Replacement:

201.12.1.101 * ME EQUIPMENT PARAMETERS

The measured values of the ME EQUIPMENT parameters shown in Table 201.103 shall be within the MANUFACTURER'S published tolerance. The MANUFACTURER shall insure that measurement equipment accuracy is sufficient to support the stated tolerances for the parameters being measured within 201.12.1.101 and stated by the MANUFACTURER when measured at PULSE RATE settings of 60 and 120 PULSES per minute with a fully charged BATTERY and the NON-IMPLANTABLE PULSE GENERATOR at 20 °C ± 2 °C. If 60 or 120 PULSES per minute are not within the range for PULSE RATE settings for the ME EQUIPMENT, then the test shall be conducted at the minimum or maximum allowable settings.

Compliance is checked by either the appropriate methods described below and in 6.1 of ISO 14708-2:20052019, or by any other method provided it can demonstrate an accuracy equal to or better than the accuracy listed in Table 201.103 which is sufficient to support the stated tolerances. In case of dispute, the test described below and in 6.1 of ISO 14708-2:20052019 shall apply.

Table 201.103 – Measurement method accuracy ME EQUIPMENT parameters

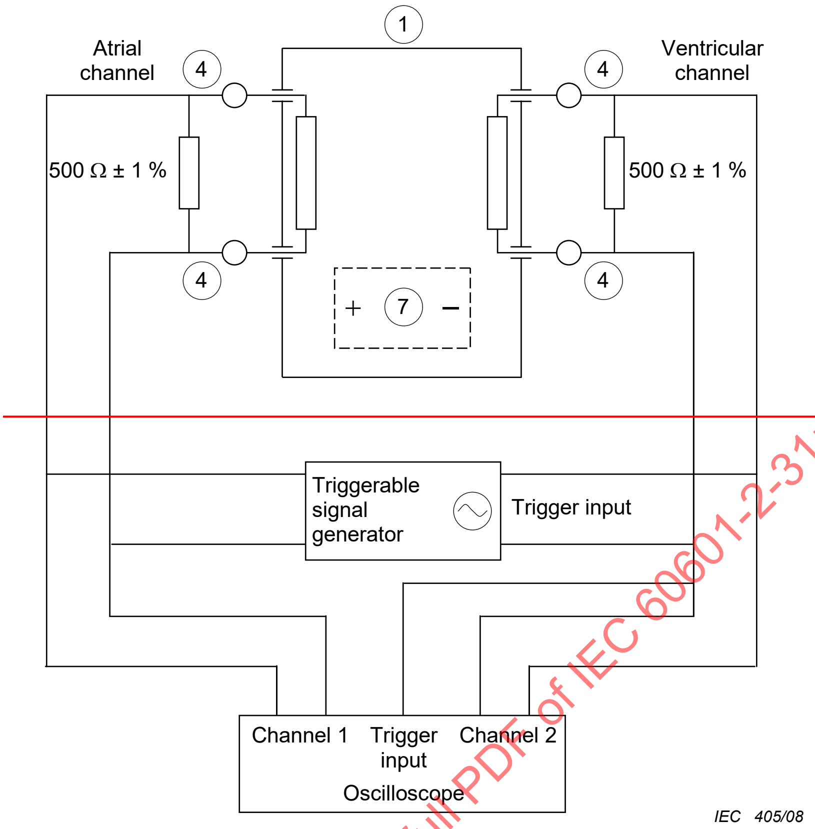
Measurement	Accuracy %
PULSE AMPLITUDE	±5
PULSE DURATION	±5
PULSE RATE	±0,5
SENSITIVITY (if applicable)	±10
ESCAPE INTERVAL	±10
REFRACTORY PERIOD(S) (if applicable)	±10
A-V INTERVAL (if applicable)	±5
MAXIMUM TRACKING RATE (if applicable)	±0,5

Measurement of MAXIMUM TRACKING RATE is made using the following test.

With a fully charged battery and the NON-IMPLANTABLE PULSE GENERATOR in an A-V sequential mode with sensing and pacing in both chambers (DDD) at 20 °C ± 2 °C, the ME EQUIPMENT is connected according to Figure 201.102108. The test apparatus is described in 6.1.3 of ISO 14708-2:20052019. Adjust the signal generator until the amplitude of the test signal is approximately $2e_{pos}$ or $2e_{neg}$ as determined in 6.1.23 of ISO 14708-2:20052019.

The delay from the triggering of the signal generator to the production of the test signal is designated D. Adjust the signal generator so that D is slightly greater than the POST-VENTRICULAR ATRIAL REFRACTORY PERIOD (PVARP). Slowly increase D until the ventricular pacing PULSE just begins to track the additional delay as observed on Channel 2 of the oscilloscope. Measure the interval between sequential pacing PULSES on Channel 2 in milliseconds. Designate that as interval T. Adjust the oscilloscope so that the display illustrated in Figure 201.103109 is obtained.

Calculate the MAXIMUM TRACKING RATE *[*PULSES *per minute] = 60 000/T [ms].*

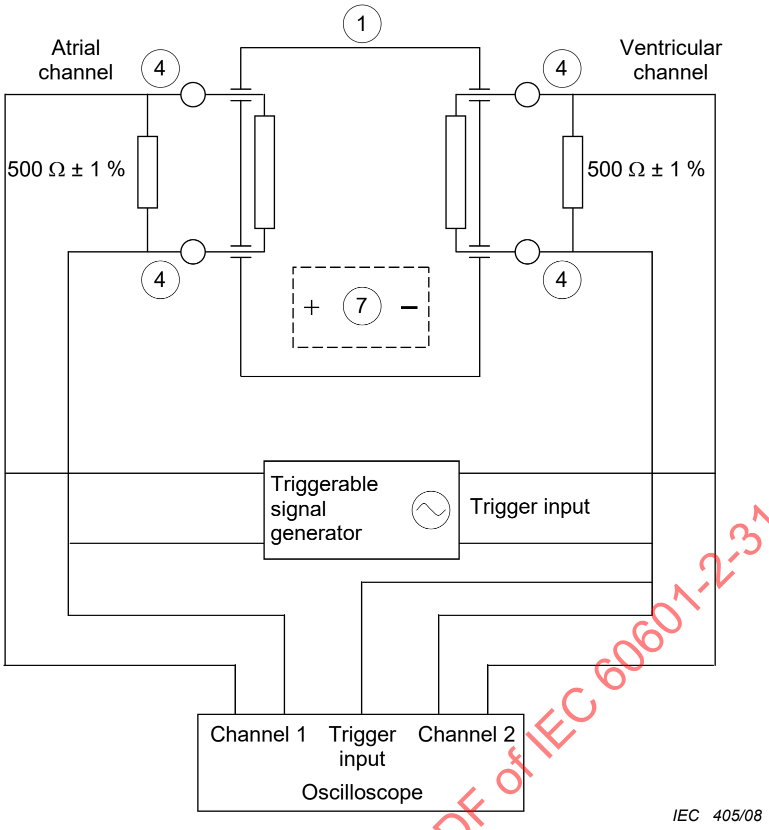


~~**Legend**~~

~~1 ME EQUIPMENT ENCLOSURE~~

~~4 PATIENT CONNECTIONS~~

~~7 INTERNAL ELECTRICAL POWER SOURCE~~

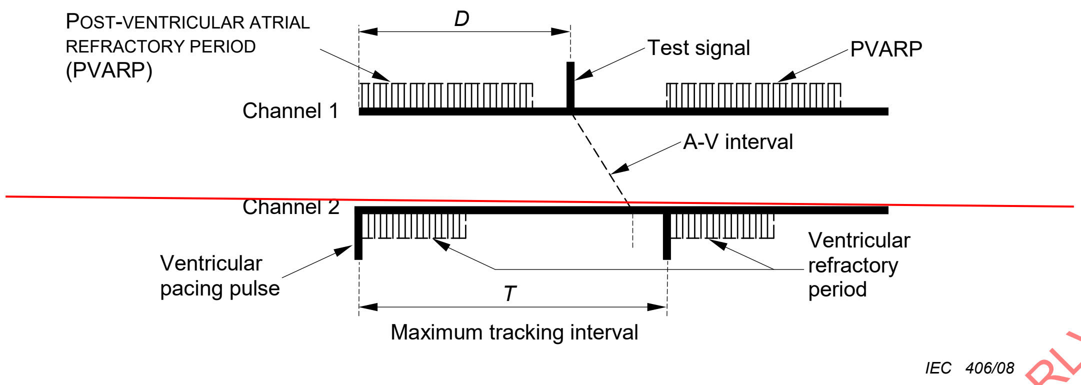


Key

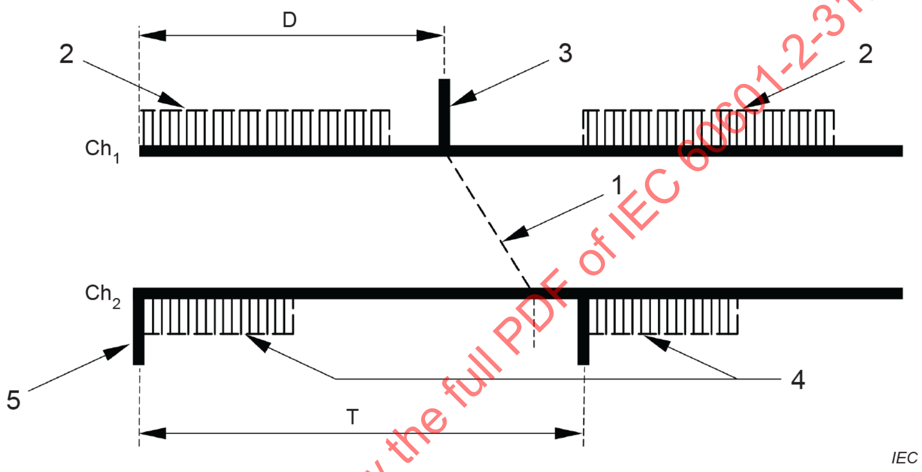
R_1	R_1 = 500 Ω ±1 %
A	ATRIAL CHANNEL
V	VENTRICULAR CHANNEL
$IN_{Trigger}$	TRIGGER INPUT
CH_1	Channel 1
CH_2	Channel 2
TSG	TRIGGERABLE SIGNAL GENERATOR
OSC	OSCILLOSCOPE
1	ME EQUIPMENT ENCLOSURE
4	PATIENT CONNECTIONS
7	INTERNAL ELECTRICAL POWER SOURCE

See also Table 5 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

Figure 201.~~102~~108 – Measuring circuit for the MAXIMUM TRACKING RATE



D > PVARP



Key

1	A-V Interval
2	POST-VENTRICULAR ATRIAL REFRACTORY PERIOD (PVARP)
3	test signal
4	ventricular refractory period
5	ventricular pacing PULSE
Ch1	Channel 1
Ch2	Channel 2
D	delay from the triggering of the signal generator to the production of the test signal (*D* > PVARP[1])
T	maximum tracking interval

[1] Atrial refractory period minus the A-V delay. See [2].

MAXIMUM TRACKING RATE [PULSES per minute] = 60 000/T [ms].

Figure 201.103109 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE

201.12.1.102 * PULSE AMPLITUDE

The PULSE AMPLITUDE expressed either as voltage or current shall not vary from the indicated value by more than the percentage listed in the MANUFACTURER'S published specifications when the load is varied from 200 Ω to 1 000 Ω, at a pacing rate of 70 PULSES per minute with a fully charged battery~~, and the NON-IMPLANTABLE PULSE GENERATOR at 20 °C ± 2 °C~~.

Compliance is checked by using the basic test method described in 6.1.~~1~~2 of ISO 14708-2:~~2005~~2019 with test loads of 200 Ω ± 1 % and 1 000 Ω ± 1 % in order to determine how PULSE AMPLITUDE changes as a function of resistance.

201.12.4 Protection against hazardous output

201.12.4.1 * Intentional exceeding of safety limits

Replacement:

If the ME EQUIPMENT incorporates features which require PULSE RATES above the rate limit (see 201.12.4.103), the runaway rate protection may be disarmed when the feature is in use. The means for disarming the runaway rate protection shall require the OPERATOR to engage the activating mechanism continuously.

Compliance is checked by inspection and by a functional test.

Additional subclauses:

201.12.4.101 * Protection against accidental change of controls and tampering

Means shall be provided so that a deliberate action is required to change settings.

Compliance is checked by inspection.

201.12.4.102 * Protection against a low battery condition

Upon activation of the BATTERY DEPLETION INDICATOR, the measured values of the ME EQUIPMENT parameters listed in 201.7.9.2.5 ~~d~~d) shall be within the MANUFACTURER'S published tolerance when measured with the NON-IMPLANTABLE PULSE GENERATOR~~ at 20 °C ± 2 °C~~ with 500 Ω ± 1 % load.

Compliance is checked by either the appropriate methods described in 6.1 of ISO 14708-2:~~2005~~2019, or by any other method provided it can demonstrate an accuracy~~ equal to or better than the precision listed in Table 201.103~~ sufficient to support the MANUFACTURER'S published tolerances. In case of dispute, the test described in 6.1 of ISO 14708-2:~~2005~~2019 shall apply.

201.12.4.103 * Rate limit (runaway protection)

Means shall be provided to limit PULSE RATE, in the event of a SINGLE FAULT CONDITION, to the value specified by the MANUFACTURER.

Compliance is checked by inspection of the MANUFACTURER'S data.

201.12.4.104 * Interference reversion

In the presence of sensed electrical~~ interference~~ ELECTROMAGNETIC DISTURBANCE or electrical energy sources, the NON-IMPLANTABLE PULSE GENERATOR shall revert to a pacing mode and PULSE RATE specified by the MANUFACTURER~~ until the interference stops~~.

Compliance is checked by inspecting the MANUFACTURER'S data.

201.12.4.105 * MAXIMUM TRACKING RATE

In DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing, a means shall be provided to set a limit at which the ventricle is paced in response to sensed atrial activity. The ME EQUIPMENT shall respond to sensed atrial activity above the MAXIMUM TRACKING RATE in a manner stated by the MANUFACTURER.

Compliance is checked by inspection and functional test.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

Additional subclauses:

201.15.101 * Output indicator

The ME EQUIPMENT shall incorporate a means to indicate when the ME EQUIPMENT has emitted a pacing PULSE.

Compliance is checked by inspection and functional test.

201.15.102 * Input indicator

If a sensing function is provided, the ME EQUIPMENT shall incorporate a means of indicating that the ME EQUIPMENT has detected signals and has responded to them as if they are associated with the electrical activity of the heart, and that it is reacting to the signals as specified by the MANUFACTURER for the selected pacing mode and other operational characteristics.

Compliance is checked by inspection and functional test.

201.16 ME SYSTEMS

Clause 16 of the general standard does not apply.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 * ELECTROMAGNETIC ~~compatibility~~ DISTURBANCES – Requirements and tests

IEC 60601-1-2:~~2007~~2014 applies except as follows:

~~202.6.2.2 Electrostatic discharge (ESD)~~

~~202.6.2.2.1 * Requirements~~

202.8.9 * IMMUNITY TEST LEVELS

Replacement:

~~ME EQUIPMENT shall comply with the requirements of 6.2.1.10 [of IEC 60601-1-2:2007] as modified below at IMMUNITY TEST LEVELS specified in Table 202.101 for air discharge.~~

ME EQUIPMENT shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 except as modified below for ELECTROSTATIC DISCHARGE.

The IMMUNITY TEST LEVELS specified in Table 202.101 shall be used. For this requirement, the following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

– no permanent degradation, or loss of function which is not recoverable~~, due to~~ shall be observed at any IMMUNITY TEST LEVEL, as a result of
  - damage of ME EQUIPMENT (components), or
  - software corruption, or
  - loss of data ~~shall be observed at any IMMUNITY TEST LEVEL~~;

– no inappropriate delivery of energy to the PATIENT shall occur at any IMMUNITY TEST LEVEL;

– at IMMUNITY TEST LEVELS 1 ~~or~~ and 2, the ME EQUIPMENT shall maintain ~~normal~~ ESSENTIAL PERFORMANCE within the specification limits;

– at IMMUNITY TEST LEVELS 3 ~~or~~ and 4, the temporary degradation or loss of function or performance which requires OPERATOR intervention is acceptable.

Table 202.101 – Static discharge requirements

~~IMMUNITY TEST LEVEL [a]~~	~~Test voltage kV~~	~~Number of single discharges~~
~~1~~	~~2~~	~~10~~
~~2~~	~~4~~	~~10~~
~~3~~	~~8~~	~~2~~
~~4~~	~~15~~	~~2~~

~~[a] The IMMUNITY TEST LEVELS for air discharge are defined in Table 1 of IEC 61000-4-2.~~

IMMUNITY TEST LEVEL [a]	Test voltage (air discharge) kV	Test voltage (contact discharge) kV
1	2	2
2	4	4
3	8	6
4	15	8

[a] The IMMUNITY test LEVELS for static discharge are defined in Table 1 of IEC 61000-4-2:2008 [3].

Compliance is checked by application of the tests in ~~6.2.2.2~~ 8.9 of IEC 60601-1-2:2014, Tables 4, 7 and 8. Evaluate the response of the ME EQUIPMENT or ME SYSTEM during and after these tests in accordance with ~~6.2.1.10 [of IEC 60601-1-2:2007]~~ 8.9 of IEC 60601-1-2:2014 as modified above, considering each discharge individually.

202.6.2.2.2 Tests

Replacement:

The test methods and equipment specified by IEC 61000-4-2 apply, with the following modifications.

a) *The time between discharges is set to an initial value of 1 s. Longer time between discharges might be required in order to be able to distinguish between a response caused by a single discharge and a response caused by a number of discharges.*

b) *Air discharges are applied to non-conductive ACCESSIBLE PARTS of the ME EQUIPMENT or ME SYSTEM and conductive non-accessible portions of ACCESSIBLE PARTS. If the ME EQUIPMENT or ME SYSTEM is labelled with the IEC 60417-5134 symbol adjacent to a connector, that connector is exempt from this testing (see 5.1.2 and 5.2.1.2 [of IEC 60601-1-2:2007]).*

c) *ME EQUIPMENT is tested in such a way as to ensure that there is no appreciable charge retention between individual test discharges. The potential on the ME EQUIPMENT may be equalized with that of the ground plane, between individual test discharges, by temporarily grounding it through two 470 kΩ resistors connected in series. This potential equalization connection shall be disconnected and moved away from the ME EQUIPMENT during application of a test discharge.*

Annexes

The annexes of the general standard apply except as follows:

Annex I

Identification of IMMUNITY pass/fail criteria

Annex I of the general standard does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Annex AA explains the reason for the provisions of this particular standard in the IEC 60601 family, as useful background in reviewing, applying and revising the standard.

The rationale is directed towards those familiar with the subject of this particular standard but who have not participated in its development. Where the reason for a requirement is considered self-evident to such persons, reasons are not given. An understanding of the reasons for the main requirements is considered to be essential for proper application of ~~the~~ this particular standard. Furthermore, as clinical practice and technology change, changes in this particular standard can be made with an understanding of previous concerns.

- **RISK ANALYSIS**

EXTERNAL PACEMAKERS are used to treat PATIENTS who have symptomatic or acute bradycardia as well as for temporary pacing related to other medical procedures. PATIENT safety is affected by the medical procedure involved, by the understanding of ME EQUIPMENT function by the clinician and by ME EQUIPMENT function. The requirements as specified in this particular standard are considered to provide for an acceptable RISK.

As a basis for establishing safety, an inventory of the RISKS to the PATIENT's safety posed by EXTERNAL PACEMAKERS was developed. The results of that analysis are summarized in Table AA.1. To facilitate the review of this document, a reference to the clause(s) in ~~the~~ this particular standard where the action is described has been added to the table.

The tentative conclusion based on clinical experience is that failure to pace is the most probable occurrence of those HAZARDS listed.

Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory

HAZARD	Cause	Action	Reference in this particular standard
FAILURE TO PACE ~~Poor connection~~	Low battery	Battery indicator	201.11.8
	~~Test of~~ Poor connection	Test of connection	201.7.9.2.13
	Threshold rise	Clinical technique	Not applicable
	Oversensing	Clinical technique	Not applicable
		Stability of parameters with battery and depletion	201.7.9.2.5 ~~dd~~d) and 201.12.4.102
		Input indicator	201.15.102
	Fault	Defibrillator equipment protection	201.8.5.5.1
		High frequency surgical equipment protection	201.8.101
		Spillage protection	201.11.6.5
		Static electric discharges	~~202.6.2.2~~ 202.8.9
		Maintenance	201.7.9.2.13
		Output indicator	201.15.101
	Maladjustment	Protective means	201.12.4.101
		Marking of controls	201.7.4
	Electrode dislodgement	Clinical technique	Not applicable
High rate	Fault	Rate limit (runaway protection)	201.12.4.103
	~~Tampering~~ Maladjustment	Protective means	201.12.4.101
	Temporary high rate	Protective means	201.12.4.1
	Atrial tachyarrhythmia	MAXIMUM TRACKING RATE	201.12.4.105
Unwanted stimulation	Undersensing	Clinical technique	Not applicable
		Stability of parameters with battery depletion	201.7.9.2.5 ~~dd~~d) and 201.12.4.102
		Input indicator	201.15.102
	Low battery	Battery indicator	201.11.8
	Maladjustment	Protective means	201.12.4.101
		Marking of controls	201.7.4
	Noise	Noise reversions	201.7.9.2.5 ~~cc~~c) and 201.12.4.104
		Warnings	201.7.9.2.2 ~~aa)~~a)
	Poor connection (LEAD or battery)	Test of connection	201.7.9.2.13
	Fault	See failure to pace	
	Microphonics	Noise reversion	201.7.9.2.5 ~~cc~~c) and 201.12.4.104
Micro/Macro shock	LEAKAGE CURRENT	LEAKAGE CURRENT limit	201.6.2 and Clause 201.8
	Injection current	Warning	201.7.9.2.2 ~~aa~~a), 201.7.9.2.2 ~~bb~~b), 201.7.9.2.2 ~~cc~~c), 201.7.9.2.2 ~~dd~~d), and 201.7.9.2.2 ~~ff~~f)
Tissue/electrode damage	PATIENT AUXILIARY CURRENT	PATIENT AUXILIARY CURRENT limit	201.8.7.3

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 – Scope

The scope of this particular standard is restricted to EXTERNAL PACEMAKERS with an INTERNAL POWER SOURCE. This implies that all requirements in the general standard and collateral standards that apply to equipment connected to a SUPPLY MAINS are not applicable even though they are not specifically identified in this document.

The scope is restricted for the following reasons.

- The power source is restricted to INTERNAL ELECTRICAL POWER SOURCE, and in particular to PRIMARY BATTERIES, as the ME EQUIPMENT is intended to be moved with the PATIENT. ME EQUIPMENT that could be used when connected to SUPPLY MAINS or powered by rechargeable batteries would have intrinsically additional safety concerns, such as: difficulty in knowing length of service time, state of the battery (recharged or not), no applicable standards, etc.
- This document excludes ME EQUIPMENT which can be directly or indirectly connected to SUPPLY MAINS.
- ~~ME EQUIPMENT which provides pacing as one of several other functions requires separate treatment appropriate to its overall function.~~
- Transthoracic and oesophageal pacing ME EQUIPMENT provides higher output energies which would be inappropriate for direct cardiac pacing.
- Antitachycardia ME EQUIPMENT presents clinical safety issues which require separate treatment appropriate to its function.

PATIENT CABLES are included because they are commonly used as a means to extend the reach of the NON-IMPLANTABLE PULSE GENERATOR while pacing the PATIENT during surgery, and for post-operative and extended pacing periods.

LEADS are not included because they require separate treatment appropriate to their type and their approach to the heart (transvenous, epicardial).

Clause 201.3 – Terms and definitions

The definitions from Clause 3 of ISO 14708-2:2019 are referred to in order to encourage common usage worldwide for terms applicable to both IMPLANTABLE and EXTERNAL PACEMAKERS. Two definitions were copied from ISO 14708-1 for convenience.

Additional definitions have been added as needed to supplement those found in the ISO 14708 series. These definitions are based on common industry usage. ~~Where possible, the definitions have been drawn from ACTIVE IMPLANTABLE MEDICAL DEVICES.~~

Subclause 201.4.11 – Power input

The requirements of this subclause are intended to apply to ME EQUIPMENT connected to SUPPLY MAINS, which does not apply to the EXTERNAL PACEMAKERS covered by this document.

Subclause 201.6.2 – Protection against electric shock

~~ME EQUIPMENT is classified as being INTERNALLY POWERED EQUIPMENT only if there is no external connection to the INTERNAL ELECTRICAL POWER SOURCE, or the electrical connection to the INTERNAL ELECTRICAL POWER SOURCE can be made only after physical and electrical separation of the INTERNAL ELECTRICAL POWER SOURCE from the remainder of the ME EQUIPMENT. ME EQUIPMENT not meeting this requirement is classified as CLASS I or CLASS II with an INTERNAL ELECTRICAL POWER SOURCE.~~

TYPE B APPLIED PART and TYPE BF APPLIED PART are deleted because only TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION.

Subclause 201.7.2.102 – ME EQUIPMENT intended for DUAL CHAMBER application

As an EXTERNAL PACEMAKER is frequently needed in an emergency situation, the information on making a correct connection to the LEADS has to be available without recourse to the instructions for use. Incorrect connecting of the output terminals or PATIENT connectors (i.e. atrial channel to ventricular LEADS) could result in inappropriate and potentially unsafe (high rate stimulation or inappropriate sensing, etc.) operation. Clear marking of both the polarity and chamber is required. If, in addition, colour is used to accentuate the difference, colours that can be differentiated regardless of colour perception (i.e., white and blue) should be used.

Subclause 201.7.2.104 – Battery compartment

Access to the battery compartment for replacement of the batteries is a common maintenance item. Quick identification of the correct type and the proper orientation of the batteries in the battery compartment are required to prevent extended loss of function and/or potential damage to the ME EQUIPMENT. An orientation for the batteries should be provided to avoid OPERATOR confusion even if the ME EQUIPMENT permits reversed connection.

Subclause 201.7.4.101 – Control or indicator for pacing output; and
Subclause 201.7.4.102 – Control or indicator for PULSE RATE

Accurate setting of output energy levels and PULSE RATE is deemed to be essential to safe operation of the ME EQUIPMENT.

Subclause 201.7.4.103 – Control for selecting pacing mode

In order to convey clearly the primary intended use of a NON-IMPLANTABLE PULSE GENERATOR, a three-letter code has been adopted. This is an adaptation of the code developed by the Heart Rhythm Society (formerly North American Society for Pacing and Electrophysiology) and the Heart Rhythm UK (formerly the British Pacing and Electrophysiology Group). To encourage common usage worldwide, the same code is used as that given in Annex ~~DD~~ C of ISO 14708-2:~~2005~~2019 for IMPLANTABLE PULSE GENERATORS.

Subclause 201.7.9.2.2 – Warnings and safety notices

Subclause 201.7.9.2.2 ~~aa~~a)

Sources of ~~electrical interference~~ ELECTROMAGNETIC DISTURBANCE can affect the operation of the ME EQUIPMENT. In the presence of excessive levels of ~~interference~~ ELECTROMAGNETIC DISTURBANCE, the ME EQUIPMENT could:

– fail to pace,
– revert to asynchronous pacing, or
– inappropriately track the ~~interference~~ ELECTROMAGNETIC DISTURBANCE as cardiac activity.

Subclause 201.7.9.2.2 ~~bb~~b)

~~An implanted LEAD or LEAD with PATIENT CABLE constitutes a direct, low resistance current path to the myocardium.~~ The danger of fibrillation resulting from alternating current leakage is greatly increased when SUPPLY MAINS operated ME EQUIPMENT is connected to the LEAD system. Extreme caution has to be taken to have proper grounding of SUPPLY MAINS operated ME EQUIPMENT used in the vicinity of the PATIENT.

Micro-shock is a term for the effects of an otherwise imperceptible electric current applied directly, or in very close proximity, to the heart muscle. The electric current is of sufficient strength, frequency, and duration to cause disruption of normal cardiac function.

Macro-shock is a term for the effects of an electric current passed through the body, usually via a skin to skin pathway. Electric shock is usually referring to macro-shock. More generally, the electric current during macro-shock is not applied directly through the heart muscle. The current in macro-shock events can vary widely from being imperceptible to being extremely destructive of tissue.

Subclause 201.7.9.2.2 ~~cc~~c) and ~~dd~~d)

The PATIENT needs to be protected from electrical impulses inadvertently introduced by making contact with the terminals of the NON-IMPLANTABLE PULSE GENERATOR, PATIENT CABLE and indwelling LEADS. Proper handling of the ME EQUIPMENT will reduce the chance of inadvertent shock while maintaining the clinically needed flexibility of connecting a variety of temporary LEADS, permanent LEADS, and heartwires to the PATIENT CABLE, or directly to the NON-IMPLANTABLE PULSE GENERATOR.

Subclause 201.7.9.2.2 ~~ee~~e)

Performance predictions, especially projections of life after the low battery indicator comes on, are dependent on an understanding of the depletion characteristics of the battery. Batteries with different physical dimensions can result in poor or intermittent contact.

Subclause 201.7.9.2.2 ~~ff~~f)

Although believed to be, at best, a rare complication of pacing, there is a theoretical possibility that a static discharge to the ~~EXTERNAL~~ NON-IMPLANTABLE PULSE GENERATOR or a PATIENT CABLE connected to it could transfer minimally sufficient energy to the PATIENT to produce cardiac depolarization. If this were to occur in an electrically unstable PATIENT during the vulnerable portion of the cardiac cycle, a potentially lethal arrhythmia might be induced. No documented cases or anecdotal reports of such an event are known. It should be noted that there are ways that one or more asynchronous PULSES can be delivered to the PATIENT (e.g. noise reversion, loss of sensing) all of which are much more likely and which typically are cautioned about in the labelling. While only rarely have these common occurrences precipitated an arrhythmia, medical literature leaves no doubt as to the potential for serious consequences. Therefore, a warning that care should be taken to discharge any static electricity that has accumulated on the attending health care professional or the PATIENT before touching the ME EQUIPMENT is appropriate.

Subclause 201.7.9.2.2 ~~gg~~g)

The PULSE energy delivered to the PATIENT is a consequence of the setting of the ~~EXTERNAL~~ NON-IMPLANTABLE PULSE GENERATOR and interaction of that output with a dynamic PATIENT/LEAD environment. The acute load presented by the temporary PATIENT/LEAD system can vary over a range of several hundred ohms. While much of this variation might be clinically inconsequential, "significant" departures from the pre-set level of energy output can occur. Since what constituted a "significant" departure from the pre-set level of energy output will vary widely from PATIENT to PATIENT depending on many factors, including the pre-set margin of safety for capture, selecting a limit that could be monitored by the ME EQUIPMENT and that would apply to all PATIENTS would necessarily leave other PATIENTS largely unprotected. The output circuitry cannot readily determine if the output resulted in capture of the heart.

Subclause 201.7.9.2.4 – Electrical power source

Well-made PRIMARY BATTERIES do not leak under the recommended conditions of storage and use. All batteries, however, have a tendency to leak under some conditions. A leaking battery can result in damage to the ME EQUIPMENT. Good practice would indicate that the battery should be removed if the ME EQUIPMENT is to be stored or left for a period without use.

This edition of the standard is disallowing rechargeable batteries as the power source for the following additional RISK associated with their use.

- Rechargeable batteries cannot be recharged indefinitely.
- Eventually, depending on battery chemistry and the pattern of charging and discharging, a rechargeable battery would no longer retain sufficient energy to meet the service life specified by the MANUFACTURER.
- A MANUFACTURER that specifies the use of rechargeable batteries would be required to provide instructions that enable the RESPONSIBLE ORGANIZATION to determine when the battery will no longer hold sufficient energy to meet the specified service life.

Service life estimate is based on batteries which are fully charged. PRIMARY BATTERIES should be fresh and fully charged as defined by the battery MANUFACTURER or supplier.

An understanding of the service life of the ME EQUIPMENT after the onset of the low battery condition is important for establishing the urgency of replacing the power source when the low battery indicator is activated.

There is a wide variety of PRIMARY BATTERIES, especially of the 9 V alkaline type, available. Use of batteries with different chemical characteristics from that recommended by the MANUFACTURER can result in: 1) a short battery life after onset of the low battery indicator; 2) degraded NON-IMPLANTABLE PULSE GENERATOR performance; and/or 3) overall reduced battery life. Although IEC 60086-1 [4] gives recognized dimensions for 9 V batteries, there are many commonly available batteries which vary in size and terminal configuration. Use of batteries other than the ones specified by the MANUFACTURER can result in erratic or no pacing.

Subclause 201.7.9.2.5 – ME EQUIPMENT description

Subclause 201.7.9.2.5 ~~aa~~a)

Knowledge of NON-IMPLANTABLE PULSE GENERATOR features and characteristics is necessary when selecting an EXTERNAL PACEMAKER for use on a PATIENT. Choosing between these features and characteristics requires that they be comparable, i.e. that they are based on common measurement techniques or common assumptions.

Subclause 201.7.9.2.5 ~~bb~~b)

NON-IMPLANTABLE PULSE GENERATORS and PATIENT CABLES are connected to a variety of LEADS with different LEAD connector pin configurations. The connector assembly grips the LEAD connector pin(s) with sufficient force to provide good electrical and mechanical connection. Knowledge of the design limits of the device can help prevent damage to the ME EQUIPMENT and failure to pace due to an inadequate connection.

Subclause 201.7.9.2.5 ~~cc~~c)

The electrical characteristics follow the outline established in 28.8.2 of ISO 14708-2:~~2005~~2019 for IMPLANTABLE PULSE GENERATORS. The test load of 500 Ω ± 1 % is the same value specified in ISO 14708-2 for IMPLANTABLE PULSE GENERATORS.

~~The operating temperature of 20 °C ± 2 °C is a typical ambient operating temperature within the typical range suggested in the rationale for Subclause 7.9.3.1 of the general standard.~~

Microphonics refers to the creation of electrical noise induced into the sensing electronics as a result of motion or vibration of the EXTERNAL PACEMAKER or LEAD.

This edition specifies particular environmental conditions for some requirements and tests.

Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

The operating temperature of 20 °C ± 2 °C is ~~also~~ the temperature under which PRIMARY BATTERY discharge tests are to be carried out as specified in 6.2 of IEC 60086-1:2015 [4].

Subclause 201.7.9.2.5 ~~dd~~d)

This requirement was taken from 28.19 d) of ~~ISO 4708-2:2005~~ ISO 14708-2:2019 for IMPLANTED PULSE GENERATORS.

Subclause 201.7.9.2.8 – Start-up PROCEDURE

Adverse environmental conditions immediately prior to use can affect the reliable operation of the ME EQUIPMENT.

Subclause 201.7.9.2.13 – Maintenance

As reliable functioning of the ME EQUIPMENT is essential for the PATIENT's safety, these maintenance items are regarded as important.

Subclause 201.8.5.5.1 – Defibrillation protection

Rationale for a 900 V/50 J requirement

While defibrillating on the chest using an external defibrillator, only a small fraction of the initial defibrillation voltage (and energy) reaches the heart and appears between the LEADS of an EXTERNAL PACEMAKER, stressing its outputs. A much higher stress to an EXTERNAL PACEMAKER, however, is provided by an internal defibrillator, which is often used during an open-heart surgery. Defibrillation electrodes (e.g. paddles) of an internal defibrillator are applied directly to the heart muscle, thus an attached EXTERNAL PACEMAKER sees only a slightly diminished voltage (energy) compared with the actual output voltage (energy) of the internal defibrillator waveform.

Previous testing of defibrillation protection (according to ISO 14117) took only the conditions arising during external defibrillation into account. In this case, the high voltage applied to the chest of the PATIENT is strongly reduced, when it arrives at the heart of the PATIENT.

The high voltage standoff requirement for EXTERNAL PACEMAKERS is determined by the maximum voltage between any two electrodes during epicardial (internal) defibrillation. The maximum energy used for epicardial (internal) defibrillation is limited to 50 J by IEC 60601-2-4 [5].

For example, a typical epicardial (internal) defibrillator (Lifepak 12®[3]) can be considered in the use condition with epicardial defibrillation electrodes. In this use case, higher output voltages are used with monophasic vs biphasic defibrillation PULSES, so monophasic waveforms represent the worst-case defibrillation waveform. The maximum voltage delivered during a 50 J monophasic delivery from a Lifepak 12 into a 50 Ω load is approximately 1 029 V. A reasonable minimum expected implant depth of the EXTERNAL PACEMAKER electrodes is 2,5 mm, which would result in a combined voltage drop from the defibrillation electrodes to the two EXTERNAL PACEMAKER electrodes of 5 mm x 28 V/mm or 140 V. As a percentage of the 1 kV applied

[3] Lifepak 12 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.

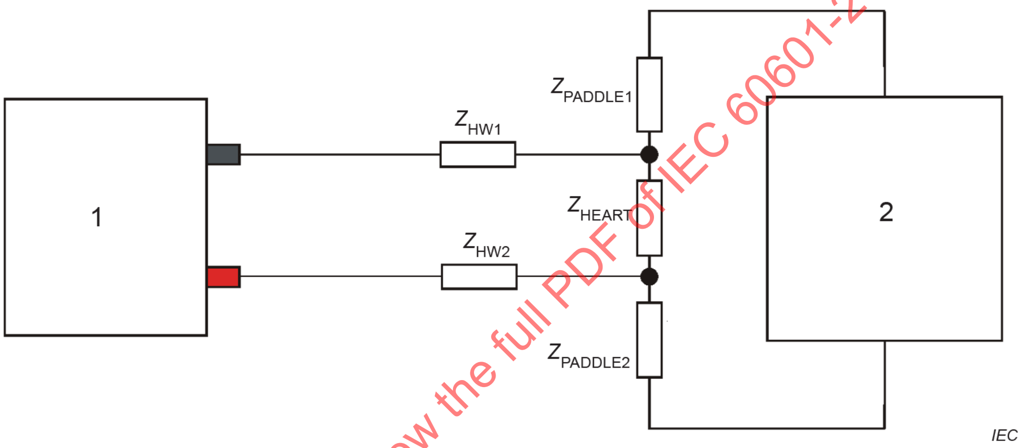
defibrillation PULSE, this would be 86 % to the EXTERNAL PACEMAKER electrodes. Multiplying this by the maximum monophasic defibrillation PULSE voltage of 1 029 V will result in a theoretical maximum voltage delivered to the EXTERNAL PACEMAKER electrodes of 884 V. Given the EXTERNAL PACEMAKER electrodes would typically not be located on opposite sides of the shortest dimension of the heart, there is additional margin provided by worst case electrode assumption used.

For the reasons described above, the defibrillation test voltage should be set to 900 V and the defibrillation waveform should have the energy of 50 J.

Characteristics for modelling internal defibrillation on open heart

Impedance of the heart

Figure AA.1 shows a possible model of internal defibrillation during open heart surgery. The brief investigation presented below describes the impedances specified in this model.



Key

1	EXTERNAL PACEMAKER (only one chamber is shown)
2	epicardial defibrillator (max. 50 J according to IEC 60601-2-4)
$Z_{PADDLE1}$	impedance of epicardial defibrillation paddles and impedance of tissue transition
$Z_{PADDLE2}$	impedance of epicardial defibrillation paddles and impedance of tissue transition
Z_{HEART}	heart impedance seen by epicardial defibrillator
Z_{HW1}	impedance of heart wire and impedance of tissue transition
Z_{HW2}	impedance of heart wire and impedance of tissue transition

Figure AA.1 – Simple model of a SINGLE CHAMBER EXTERNAL PACEMAKER during defibrillation

Schwarz [6] compares biphasic shocks with monophasic sine wave shocks for direct epicardial defibrillation during open chest cardiothoracic surgery. The monophasic shocks were generated by a Lifepak 12 defibrillator/monitor (50 µF capacitance, 21 mH inductance with internal resistance of 11 Ω). The biphasic shocks were delivered by a biphasic Lifepak 12 defibrillator/monitor. Regarding the biphasic PULSE shape, the publication [7] was referenced, where a 200 µF capacitor without inductor was used to generate the biphasic PULSES for external defibrillation. In most cases, 5,1 cm-diameter internal paddles were used.

We find in [6]:

"The mean delivered peak current for the biphasic shock group was calculated to be 5,6 A at the mean threshold energy (6,8 J) and the mean measured defibrillation impedance of ***45 Ω ± 9 Ω*** *(range,* ***30 Ω – 79 Ω****). The mean delivered peak current for the monophasic shock group was 10,6 A at the mean threshold energy (11,0 J). This mean current was estimated by assuming that the monophasic shock group had the same mean impedance as that measured for the biphasic shock group."*

It seems that the impedance in this study was measured by the biphasic defibrillator directly. Due to this fact, we have to assume that the measured defibrillation impedance includes both the impedance of the heart and of both internal paddles as given by Formula (AA.1):

$$Z_{\text{DEFIB}} = Z_{\text{HEART}} + Z_{\text{PADDLE1}} + Z_{\text{PADDLE2}} \qquad \text{(AA.1)}$$

The maximum measured value would be according to Formula (AA.2) as found in [6]:

$$Z_{\text{DEFIB,MAX}} = 79\ \Omega \qquad \text{(AA.2)}$$

In [8], the heart impedance was explicitly measured on pigs[4]. Experimental series special defibrillation electrodes for open heart were used. All measurements were done using Gurvich-Venin bipolar quasi-sinusoidal defibrillation PULSES. Figure 6 in [8] shows a detailed diagram of measured heart impedance. It could be meant that only Z_{HEART} is presented in this figure. According to the test setup shown in [8], the measured value according to Formula (AA.1) appears to have been measured with respect to the defibrillation current. For values of the defibrillation current in the range between 0 A to 3 A, there is a region where the defibrillation impedance can change quite a lot with the highest value being about 31 Ω. However, for higher defibrillation currents, Z_{DEFIB} seems to be quite stable and was measured in a range between 20 Ω to 23 Ω. These are fairly lower impedance values than those obtained by [8].

From [6] and [8], we conclude that only the impedance represented by Formula (AA.1) was obtained, so we still cannot differentiate between Z_{HEART}, Z_{PADDLE1} and Z_{PADDLE2}.

For tests of defibrillation protection of EXTERNAL PACEMAKERS, the heart impedance could be set to $Z_{\text{HEART}} = 50\ \Omega$ as higher value of the heart impedance is not expected. As the paddles introduce a voltage dividing behaviour into the entire defibrillation protection configuration, the impedance of them could be neglected and thus set to 0 Ω.

Impedance of heart wires

Heart wires are intended for temporary stimulation of the heart during and after cardiac surgery. The stimulation is used to maintain a certain heart rhythm and/or to treat arrhythmia occurring intra- and/or postoperatively.

Heart wires are temporarily implanted epicardial electrodes at the ventricle and/or atrium. The fixation on the epicardium is achieved by special electrode anchor mechanisms. The distal end of heart wires can be equipped with small heart needles for implantation into the epicardium or are attached with sutures. The proximal end is equipped with a thorax needle for puncturing the chest and leading the wire out of the thorax. Heart wires are connected to EXTERNAL PACEMAKERS

4 Pig heart is regarded to be very similar to that of a human.

and have to be explanted after 5 to 7 days by pulling gently on the wire in a certain way. Heart wires are often called "temporary myocardial electrodes" (TME).

If the internal defibrillation paddles had a direct contact with the heart wires, then the heart wire impedance would have to have an impedance Z_{HW} somewhere between 10 Ω and 150 Ω. In this case, the impedance of electrode/tissue transition is omitted. It is unlikely, however, that both defibrillator paddles will contact the heart wires.

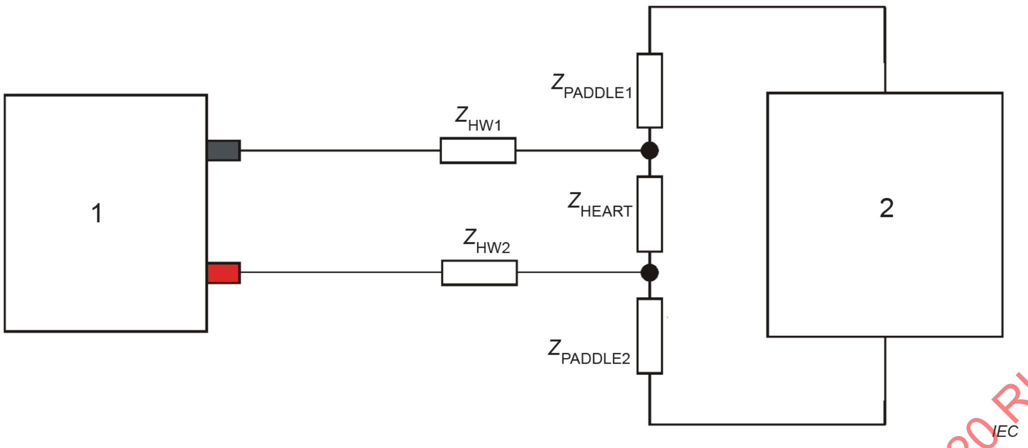
Normally, the total impedance seen by an EXTERNAL PACEMAKER is well within the range 200 Ω to 1 000 Ω specified in IEC 60601-2-31:2008 in 201.12.1.102[5]. There can be much lower impedance than 200 Ω achieved. However, this case does not represent a correct application of heart wire.

Taking all this information presented above into account and having in mind that a defibrillation-protection test should use a reasonably foreseeable worst-case condition, we consider the case in which one heart wire is directly connected with the internal defibrillation paddle, with the second internal paddle not being in any direct contact with the second heart wire. The Z_{HW} would then be roughly 200 Ω/2 ≈ 100 Ω. This value could be lowered to 80 Ω to take any inequality in electrode/tissue impedance into account.

Example test meeting the requirements

Z_{HEART} would unlikely be more than 50 Ω, which should already be treated as an extreme value. Z_{HEART} ≈ 50 Ω would be a good value for a worst case in defibrillation model. For an easy test setup, the impedance of internal paddles $Z_{PADDLE1}$ and $Z_{PADDLE2}$ could actually be set to 0 Ω, since these elements only divide the output voltage of the defibrillator before it appears at Z_{HEART}. The test voltage could then be directly adjusted to 900 V.

5 For impedance smaller than 200 Ω the accuracy of PACEMAKER pulses would get worse. Eventually, a short condition would occur to the PACEMAKER, which would be considered as a fault condition.



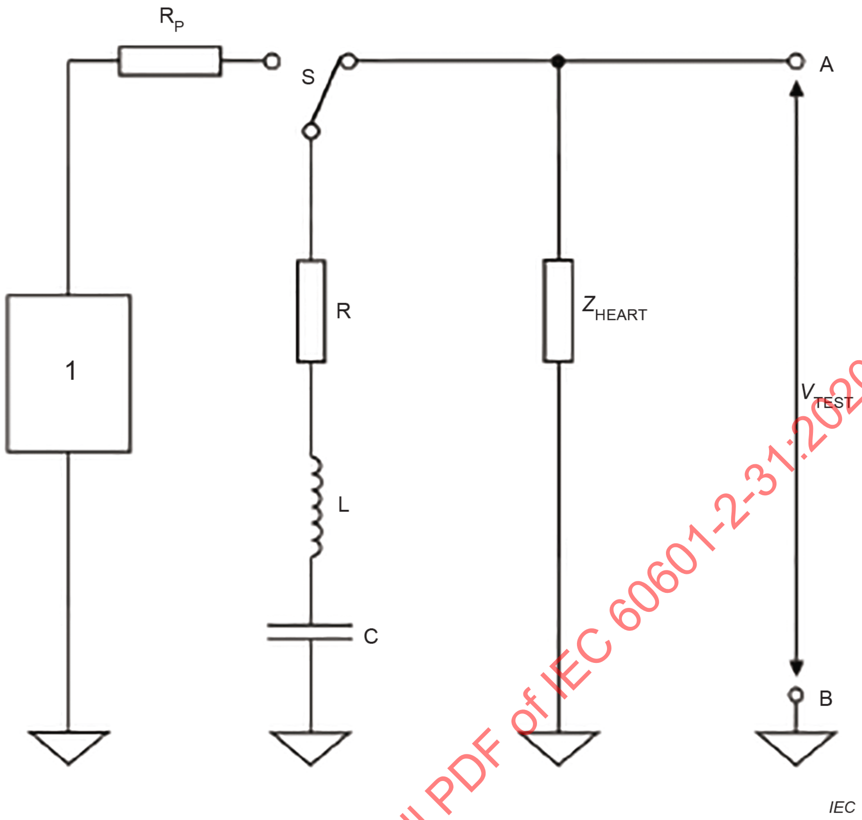
Key

①	SINGLE CHAMBER EXTERNAL PACEMAKER
②	epicardial defibrillator (max. 50 J according to IEC 60601-2-4)
$Z_{PADDLE1}$	impedance of epicardial defibrillation paddles and impedance of tissue transition; R = 0 Ω
$Z_{PADDLE2}$	impedance of internal defibrillation paddles and impedance of tissue transition; R = 0 Ω
Z_{HEART}	heart impedance seen by epicardial defibrillator; R = 50 Ω
Z_{HW1}	impedance of heart wire and impedance of tissue transition; R = 0 Ω
Z_{HW2}	impedance of heart wire and impedance of tissue transition; R = 80 Ω

Figure AA.2 – First proposal for a defib-protection test of SINGLE CHAMBER EXTERNAL PACEMAKER

Defibrillation test voltage generator

Figure AA.3 represents an example circuit for generation of the defibrillation test voltage. In practice, component tolerances used to construct this circuit will affect the energy delivered to the EUT. Therefore, an analysis of the effects of tolerances was undertaken to arrive at a set of component values that would minimally meet the needs for this test under foreseeable tolerance combinations. Figure AA.4 shows the variation in delivered PULSE waveform timing for a range of value for capacitor C.



Key

1	voltage generator
R	resistor in series with L and C
L	inductance
C	capacitor
R_P	current limiting resistor
Z_{HEART}	heart impedance seen by epicardial defibrillator; R = 50 Ω; simulated with an ohmic resistor
V_{TEST}	test voltage
A, B	output terminals of the defibrillator test voltage generator

Figure AA.3 – Circuit for a defibrillation test generator for defibrillation test according to conditions during open heart surgery

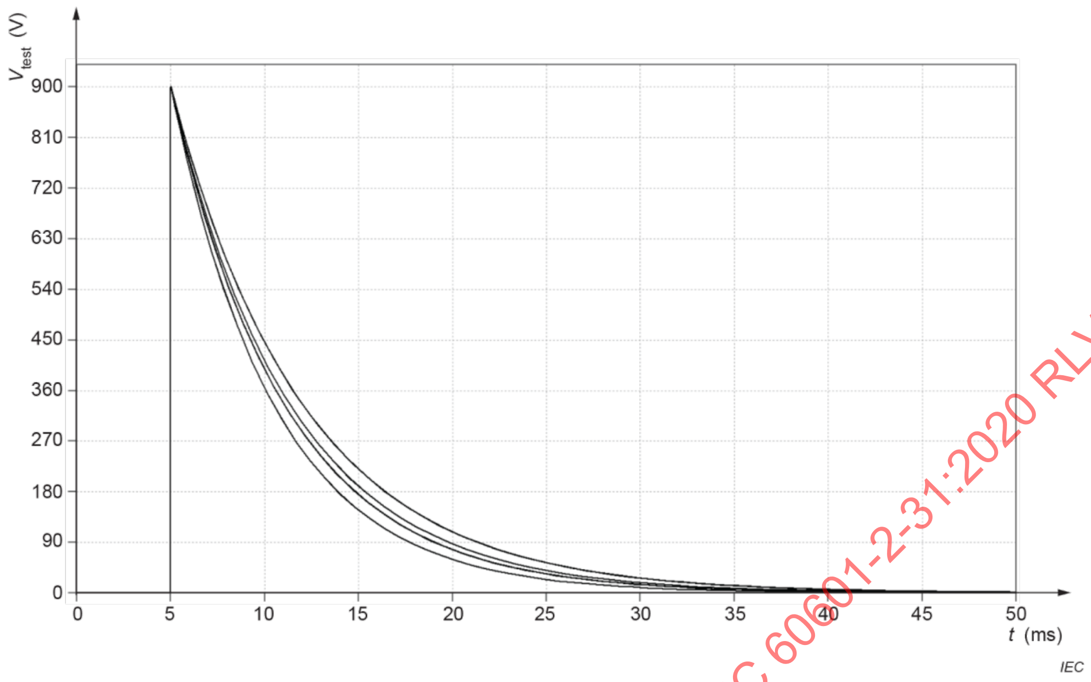


Figure AA.4 – Defibrillation PULSE generated by the defibrillation test generator from Figure AA.3

Z_{HEART}, in the example circuit of Figure AA.3 simulated with an ohmic resistor, is assumed to be 50 Ω ± 5 %. The test generator should provide output PULSES having 50 J. The energy delivered by the generator mainly depends on the value of the used capacitor. The rise time of the generated PULSE is mainly dependent on the applied inductor *L*. IEC 60601-2-4 [5] provides a test circuit for immunity of pacing circuitry to defibrillation pulses. The circuit specifies a series inductance of 500 µH. For the purposes of this document, a series inductance of 25 µH is used, thereby leading to a more challenging rise time test.

Calculations of the rise time show that the rise time t_r very well fits into the interval of 1 µs < t_r < 5 µs. Please see Figure AA.5 for the calculated rise times for components with applied tolerances. It should be noted that for those calculations the range of capacitance values was extended to include the range of 114 µF to 132,63 µF to take the three capacitance values proposed below and their tolerances of ±5 % into account. Looking at Figure AA.5, we see that the value of t_r(taken the definition of a rise time between 10 % and 90 % of the slope) is about 1 µs to 1,25 µs. It should however be noted here that the calculated rise times do not take any further damping factors, like the inductance of internal connections or cables into account. The real PULSE rise times are expected to be somewhat longer.

The resistance *R* should be chosen in such a way that *R* + *RL* = 1 Ω with a tolerance of ±5 %.

The calculations below (see Tables AA.2, AA.3 and AA.4) show the dependence of output PULSE energy for a capacitance tolerance of ±5 % for three different capacitance values: 120 µF, 122 µF and 126,32 µF. On the one hand, only for the largest values, all PULSE energies are greater than 50 J. On the other hand, 122 µF can easily be built of two capacitors: 100 µF + 22 µF.

Table AA.2 – PULSE energies calculated for C = 120 µF ± 5 %

V_{set} = 925 V					
C = 120 µF ± 5 %		L = 25 µH ± 5 %		$R + RL$ = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	**C**	**L**	**Z_{HEART}**	**V_{out}**	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	114	23,75	47,5	903	**47,7**
2	120	23,75	47,5	903	**50,2**
3	126	23,75	47,5	903	**52,7**
4	114	25,00	47,5	903	**47,7**
5	120	25,00	47,5	903	**50,2**
6	126	25,00	47,5	903	**52,7**
7	114	26,25	47,5	903	**47,7**
8	120	26,25	47,5	903	**50,2**
9	126	26,25	47,5	903	**52,7**
10	114	23,75	50,0	903	**47,8**
11	120	23,75	50,0	903	**50,2**
12	126	23,75	50,0	903	**52,7**
13	114	25,00	50,0	903	**47,8**
14	120	25,00	50,0	903	**50,2**
15	126	25,00	50,0	903	**52,7**
16	114	26,25	50,0	903	**47,8**
17	120	26,25	50,0	903	**50,2**
18	126	26,25	50,0	903	**52,7**
19	114	23,75	52,5	903	**47,8**
20	120	23,75	52,5	903	**50,3**
21	126	23,75	52,5	903	**52,8**
22	114	25,00	52,5	903	**47,8**
23	120	25,00	52,5	903	**50,3**
24	126	25,00	52,5	903	**52,8**
25	114	26,25	52,5	903	**47,8**
26	120	26,25	52,5	903	**50,3**
27	126	26,25	52,5	903	**52,8**

Table AA.3 – PULSE energies calculated for *C* = 122 µF ± 5 %

V_{set} = 925 V					
C = 122 µF ± 5 %		*L* = 25 µH ± 5 %		*R* + *RL* = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	***C***	***L***	Z_{HEART}	V_{out}	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	115,9	23,75	47,5	903	**48,5**
2	122,0	23,75	47,5	903	**51,0**
3	128,1	23,75	47,5	903	**53,5**
4	115,9	25,00	47,5	903	**48,5**
5	122,0	25,00	47,5	903	**51,0**
6	128,1	25,00	47,5	903	**53,5**
7	115,9	26,25	47,5	903	**48,5**
8	122,0	26,25	47,5	903	**51,0**
9	128,1	26,25	47,5	903	**53,5**
10	115,9	23,75	50,0	903	**48,5**
11	122,0	23,75	50,0	903	**51,1**
12	128,1	23,75	50,0	903	**53,6**
13	115,9	25,00	50,0	903	**48,5**
14	122,0	25,00	50,0	903	**51,1**
15	128,1	25,00	50,0	903	**53,6**
16	115,9	26,25	50,0	903	**48,5**
17	122,0	26,25	50,0	903	**51,1**
18	128,1	26,25	50,0	903	**53,6**
19	115,9	23,75	52,5	903	**48,6**
20	122,0	23,75	52,5	903	**51,1**
21	128,1	23,75	52,5	903	**53,6**
22	115,9	25,00	52,5	903	**48,6**
23	122,0	25,00	52,5	903	**51,1**
24	128,1	25,00	52,5	903	**53,6**
25	115,9	26,25	52,5	903	**48,6**
26	122,0	26,25	52,5	903	**51,1**
27	128,1	26,25	52,5	903	**53,6**

Table AA.4 – PULSE energies calculated for C = 126,32 µF ± 5 %

V_{set} = 925 V					
C = 126,32 µF ± 5 %		L = 25 µH ± 5 %		R + RL = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	C	L	Z_{HEART}	V_{out}	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	120,00	23,75	47,5	903	**50,2**
2	126,32	23,75	47,5	903	**52,8**
3	132,63	23,75	47,5	903	**55,4**
4	120,00	25,00	47,5	903	**50,2**
5	126,32	25,00	47,5	903	**52,8**
6	132,63	25,00	47,5	903	**55,4**
7	120,00	26,25	47,5	903	**50,2**
8	126,32	26,25	47,5	903	**52,8**
9	132,63	26,25	47,5	903	**55,4**
10	120,00	23,75	50,0	903	**50,2**
11	126,32	23,75	50,0	903	**52,8**
12	132,63	23,75	50,0	903	**55,4**
13	120,00	25,00	50,0	903	**50,2**
14	126,32	25,00	50,0	903	**52,8**
15	132,63	25,00	50,0	903	**55,4**
16	120,00	26,25	50,0	903	**50,2**
17	126,32	26,25	50,0	903	**52,8**
18	132,63	26,25	50,0	903	**55,4**
19	120,00	23,75	52,5	903	**50,3**
20	126,32	23,75	52,5	903	**52,9**
21	132,63	23,75	52,5	903	**55,5**
22	120,00	25,00	52,5	903	**50,3**
23	126,32	25,00	52,5	903	**52,9**
24	132,63	25,00	52,5	903	**55,5**
25	120,00	26,25	52,5	903	**50,3**
26	126,32	26,25	52,5	903	**52,9**
27	132,63	26,25	52,5	903	**55,5**

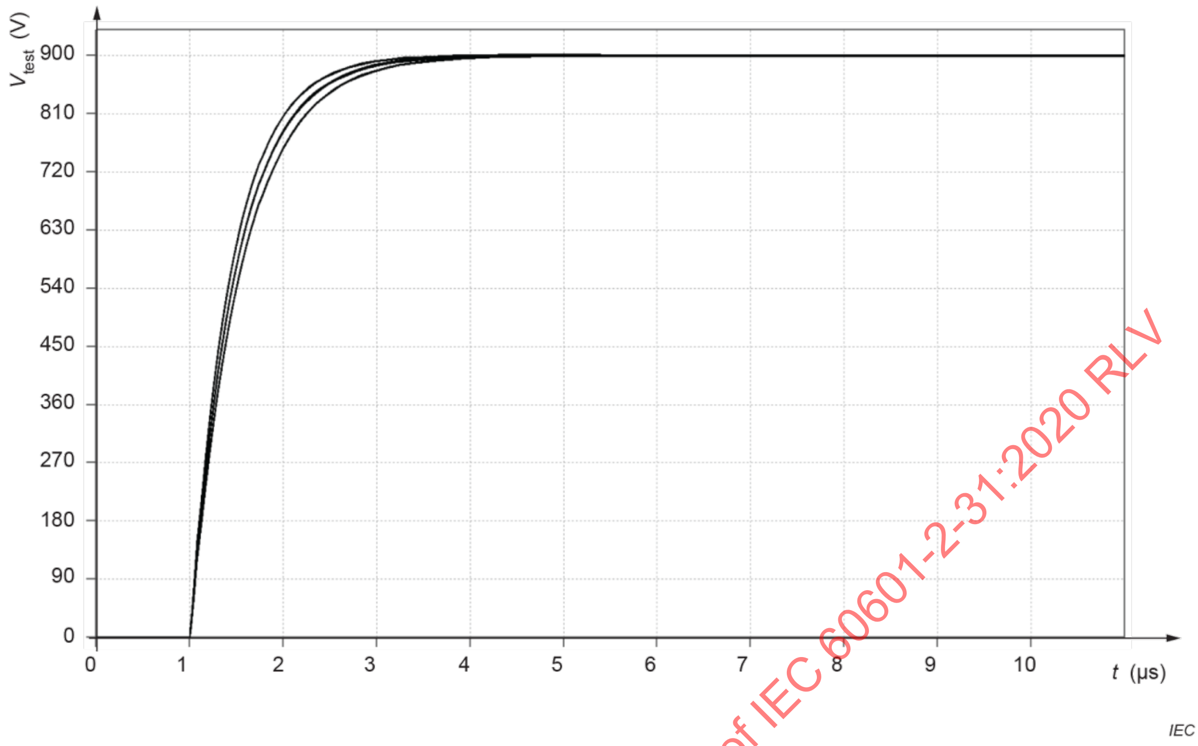


Figure AA.5 – Rise times of a defibrillation PULSE according to the circuit proposed in Figure AA.3

Subclause 201.8.5.5.2 – Energy reduction test

The applicability of the energy reduction clause was considered at length during the development of the third edition of this document.

There are two primary pathways by which energy reduction might occur. The first of these might be from the thorax to an earth grounded piece of equipment.

EXTERNAL PACEMAKERS within the scope of this particular standard differ from the ME EQUIPMENT considered in the general standard, in that they are not mains connected, and therefore cannot provide a shunting pathway to earth that would lead to an energy reduction.

A second pathway for energy reduction would be through the external PULSE generator itself by way of the attached heart wires. This might occur during the use of either internally or externally applied paddles. This effect is addressed primarily by the defibrillation protection clause.

Furthermore, these two scenarios were presented to a group of clinicians during a meeting of the AAMI CRMD committee in 2017. Their conclusion as to the need for a test of the effect of energy reduction effect caused by the presence of the EXTERNAL PACEMAKER was that it would be unnecessary. None of the physicians responded that they had seen the effect, and they further explained that even if there were an effect, that they would simply increase defibrillation energy, make repeated defibrillation attempts, or go so far as to remove the EXTERNAL PACEMAKER or LEAD connections in order to ensure the safety of the PATIENT.

Subclause 201.8.7.3 – Allowable values

A net direct current between electrodes in the body can result in damage to the tissue and the electrodes. Subclause 16.2 of ISO 14708-2:~~2005~~2019 requires that no PATIENT AUXILIARY CURRENT of more than 0,1 µA shall be detected in any current pathway. Since NON-IMPLANTABLE PULSE GENERATORS are used for relatively short periods of time, a higher level of PATIENT AUXILIARY CURRENT should be tolerated both under NORMAL (1 µA) and SINGLE FAULT (5 µA) conditions.

Where the AC component of the current is intended to produce a physiological effect, it is therefore outside the definition of PATIENT AUXILIARY CURRENT.

Subclause 201.8.7.4.1 – General

Subclause 201.8.7.4.1 aa)

Due to capacitive coupling between the APPLIED PART and other parts, a certain amount of LEAKAGE CURRENT is unavoidable. During the pacing PULSE, LEAKAGE CURRENTS can be higher, but will be much smaller than the intended pacing PULSE current and will not present a HAZARD to the PATIENT and the OPERATOR.

Subclause 201.8.7.4.8 – Measurement of the PATIENT AUXILIARY CURRENT

The test PROCEDURE is based on the one in 16.2 of ISO 14708-2:~~2005~~2019.

~~The NON-IMPLANTABLE PULSE GENERATOR may provide a "recharge" pulse whose area (integral of amplitude over time) is equal to the pacing pulse and of opposite polarity. The purpose of a recharge pulse is to make the net current through the tissue and the lead zero. Since the "recharge" pulse would immediately follow the pace pulse, the measurement for PATIENT AUXILIARY CURRENT (d.c. offset) is performed just before the start of the pace pulse so that the "recharge" pulse is not included in the measurement.~~

Subclause 201.11.6.5 – Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

The ME EQUIPMENT is likely to be used in close proximity to liquids which could be inadvertently spilled on the device while in operation, e.g. food and drink, urine, intravenous solutions, etc. The ME EQUIPMENT also has the potential to be carried and used outside medically used rooms. Therefore, a certain degree of protection against spillage and rainfall was deemed to be necessary.

Saline solution with a concentration of 9 g/l was selected as a worst-case solution simulating body fluids. 400 ml was selected to simulate a filled large glass or coffee cup. Wiping the ME EQUIPMENT dry after 30 s would be a normal response to a spill. The ME EQUIPMENT should continue to operate normally during and after the spill.

If saline penetrates the electronic compartment, undesired conduction paths or dendrites might develop within the circuitry. A 24 h delay between the solution exposure and the inspection was selected, so that sufficient time would pass for any saline that had entered the electronic compartment to migrate within the electronic compartment, and/or dendrites to develop.

Therefore, the integrity of the liquid ingress protection is assessed in two ways:

1) by assuring that the device function is not impaired during the spill (undesired conduction paths bridging intended conduction paths); and
2) visually by ensuring that no liquid, dendrites or stains are found in the electronics after the saline has had time to seep into and migrate within the electronic compartment.

Subclause 201.11.8 – Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

The requirement for a BATTERY DEPLETION INDICATOR is essential to avoid unexpected change in characteristics or function caused by depletion of the battery.

Subclause 201.12.1.101 – ME EQUIPMENT parameters

~~The parameter measurement accuracies listed in Table 201.103 are based on data taken from 6.1 of ISO 14708-2:2005 which have been accepted as adequate for implantable pacemakers.~~ The purpose of the test methods in 6.1 of ISO 14708-2:~~2005~~2019 are to allow overall assessment of NON-IMPLANTABLE PULSE GENERATOR function without elaborate instrumentation or equipment. ~~The accuracies listed in Table 201.103 provide a "worst case" for comparing test methods to the methods listed in 6.1 of ISO 14708-2:2005.~~

The intention is that compliance be measured using the test similar to those specified in 6.1 of ISO 14708-2:~~2005~~2019 with fully charged batteries ~~operating at 20 °C~~. ~~A temperature of 20 °C ± 2 °C was selected for testing of the EQUIPMENT because it is:~~

~~1) a typical ambient temperature in medically controlled spaces; and~~

~~2) the temperature under which the discharge characteristics of the primary battery are determined according to 6.2 of IEC 60086-1 [2].~~

This edition specifies particular environmental conditions for some requirements and tests.

Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

To test the parameter stability at different rates settings, values of 60 PULSES and 120 PULSES per minute were selected as typical.

The test method for MAXIMUM TRACKING RATE is patterned on the test methods and uses the test apparatus and terminology described in 6.1 of ISO 14708-2:~~2005~~2019.

Subclause 201.12.1.102 – PULSE AMPLITUDE

Experience has shown that 200 Ω to 1 000 Ω represents the range of LEAD impedances, including the heart tissue, which are likely to be encountered in temporary pacing. 500 Ω is the typical value. Variation due to changing load is to be measured at a fixed pacing rate. A rate of 70 PULSES per minute was selected as a common rate available in all devices.

Subclause 201.12.4.1 – Intentional exceeding of safety limits

If high pacing rates are used in specific circumstances, extra precautions should be taken to prevent accidental high rate stimulation and to prevent the ME EQUIPMENT from being inadvertently left with the runaway rate protection feature disabled.

Subclause 201.12.4.101 – Protection against accidental change of controls and tampering

Maladjustment of the controls can result in a ~~hazard~~ HAZARDOUS SITUATION; therefore, appropriate steps should be taken to reduce this possibility.

Subclause 201.12.4.102 – Protection against a low battery condition

The published tolerances listed in 201.7.9.2.5 ~~cc~~c) are intended to extend over the service life of the power source, from fully charged to the detection of the low battery condition. If the

ME EQUIPMENT changes its behaviour or is unable to maintain the tolerances listed in 201.7.9.2.5 ~~cc~~c), the new behaviour is described in 201.7.9.2.5 ~~dd~~d) and tested using the same test methods as those used to characterize the electrical parameters listed in 201.7.9.2.5 ~~cc~~c).

Subclause 201.12.4.103 – Rate limit (runaway protection)

This feature is required in order to prevent unexpected and dangerously high pacing rates from occurring in the event of a SINGLE FAULT CONDITION.

Subclause 201.12.4.104 – Interference reversion

The ME EQUIPMENT during NORMAL USE might be used in areas where strong continuous electrical ~~interference~~ ELECTROMAGNETIC DISTURBANCE is present. For maximum safety under these conditions, the ME EQUIPMENT should revert to a stated mode of operation ~~until the interference stops~~.

Subclause 201.12.4.105 – MAXIMUM TRACKING RATE

If DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing are available in the ME EQUIPMENT, a means should be provided to limit the ventricular pacing rate in response to sensed atrial activity to prevent deterioration of the haemodynamic state of the PATIENT. This value is independent of the runaway limit which is intended to prevent an excessively high pacing rate in the event of a SINGLE FAULT CONDITION.

Subclause 201.15.101 – Output indicator

An output indicator is a quick non-invasive indication of device operation. However, a circuit which monitors the actual output PULSE cannot readily determine if that output resulted in capture of the heart. Determining proper ME EQUIPMENT function and capture of the heart requires expert examination of the electrocardiogram.

Subclause 201.15.102 – Input indicator

An input indicator provides an indication that the device has detected the electrical activity of the heart and will react to the signal as specified by the MANUFACTURER for the selected pacing mode and other operational characteristics of the ME EQUIPMENT.

~~**Subclause 202 – Electromagnetic compatibility – Requirements and tests**~~

~~**Subclause 202.6.2.2 – Electrostatic discharge (ESD)**~~

~~**Subclause 202.6.2.2.1 – Requirements**~~

~~EXTERNAL PACEMAKERS are used in environments where no special precautions have been taken to reduce the probability and magnitude of static discharges, such as humidity controlled rooms, static treated carpets, etc. In these conditions the ME EQUIPMENT is likely to be exposed to static discharges which could damage an unprotected device. Severity level 4 was chosen as the maximum test level because 15 kV is a practically achievable value for the electrostatic voltage to which the operator might be charged. See Figure A.1 in IEC 61000-4-2.~~

~~The AIR DISCHARGE METHOD was chosen because a likely scenario has the USER walking across a tiled or carpeted floor and then discharging to the EQUIPMENT through an air gap as he reaches for the device.~~

~~Multiple discharges are needed to test ESD effects on timing sequences within the device, especially where microprocessors and software are involved. Subclause 8.3.1 of IEC 61000-4-2 specifies at least ten single discharges. This number should be increased as~~

~~device complexity increases. At the higher voltage levels, the number of discharges is decreased to two out of concern for inducing errors due to the testing rather than simulation of the environment, since the probability of higher voltages occurring is lower than the probability of the lower voltage levels. Also, because the probability of the higher voltages is lower, some temporary degradation requiring operator intervention or system reset is allowed at severity levels 3 and 4.~~

Subclause 202.8.9 – IMMUNITY TEST LEVELS

EXTERNAL PACEMAKERS are used in a professional healthcare facility environment, for example, physician offices, hospitals (emergency rooms, PATIENT rooms, intensive care, and surgery rooms).

Because EXTERNAL PACEMAKERS are used in conjunction with pacing LEADS which provide a low-impedance pathway to the heart, it is a standard of care and a recommended practice that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface before touching the PATIENT, the cable, the LEADS, or the EXTERNAL PACEMAKER. Also, static electricity from the PATIENT should be neutralized by touching the PATIENT away from (i.e., distal to) the LEADS.

In these conditions, the ME EQUIPMENT is less likely than in a HOME HEALTHCARE ENVIRONMENT to be exposed to static discharges which could damage an unprotected device. Severity level 4 was chosen as the maximum test level because 15 kV is a practically achievable value for the electrostatic voltage to which the OPERATOR might be charged. See Figure A.1 in IEC 61000-4-2:2008 [3].

Multiple discharges are needed to test ESD effects on timing sequences within the device, especially where microprocessors and software are involved. Subclause 8.3.2 of IEC 61000-4-2:2008 [3] recommends at least ten single discharges. Because the probability of the higher voltages is lower, some temporary degradation requiring OPERATOR intervention or system reset is allowed at severity levels 3 and 4.

OPERATOR intervention is acceptable, given that external pacing is performed under highly monitored conditions, with the EXTERNAL PACEMAKER secured out of the reach of the PATIENT and the PATIENT in a non-ambulatory state. Intervention with the accessibility of a back-up within a reasonable time is considered a standard of care. For example, it is standard practice for the user to monitor the PATIENT's ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during evaluation of stimulation and sensing thresholds, EXTERNAL PACEMAKER and pacing LEAD connections and adjustments, and atrial high-rate burst pacing therapy.

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Index of defined terms used in this particular standard

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IEC 60601-2-31

Edition 3.0 2020-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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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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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:

FDIS	Report on voting
62D/1719/FDIS	62D/1732A/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 10 P members out of 10 having cast a vote.

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

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 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 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*

201.3 * Terms and definitions

For the purposes of this document, the terms and definitions specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, ISO 14117:2019, and ISO 14708-2:2019 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 53.

Addition:

201.3.201
ACTIVE IMPLANTABLE MEDICAL DEVICE
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in place after the procedure

[SOURCE: ISO 14708-1:2014, 3.2, modified – The words "in place" have been added to the definition, and the note to entry has been deleted.]

201.3.202
BATTERY DEPLETION INDICATOR
means of indicating when the battery should be replaced

201.3.203
CARDIAC PACEMAKER
ME EQUIPMENT intended to treat bradyarrhythmias

201.3.204
DUAL CHAMBER
relating to both atrium and ventricle

201.3.205
EXTERNAL PACEMAKER
CARDIAC PACEMAKER consisting of a NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE(S) (if used)

201.3.206
LEAD
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length between the EXTERNAL PACEMAKER and the PATIENT'S heart

[SOURCE: ISO 14708-1:2014, 3.13, modified – The words "between the EXTERNAL PACEMAKER and the PATIENT'S heart" have been added to the definition, and the note to entry has been deleted.]

201.3.207
MAXIMUM TRACKING RATE
maximum PULSE RATE at which the multi-chamber NON-IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a sensed atrial signal

[SOURCE: ISO 14708-2:2019, 3.30, modified – The word "IMPLANTABLE " has been replaced by "multi-chamber NON-IMPLANTABLE" and the word "triggering" by "sensed atrial".]

201.3.208
NON-IMPLANTABLE PULSE GENERATOR
ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE which is intended for use outside the body and which produces a periodic electrical PULSE intended to stimulate the heart through a LEAD (or combination of a LEAD and PATIENT CABLE)

201.3.209
PATIENT CABLE
cable used to extend the distance between the NON-IMPLANTABLE PULSE GENERATOR and the pacing LEAD

201.3.210
POST-VENTRICULAR ATRIAL REFRACTORY PERIOD
PVARP
refractory period in atrial channel after paced or sensed event in ventricular channel, used in DUAL CHAMBER modes

Note 1 to entry: This note applies to the French language only.

201.3.211
PRIMARY BATTERY
one or more cells, which are not designed to be electrically recharged, that are fitted with devices necessary for use, for example case, terminals, marking and protective devices

[SOURCE: IEC 60050-482:2004, 482-01-04, modified – The word "primary" has been added to the term, and the words "which are not designed to be electrically recharged" have been added to the definition.]

201.3.212
SINGLE CHAMBER
relating to either atrium or ventricle

201.3.213
BASIC RATE
PULSE RATE of a NON-IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

[SOURCE: ISO 14708-2:2019, 3.26, modified – The words "an implantable" have been replaced by "a NON-IMPLANTABLE".]

201.3.214
ESCAPE INTERVAL
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of a NON-IMPLANTABLE PULSE GENERATOR

[SOURCE: ISO 14117:2019, 3.128, modified – The words "an implantable" have been replaced by "a NON-IMPLANTABLE".]

201.3.215
INTERFERENCE PULSE RATE
PULSE RATE with which the NON-IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity that it recognizes as interference

[SOURCE: ISO 14117:2019, 3.129, modified – The words "an implantable" have been replaced by "NON-IMPLANTABLE".]

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
BATTERY DEPLETION INDICATOR	201.11.8
ME EQUIPMENT parameter stability	201.12.1.101
PULSE AMPLITUDE stability	201.12.1.102
Disabling runaway rate protection	201.12.4.1
Deliberate action required to change settings	201.12.4.101
Parameter stability at onset of the BATTERY DEPLETION INDICATOR	201.12.4.102
Runaway protection	201.12.4.103
Interference reversion in the presence of sensed ELECTROMAGNETIC DISTURBANCE or electrical energy sources	201.12.4.104
Limit at which the ventricle is paced in response to sensed atrial activity	201.12.4.105

201.4.10.1 Source of power for ME EQUIPMENT

Replacement:

ME EQUIPMENT shall be powered by a PRIMARY BATTERY.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

This subclause of the general standard does not apply.

201.4.11 * Power input

This subclause of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

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

Replacement:

ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

ME EQUIPMENT shall be recognized as INTERNALLY POWERED only if no external connections to an electrical power source are provided.

APPLIED PARTS shall be classified as TYPE CF APPLIED PARTS. APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS.

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

Additional subclauses:

201.7.2.101 ME EQUIPMENT intended for SINGLE CHAMBER application

If the ME EQUIPMENT is intended for SINGLE CHAMBER applications, the connector terminals (if used) shall be conspicuously marked positive (+) and negative (–).

201.7.2.102 * ME EQUIPMENT intended for DUAL CHAMBER application

If the ME EQUIPMENT is intended for DUAL CHAMBER application, the connector terminals (if used) shall be marked according to Table 201.102. If colour is used to differentiate between channels in a DUAL CHAMBER application, then the ventricular channel should be marked with the colour white and the atrial channel should be marked with a contrasting colour.

Table 201.102 – DUAL CHAMBER connector terminal marking

Channel	Symbol		Terminal label
	Positive terminal	Negative terminal	
Atrial channel	A+	A–	ATRIUM
Ventricular channel	V+	V–	VENTRICLE

201.7.2.103 Bipolar connectors

When bipolar connectors are used, they shall have keyways that prevent inadvertent polarity reversal.

201.7.2.104 * Battery compartment

The means of access to the battery compartment shall be easily identifiable. The battery compartment shall be clearly and permanently marked with the IEC battery nomenclature, the voltage and type. The battery compartment shall be clearly and permanently marked to show the correct orientation of the battery or batteries.

201.7.4 Marking of controls and instruments

Additional subclauses:

201.7.4.101 * Control or indicator for pacing output

If constant current output is used, the control for selecting pacing output or the relevant indicating means shall be marked in terms of current in milliamperes (mA) through a resistive load of 500 Ω ± 1 %. If a constant voltage output is used, the pacing output or the relevant indicating means shall be marked in terms of volts (V) across a resistive load of 500 Ω ± 1 %.

201.7.4.102 * Control or indicator for PULSE RATE

The control for selecting PULSE RATE or the relevant indicating means shall be marked in terms of reciprocal minutes.

201.7.4.103 * Control for selecting pacing mode

If a means of selecting the pacing mode is provided, the ME EQUIPMENT shall indicate, as well as the mode selected, the possible pacing modes using the codes described in Annex C of ISO 14708-2:2019.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2.2 * Warning and safety notices

Replacement:

The instructions for use shall include all warning and safety notices.

General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments.

The instructions for use shall include the following.

a) * Warnings regarding potential changes in the behaviour of the NON-IMPLANTABLE PULSE GENERATOR caused by ELECTROMAGNETIC DISTURBANCE sources (e.g. communication transmitters in hospitals, emergency transport vehicles, cellular telephones, etc.) and the effects of therapeutic and diagnostic energy sources (e.g. external cardioversion, diathermy, transcutaneous electrical nerve stimulators [TENS] devices, high-frequency surgical equipment, magnetic resonance imaging or similar sources) on the NON-IMPLANTABLE PULSE GENERATOR. This shall include advice on recognizing when the behaviour of the NON-IMPLANTABLE PULSE GENERATOR is being influenced by external ELECTROMAGNETIC DISTURBANCE or electrical energy sources and steps to be taken to avoid interference.
b) * A warning about the danger of inadvertently introducing LEAKAGE CURRENT into the heart if SUPPLY MAINS-operated equipment is connected to the LEAD system.
c) * A warning that the PATIENT CABLE shall be connected to the NON-IMPLANTABLE PULSE GENERATOR before the pacing LEADS are connected to the PATIENT CABLE.
d) * A warning that when handling indwelling LEADS, the terminal pins or exposed metal are not to be touched nor be allowed to contact electrically conductive or wet surfaces.
e) * A warning regarding the HAZARDS of using PRIMARY BATTERIES other than those recommended by the MANUFACTURER (for example, short BATTERY life after the indication of low BATTERY condition, degraded ME EQUIPMENT performance, overall reduced BATTERY life, and erratic or no pacing).
f) * A warning that, before handling the NON-IMPLANTABLE PULSE GENERATOR, the PATIENT CABLE or indwelling LEADS, steps shall be taken to equalize the electrostatic potential between the user and the PATIENT, for example by touching the PATIENT at a site remote from the pacing LEADS.
g) * A caution that, when clinically indicated, supplemental monitoring of the PATIENT should be considered.

201.7.9.2.4 * Electrical power source

Replacement:

The instructions for use shall contain advice on removal of the PRIMARY BATTERY if the ME EQUIPMENT is to be stored or when a long period of disuse is anticipated.

The instructions for use shall state the recommended PRIMARY BATTERY specification.

The instructions for use shall contain the estimated service time from a fully charged BATTERY at 20 °C ambient temperature when operating under specified conditions.

The instructions for use shall contain the estimated service time following activation of the BATTERY DEPLETION INDICATOR when operating under specified conditions.

The instructions for use shall contain the information (including a reference to the appropriate PRIMARY BATTERY specified in IEC 60086-2 [1] [2] giving the identity of the PRIMARY BATTERIES to be used.

201.7.9.2.5 * ME EQUIPMENT description

Addition:

The instructions for use shall include the following.

2 Numbers in square brackets refer to the Bibliography.

a) * A general description, explanation of function available, and a description of each heart/PULSE GENERATOR interaction for each available pacing mode. See Clause C.3 of ISO 14708-2:2019 for a description of pacing modes.

b) * The connector configuration, the geometry and/or dimensions of the receiving connectors and instructions for connecting the LEAD(S) or PATIENT CABLE(S) to the NON-IMPLANTABLE PULSE GENERATOR.

c) * The electrical characteristics (including tolerances where applicable) with 500 Ω ± 1 % load, unless otherwise stated, as follows:
   - ranges of BASIC RATE, ESCAPE INTERVAL, MAXIMUM TRACKING RATE and INTERFERENCE PULSE RATES (as applicable);
   - PULSE AMPLITUDE(S);
   - PULSE DURATION(S);
   - the SENSITIVITY range for both positive and negative polarities (if a sensing function is provided);
   - sensing amplifier blanking period(s) (if a sensing function is provided);
   - the REFRACTORY PERIOD(S) (pacing and sensing) and A-V INTERVAL(S) (as applicable);
   - mode of operation in the presence of sensed ELECTROMAGNETIC DISTURBANCE or electrical energy sources;
   - the rate limit (runaway protection), in reciprocal minutes.

d) * The electrical characteristics listed below and as reported in 201.7.9.2.5 c) upon activation of the BATTERY DEPLETION INDICATOR, unless these are unchanged from the values previously reported:
   - BASIC RATE or equivalent PULSE INTERVAL;
   - PULSE AMPLITUDES(s);
   - PULSE DURATION(s);
   - SENSITIVITY (if a sensing function is provided);
   - mode change (if applicable).

201.7.9.2.8 * Start-up PROCEDURE

Addition:

The instructions for use shall contain any environmental limitations regarding storing the ME EQUIPMENT immediately prior to use.

201.7.9.2.13 * Maintenance

Addition:

The instructions for use shall contain details for replacing the PRIMARY BATTERY and the means of ascertaining when replacement is required.

The instructions for use shall contain information calling the RESPONSIBLE ORGANIZATION'S attention to the need for periodic maintenance, as well as to the need for maintenance after any malfunction or accident of the ME EQUIPMENT irrespective of usage, especially:

- cleaning and disinfection of reusable PATIENT CABLES;
- cleaning and disinfection of the NON-IMPLANTABLE PULSE GENERATOR;
- inspection of cables and connections for possible defects, for example, loosening of connections and other wear and tear from such causes as PATIENT movement;
- inspection of the NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE for signs of physical damage or contamination, in particular damage or contamination that can have a detrimental effect on the electrical isolation properties of the ME EQUIPMENT;

– functional checks, calibration, activation of keys, switches, etc., especially if the ME EQUIPMENT has suffered severe shock, for example, by being dropped.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 * Defibrillation protection

Replacement:

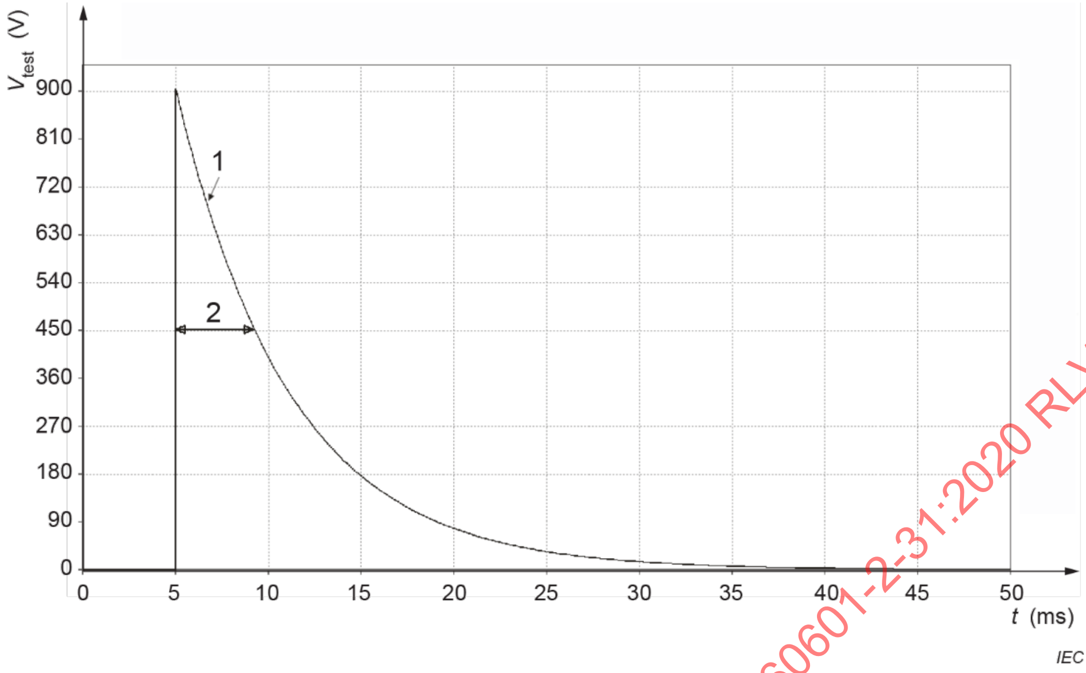
201.8.5.5.1.1 General requirements

The ME EQUIPMENT shall be designed so that defibrillation of the PATIENT using an internal defibrillator will not permanently affect the ME EQUIPMENT, provided that the internal defibrillator electrodes (e.g. paddles) are placed according to the ME EQUIPMENT MANUFACTURER's recommendations.

201.8.5.5.1.2 Test of defibrillation protection

Test equipment: Use a defibrillation test voltage generator providing a decaying exponential waveform presented in Figure 201.101 with the following characteristics: a maximum voltage V_{test} of 900 V $^{+2,5}_{-0}$ % and an energy of 50 J to 55 J, having T_{w50} = 4,05 ms to 4,6 ms, where T_{w50} is the time interval during which the test voltage is above 50 % of the maximum value V_{test}, if discharged into a load resistance R_{heart} = 50 Ω ± 1 %.

NOTE 1 The resistance R_{heart} = 50 Ω ± 1 % simulates the resistance of the heart seen by a defibrillator during open heart surgery.



Key

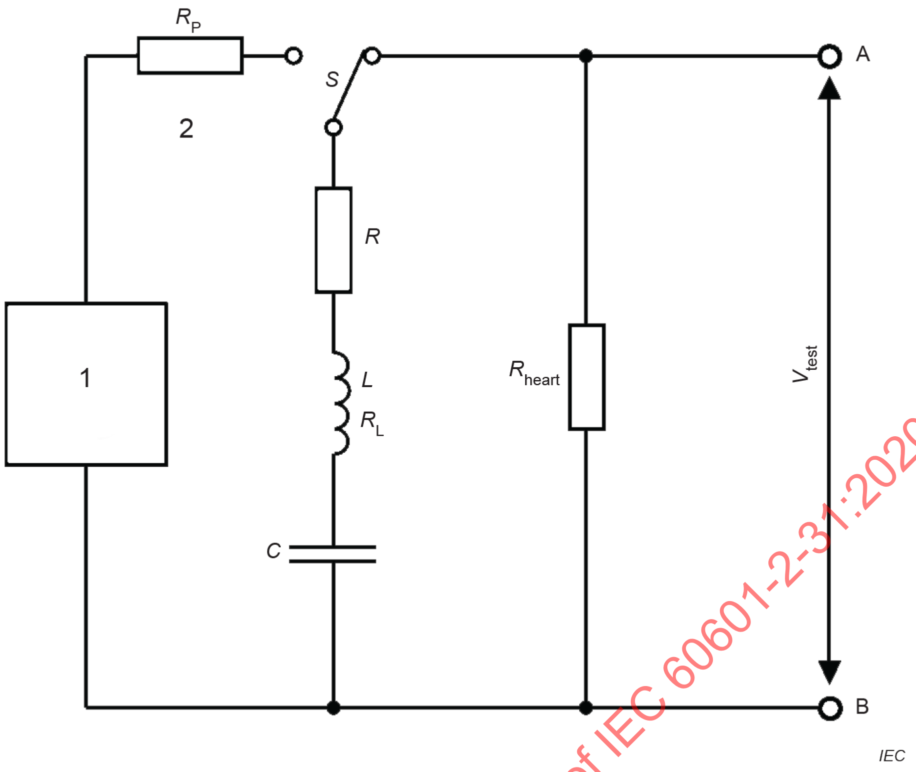
1 decaying exponential test waveform

2 T_{w50} = 4,05 ms to 4,6 ms: time interval during which the test voltage is above 50 % of the maximum value V_{test}

Figure 201.101 – Test waveform V_{test} implemented by example RCL circuit using C = 120 µF, L = 25 µH, RL + R = 1 Ω

Figure 201.102 illustrates an example schematic of such a defibrillation test generator with C = 120 µF ± 5% , L = 25 µH ± 5 %, R_L + R = 1 Ω ± 5 %, where R_L is the resistance of the inductance L, and R is the output resistance of the defibrillation test voltage generator.

NOTE 2 The current limiting resistor R_P can be used to protect the voltage generator during capacitor charging.



Key

1	voltage generator
2	current limiting resistor
S	switch for applying the test voltage
L	25 µh ± 5 % inductance
R_L	resistance of inductor
R	resistor in series with *L* and *C*
C	120 µF ± 5 % capacitor
R_{heart}	50 Ω ± 1 % load resistance, which simulates the resistance of the heart seen by a defibrillator during open heart surgery
V_{test}	test voltage
A,B	output terminals of the defibrillation test voltage generator

Figure 201.102 – Example circuit of defibrillation test voltage generator for generating a decaying exponential waveform

Test PROCEDURE: Connect the output V_{test} with its terminals A and B to the EXTERNAL PACEMAKER as described below.

The ME EQUIPMENT shall be categorized into one or more of two groups of EXTERNAL PACEMAKERS as appropriate and connected as indicated:

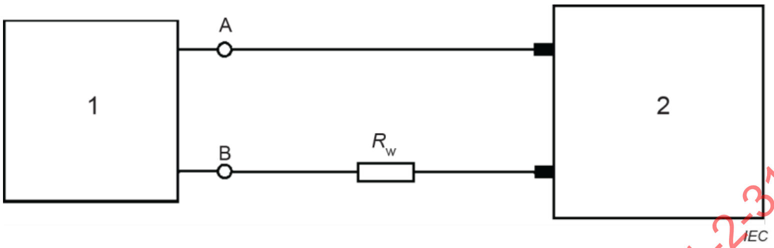
– SINGLE CHAMBER EXTERNAL PACEMAKER:

  The test voltage V_{test} is applied between one EXTERNAL PACEMAKER PATIENT CONNECTION connected to the terminal A of the defibrillation test voltage generator and the second EXTERNAL PACEMAKER PATIENT CONNECTION connected via an 80 Ω resistor to the terminal B of the defibrillation test voltage generator. The test setup is shown in Figure 201.103.

– Multi-chamber EXTERNAL PACEMAKER:

The test voltage V_{test} is applied to each EXTERNAL PACEMAKER PATIENT CONNECTION, being connected to the terminal A of the defibrillation test voltage generator, in turn with all the remaining EXTERNAL PACEMAKER PATIENT CONNECTIONS being connected together via 80 Ω resistors to the terminal B of the defibrillation test voltage generator. Figure 201.104 provides the test setup for a DUAL CHAMBER EXTERNAL PACEMAKER, whereas Figure 201.105 shows the test setup for a triple chamber EXTERNAL PACEMAKER (e.g. bi-ventricular).

NOTE 3 The 80 Ω resistors shown in the test setups below simulate the impedance of applied heart wires and the tissue between the internal defibrillator and the EXTERNAL PACEMAKER terminals.



Key

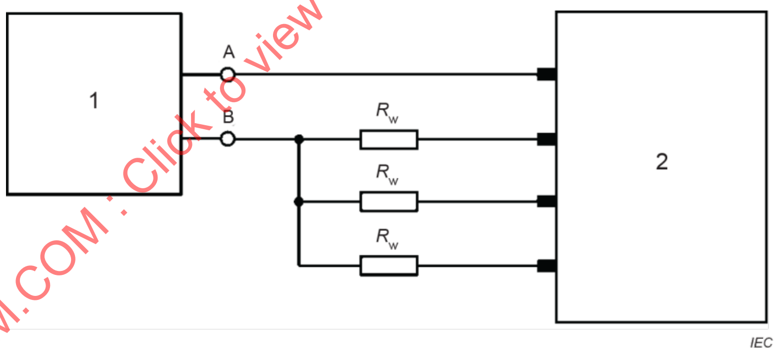
1 defibrillation test voltage generator

2 SINGLE CHAMBER EXTERNAL PACEMAKER

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.103 – Test setup for a SINGLE CHAMBER external CARDIAC PACEMAKER



Key

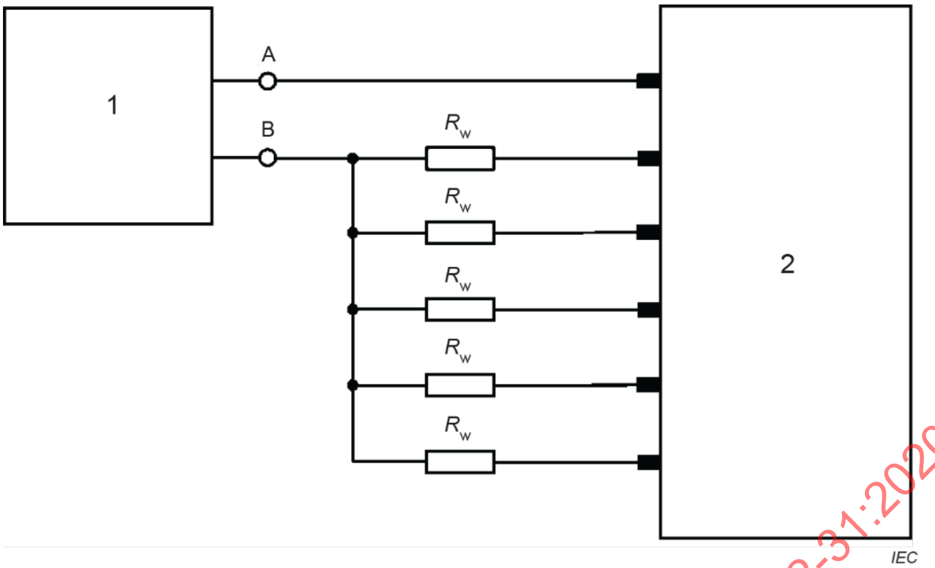
1 defibrillation test voltage generator

2 DUAL CHAMBER EXTERNAL PACEMAKER

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.104 – Test setup for a DUAL CHAMBER external CARDIAC PACEMAKER



Key

1 defibrillation test voltage generator

2 multi CHAMBER EXTERNAL PACEMAKER, e.g. bi-ventricular EXTERNAL PACEMAKER providing three pacing CHAMBERS

R_w 80 Ω ± 1 %, resistor simulating the impedance of heart wires and tissue between defibrillator and EXTERNAL PACEMAKER

A, B output terminals of the defibrillation test voltage generator

Figure 201.105 – Test setup for a triple chamber external CARDIAC PACEMAKER, e.g. bi-ventricular external CARDIAC PACEMAKER

Test by applying a sequence of three voltage PULSES of positive polarity at intervals of 20 s to 25 s. Then, after an interval of 60 s (minimum), repeat the test with PULSES of negative polarity (see Figure 201.106).

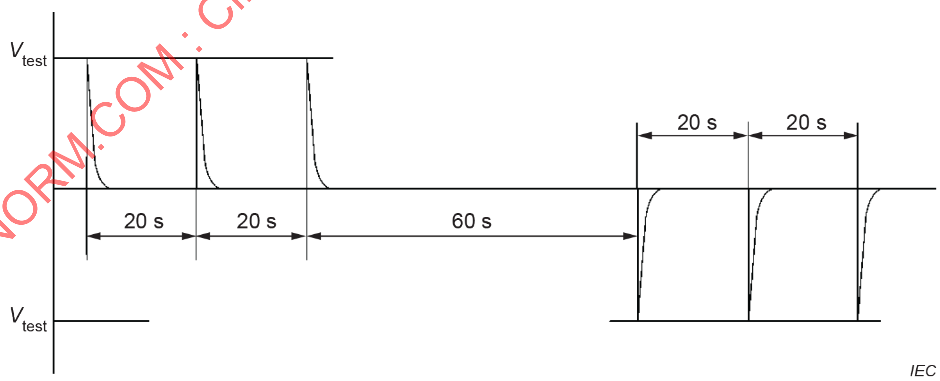


Figure 201.106 – Timing sequence

Compliance shall be confirmed if, after completing the test PROCEDURE, the ME EQUIPMENT continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

201.8.5.5.2 * Energy reduction test

This subclause of the general standard does not apply.

201.8.7.3 * Allowable values

Amendment:

In Table 3 of IEC 60601-1:2005, replace the values for PATIENT AUXILIARY CURRENT for TYPE CF APPLIED PARTS for DC by 1 µA in NORMAL CONDITION (NC) and 5 µA in SINGLE FAULT CONDITION (SFC).

201.8.7.4 Measurements

201.8.7.4.1 * General

Addition:

aa) * The NON-IMPLANTABLE PULSE GENERATOR output should be disabled during LEAKAGE CURRENT testing if possible. If the output is to be active, its contribution should not be considered part of the LEAKAGE CURRENT.

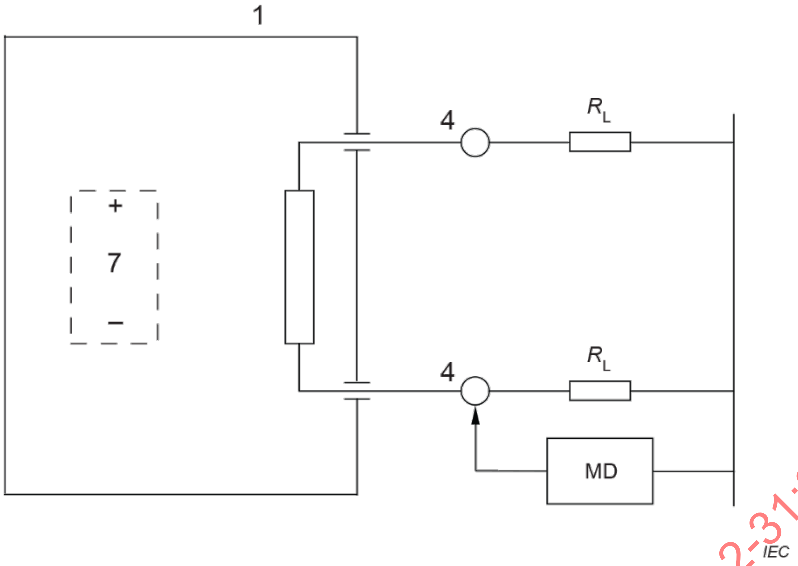
201.8.7.4.8 * Measurement of the PATIENT AUXILIARY CURRENT

Replacement:

For measurement of the PATIENT AUXILIARY CURRENT, the ME EQUIPMENT is connected as shown in Figure 201.107. Each PATIENT CONNECTION is connected to a common bus through a 500 Ω ± 1 % load resistor (R_L). Using a measuring device (MD) consisting of a DC voltmeter, resolution better than 2 µV, fed through a low pass filter with a time constant of at least 10 s, measure the average direct voltage across each load resistor. Steady state condition shall be reached before the measurement is made.

The NON-IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the MANUFACTURER (i.e., the factory recommended settings) but with the PULSE AMPLITUDE and PULSE DURATION programmed to the highest available settings.

The low pass filter can be implemented by a four-element RC filter with elements built from 1 MΩ resistors and 10 µF metalized polypropylene capacitors. The input resistance of the DC voltmeter should be ≥ 400 MΩ.



Key

1	ME EQUIPMENT ENCLOSURE
4	PATIENT CONNECTIONS
7	INTERNAL ELECTRICAL POWER SOURCE
R_L	load resistor
MD	measuring device (see 201.8.7.4.8)

Figure 201.107 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE

Additional subclause:

201.8.101 High-frequency surgical ME EQUIPMENT protection

The ME EQUIPMENT shall comply with 6.1.2 of ISO 14117:2019.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replacement:

The ME EQUipment shall be so constructed that the ingress of liquids (accidental wetting), shall not result in an unacceptable RISK.

Compliance is checked by the following test.

The ME EQUIPMENT is placed in the least favourable position of NORMAL USE with the PATIENT CABLE attached. The ME EQUIPMENT is subjected to a spill of 400 ml of 9 g/l saline solution from a height of 30 cm. The entire 400 ml is poured over the ME EQUIPMENT in less than 5 s. Following the spill, the ME EQUIPMENT is not to be resting in a depth of more than 5 mm of saline solution.

Immediately after 30 s of exposure, the ME EQUIPMENT is removed from the saline solution and visible moisture on the outside of the ENCLOSURE is removed.

The ME EQUIPMENT is to operate within specification during and after the spill.

After at least 24 h have passed, the ME EQUIPMENT is to operate within specification. The ME EQUIPMENT is then disassembled and inspected. Any evidence that liquid has entered the electronic compartment constitutes a failure.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Replacement:

The ME EQUIPMENT shall be equipped with a BATTERY DEPLETION INDICATOR which clearly indicates when the power source is to be replaced.

Compliance is checked by inspection and by functional test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Replacement:

201.12.1.101 * ME EQUIPMENT PARAMETERS

The measured values of the ME EQUIPMENT parameters shown in Table 201.103 shall be within the MANUFACTURER'S published tolerance. The MANUFACTURER shall insure that measurement equipment accuracy is sufficient to support the stated tolerances for the parameters being measured within 201.12.1.101 and stated by the MANUFACTURER when measured at PULSE RATE settings of 60 and 120 PULSES per minute with a fully charged BATTERY. If 60 or 120 PULSES per minute are not within the range for PULSE RATE settings for the ME EQUIPMENT, then the test shall be conducted at the minimum or maximum allowable settings.

Compliance is checked by either the appropriate methods described below and in 6.1 of ISO 14708-2:2019, or by any other method provided it can demonstrate an accuracy which is sufficient to support the stated tolerances. In case of dispute, the test described below and in 6.1 of ISO 14708-2:2019 shall apply.

Table 201.103 – ME EQUIPMENT parameters

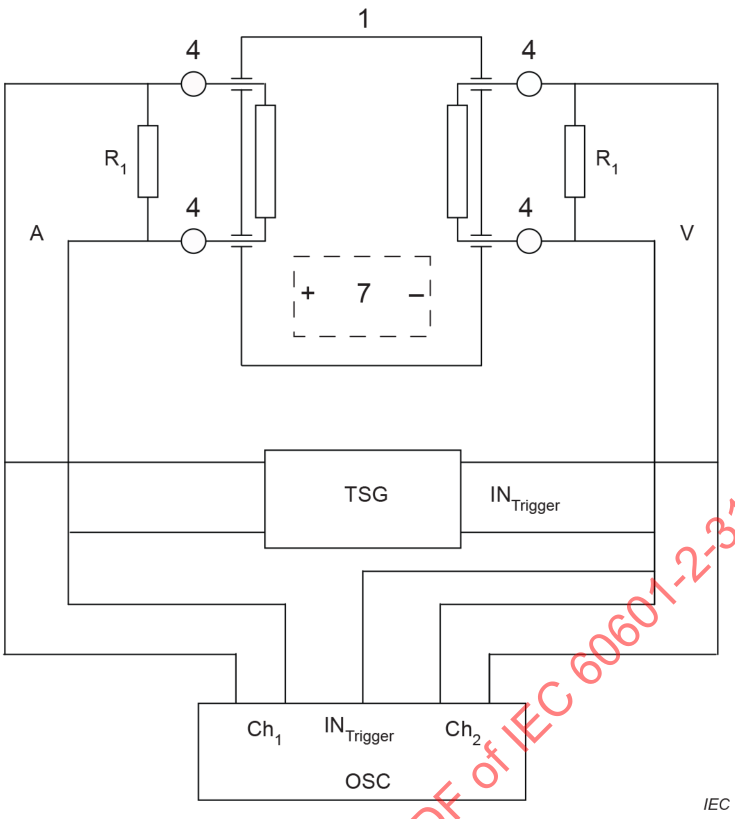
Measurement
PULSE AMPLITUDE
PULSE DURATION
PULSE RATE
SENSITIVITY (if applicable)
ESCAPE INTERVAL
REFRACTORY PERIOD(S) (if applicable)
A-V INTERVAL (if applicable)
MAXIMUM TRACKING RATE (if applicable)

Measurement of MAXIMUM TRACKING RATE is made using the following test.

With a fully charged battery and the NON-IMPLANTABLE PULSE GENERATOR in an A-V sequential mode with sensing and pacing in both chambers (DDD), the ME EQUIPMENT is connected according to Figure 201.108. The test apparatus is described in 6.1.3 of ISO 14708-2:2019. Adjust the signal generator until the amplitude of the test signal is approximately $2e_{pos}$ *or* $2e_{neg}$ *as determined in 6.1.3 of ISO 14708-2:2019.*

The delay from the triggering of the signal generator to the production of the test signal is designated D. Adjust the signal generator so that D is slightly greater than the POST-VENTRICULAR ATRIAL REFRACTORY PERIOD (PVARP). Slowly increase D until the ventricular pacing PULSE just begins to track the additional delay as observed on Channel 2 of the oscilloscope. Measure the interval between sequential pacing PULSES on Channel 2 in milliseconds. Designate that as interval T. Adjust the oscilloscope so that the display illustrated in Figure 201.109 is obtained.

Calculate the MAXIMUM TRACKING RATE [PULSES per minute] = 60 000/T [ms].

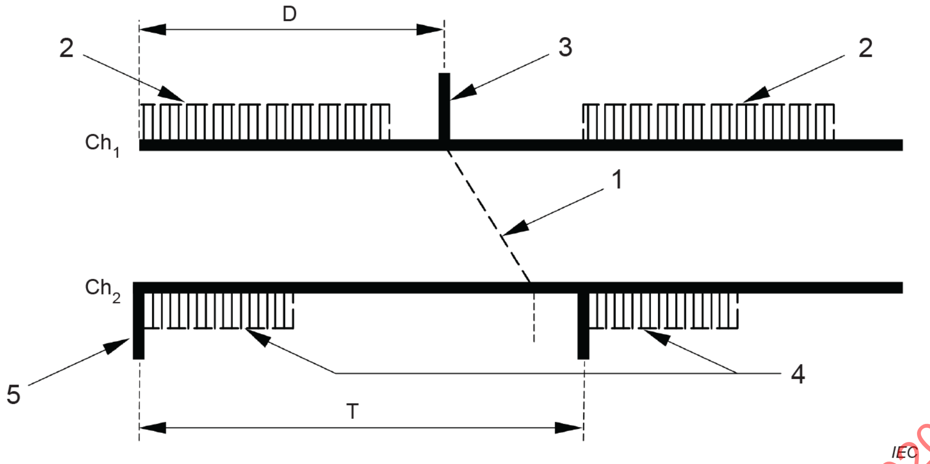


Key

R_1	R_1 = 500 Ω ±1 %
A	ATRIAL CHANNEL
V	VENTRICULAR CHANNEL
$IN_{Trigger}$	TRIGGER INPUT
CH_1	Channel 1
CH_2	Channel 2
TSG	TRIGGERABLE SIGNAL GENERATOR
OSC	OSCILLOSCOPE
(1)	ME EQUIPMENT ENCLOSURE
(4)	PATIENT CONNECTIONS
(7)	INTERNAL ELECTRICAL POWER SOURCE

See also Table 5 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

Figure 201.108 – Measuring circuit for the MAXIMUM TRACKING RATE



Key

1	A-V Interval
2	POST-VENTRICULAR ATRIAL REFRACTORY PERIOD (PVARP)
3	test signal
4	ventricular refractory period
5	ventricular pacing PULSE
Ch1	Channel 1
Ch2	Channel 2
D	delay from the triggering of the signal generator to the production of the test signal (*D* > PVARP[1])
T	maximum tracking interval

[1] Atrial refractory period minus the A-V delay. See [2].

MAXIMUM TRACKING RATE [PULSES per minute] = 60 000/T [ms].

Figure 201.109 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE

201.12.1.102 * PULSE AMPLITUDE

The PULSE AMPLITUDE expressed either as voltage or current shall not vary from the indicated value by more than the percentage listed in the MANUFACTURER'S published specifications when the load is varied from 200 Ω to 1 000 Ω, at a pacing rate of 70 PULSES per minute with a fully charged battery.

Compliance is checked by using the basic test method described in 6.1.2 of ISO 14708-2:2019 with test loads of 200 Ω ± 1 % and 1 000 Ω ± 1 % in order to determine how PULSE AMPLITUDE changes as a function of resistance.

201.12.4 Protection against hazardous output

201.12.4.1 * Intentional exceeding of safety limits

Replacement:

If the ME EQUIPMENT incorporates features which require PULSE RATES above the rate limit (see 201.12.4.103), the runaway rate protection may be disarmed when the feature is in use. The means for disarming the runaway rate protection shall require the OPERATOR to engage the activating mechanism continuously.

Compliance is checked by inspection and by a functional test.

Additional subclauses:

201.12.4.101 * Protection against accidental change of controls and tampering

Means shall be provided so that a deliberate action is required to change settings.

Compliance is checked by inspection.

201.12.4.102 * Protection against a low battery condition

Upon activation of the BATTERY DEPLETION INDICATOR, the measured values of the ME EQUIPMENT parameters listed in 201.7.9.2.5 d) shall be within the MANUFACTURER'S published tolerance when measured with the NON-IMPLANTABLE PULSE GENERATOR with 500 Ω ± 1 % load.

Compliance is checked by either the appropriate methods described in 6.1 of ISO 14708-2:2019, or by any other method provided it can demonstrate an accuracy sufficient to support the MANUFACTURER'S published tolerances. In case of dispute, the test described in 6.1 of ISO 14708-2:2019 shall apply.

201.12.4.103 * Rate limit (runaway protection)

Means shall be provided to limit PULSE RATE, in the event of a SINGLE FAULT CONDITION, to the value specified by the MANUFACTURER.

Compliance is checked by inspection of the MANUFACTURER'S data.

201.12.4.104 * Interference reversion

In the presence of sensed electrical ELECTROMAGNETIC DISTURBANCE or electrical energy sources, the NON-IMPLANTABLE PULSE GENERATOR shall revert to a pacing mode and PULSE RATE specified by the MANUFACTURER.

Compliance is checked by inspecting the MANUFACTURER'S data.

201.12.4.105 * MAXIMUM TRACKING RATE

In DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing, a means shall be provided to set a limit at which the ventricle is paced in response to sensed atrial activity. The ME EQUIPMENT shall respond to sensed atrial activity above the MAXIMUM TRACKING RATE in a manner stated by the MANUFACTURER.

Compliance is checked by inspection and functional test.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

Additional subclauses:

201.15.101 * Output indicator

The ME EQUIPMENT shall incorporate a means to indicate when the ME EQUIPMENT has emitted a pacing PULSE.

Compliance is checked by inspection and functional test.

201.15.102 * Input indicator

If a sensing function is provided, the ME EQUIPMENT shall incorporate a means of indicating that the ME EQUIPMENT has detected signals and has responded to them as if they are associated with the electrical activity of the heart, and that it is reacting to the signals as specified by the MANUFACTURER for the selected pacing mode and other operational characteristics.

Compliance is checked by inspection and functional test.

201.16 ME SYSTEMS

Clause 16 of the general standard does not apply.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.8.9 * IMMUNITY TEST LEVELS

Replacement:

ME EQUIPMENT shall comply with the requirements of 8.9 of IEC 60601-1-2:2014 except as modified below for ELECTROSTATIC DISCHARGE.

The IMMUNITY TEST LEVELS specified in Table 202.101 shall be used. For this requirement, the following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

– no permanent degradation, or loss of function which is not recoverable shall be observed at any IMMUNITY TEST LEVEL, as a result of

- damage of ME EQUIPMENT (components), or
- software corruption, or
- loss of data;

– no inappropriate delivery of energy to the PATIENT shall occur at any IMMUNITY TEST LEVEL;

– at IMMUNITY TEST LEVELS 1 and 2, the ME EQUIPMENT shall maintain ESSENTIAL PERFORMANCE within the specification limits;

– at IMMUNITY TEST LEVELS 3 and 4, the temporary degradation or loss of function or performance which requires OPERATOR intervention is acceptable.

Table 202.101 – Static discharge requirements

IMMUNITY TEST LEVEL [a]	Test voltage (air discharge) kV	Test voltage (contact discharge) kV
1	2	2
2	4	4
3	8	6
4	15	8

[a] The IMMUNITY test LEVELS for static discharge are defined in Table 1 of IEC 61000-4-2:2008 [3].

Compliance is checked by application of the tests in 8.9 of IEC 60601-1-2:2014, Tables 4, 7 and 8. Evaluate the response of the ME EQUIPMENT or ME SYSTEM during and after these tests in accordance with 8.9 of IEC 60601-1-2:2014 as modified above, considering each discharge individually.

Annexes

The annexes of the general standard apply except as follows:

Annex I

Identification of IMMUNITY pass/fail criteria

Annex I of the general standard does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Annex AA explains the reason for the provisions of this particular standard in the IEC 60601 family, as useful background in reviewing, applying and revising the standard.

The rationale is directed towards those familiar with the subject of this particular standard but who have not participated in its development. Where the reason for a requirement is considered self-evident to such persons, reasons are not given. An understanding of the reasons for the main requirements is considered to be essential for proper application of this particular standard. Furthermore, as clinical practice and technology change, changes in this particular standard can be made with an understanding of previous concerns.

- **RISK ANALYSIS**

EXTERNAL PACEMAKERS are used to treat PATIENTS who have symptomatic or acute bradycardia as well as for temporary pacing related to other medical procedures. PATIENT safety is affected by the medical procedure involved, by the understanding of ME EQUIPMENT function by the clinician and by ME EQUIPMENT function. The requirements as specified in this particular standard are considered to provide for an acceptable RISK.

As a basis for establishing safety, an inventory of the RISKS to the PATIENT's safety posed by EXTERNAL PACEMAKERS was developed. The results of that analysis are summarized in Table AA.1. To facilitate the review of this document, a reference to the clause(s) in this particular standard where the action is described has been added to the table.

The tentative conclusion based on clinical experience is that failure to pace is the most probable occurrence of those HAZARDS listed.

Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory

HAZARD	Cause	Action	Reference in this particular standard
FAILURE TO PACE	Low battery	Battery indicator	201.11.8
	Poor connection	Test of connection	201.7.9.2.13
	Threshold rise	Clinical technique	Not applicable
	Oversensing	Clinical technique	Not applicable
		Stability of parameters with battery and depletion	201.7.9.2.5 d) and 201.12.4.102
		Input indicator	201.15.102
	Fault	Defibrillator equipment protection	201.8.5.5.1
		High frequency surgical equipment protection	201.8.101
		Spillage protection	201.11.6.5
		Static electric discharges	202.8.9
		Maintenance	201.7.9.2.13
		Output indicator	201.15.101
	Maladjustment	Protective means	201.12.4.101
		Marking of controls	201.7.4
	Electrode dislodgement	Clinical technique	Not applicable
High rate	Fault	Rate limit (runaway protection)	201.12.4.103
	Maladjustment	Protective means	201.12.4.101
	Temporary high rate	Protective means	201.12.4.1
	Atrial tachyarrhythmia	MAXIMUM TRACKING RATE	201.12.4.105
Unwanted stimulation	Undersensing	Clinical technique	Not applicable
		Stability of parameters with battery depletion	201.7.9.2.5 d) and 201.12.4.102
		Input indicator	201.15.102
	Low battery	Battery indicator	201.11.8
	Maladjustment	Protective means	201.12.4.101
		Marking of controls	201.7.4
	Noise	Noise reversions	201.7.9.2.5 c) and 201.12.4.104
		Warnings	201.7.9.2.2 a)
	Poor connection (LEAD or battery)	Test of connection	201.7.9.2.13
	Fault	See failure to pace	
	Microphonics	Noise reversion	201.7.9.2.5 c) and 201.12.4.104
Micro/Macro shock	LEAKAGE CURRENT	LEAKAGE CURRENT limit	201.6.2 and Clause 201.8
	Injection current	Warning	201.7.9.2.2 a), 201.7.9.2.2 b), 201.7.9.2.2 c), 201.7.9.2.2 d), and 201.7.9.2.2 f)
Tissue/electrode damage	PATIENT AUXILIARY CURRENT	PATIENT AUXILIARY CURRENT limit	201.8.7.3

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 – Scope

The scope of this particular standard is restricted to EXTERNAL PACEMAKERS with an INTERNAL POWER SOURCE. This implies that all requirements in the general standard and collateral standards that apply to equipment connected to a SUPPLY MAINS are not applicable even though they are not specifically identified in this document.

The scope is restricted for the following reasons.

- The power source is restricted to INTERNAL ELECTRICAL POWER SOURCE, and in particular to PRIMARY BATTERIES, as the ME EQUIPMENT is intended to be moved with the PATIENT. ME EQUIPMENT that could be used when connected to SUPPLY MAINS or powered by rechargeable batteries would have intrinsically additional safety concerns, such as: difficulty in knowing length of service time, state of the battery (recharged or not), no applicable standards, etc.
- This document excludes ME EQUIPMENT which can be directly or indirectly connected to SUPPLY MAINS.
- Transthoracic and oesophageal pacing ME EQUIPMENT provides higher output energies which would be inappropriate for direct cardiac pacing.
- Antitachycardia ME EQUIPMENT presents clinical safety issues which require separate treatment appropriate to its function.

PATIENT CABLES are included because they are commonly used as a means to extend the reach of the NON-IMPLANTABLE PULSE GENERATOR while pacing the PATIENT during surgery, and for post-operative and extended pacing periods.

LEADS are not included because they require separate treatment appropriate to their type and their approach to the heart (transvenous, epicardial).

Clause 201.3 – Terms and definitions

The definitions from Clause 3 of ISO 14708-2:2019 are referred to in order to encourage common usage worldwide for terms applicable to both IMPLANTABLE and EXTERNAL PACEMAKERS. Two definitions were copied from ISO 14708-1 for convenience.

Additional definitions have been added as needed to supplement those found in the ISO 14708 series. These definitions are based on common industry usage.

Subclause 201.4.11 – Power input

The requirements of this subclause are intended to apply to ME EQUIPMENT connected to SUPPLY MAINS, which does not apply to the EXTERNAL PACEMAKERS covered by this document.

Subclause 201.6.2 – Protection against electric shock

TYPE B APPLIED PART and TYPE BF APPLIED PART are deleted because only TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION.

Subclause 201.7.2.102 – ME EQUIPMENT intended for DUAL CHAMBER application

As an EXTERNAL PACEMAKER is frequently needed in an emergency situation, the information on making a correct connection to the LEADS has to be available without recourse to the instructions for use. Incorrect connecting of the output terminals or PATIENT connectors (i.e. atrial channel to ventricular LEADS) could result in inappropriate and potentially unsafe (high rate stimulation or inappropriate sensing, etc.) operation. Clear marking of both the polarity and chamber is required. If, in addition, colour is used to accentuate the difference, colours that can be differentiated regardless of colour perception (i.e., white and blue) should be used.

Subclause 201.7.2.104 – Battery compartment

Access to the battery compartment for replacement of the batteries is a common maintenance item. Quick identification of the correct type and the proper orientation of the batteries in the battery compartment are required to prevent extended loss of function and/or potential damage to the ME EQUIPMENT. An orientation for the batteries should be provided to avoid OPERATOR confusion even if the ME EQUIPMENT permits reversed connection.

Subclause 201.7.4.101 – Control or indicator for pacing output; and
Subclause 201.7.4.102 – Control or indicator for PULSE RATE

Accurate setting of output energy levels and PULSE RATE is deemed to be essential to safe operation of the ME EQUIPMENT.

Subclause 201.7.4.103 – Control for selecting pacing mode

In order to convey clearly the primary intended use of a NON-IMPLANTABLE PULSE GENERATOR, a three-letter code has been adopted. This is an adaptation of the code developed by the Heart Rhythm Society (formerly North American Society for Pacing and Electrophysiology) and the Heart Rhythm UK (formerly the British Pacing and Electrophysiology Group). To encourage common usage worldwide, the same code is used as that given in Annex C of ISO 14708-2:2019 for IMPLANTABLE PULSE GENERATORS.

Subclause 201.7.9.2.2 – Warnings and safety notices

Subclause 201.7.9.2.2 a)

Sources of ELECTROMAGNETIC DISTURBANCE can affect the operation of the ME EQUIPMENT. In the presence of excessive levels of ELECTROMAGNETIC DISTURBANCE, the ME EQUIPMENT could:

– fail to pace,
– revert to asynchronous pacing, or
– inappropriately track the ELECTROMAGNETIC DISTURBANCE as cardiac activity.

Subclause 201.7.9.2.2 b)

The danger of fibrillation resulting from alternating current leakage is greatly increased when SUPPLY MAINS operated ME EQUIPMENT is connected to the LEAD system. Extreme caution has to be taken to have proper grounding of SUPPLY MAINS operated ME EQUIPMENT used in the vicinity of the PATIENT.

Micro-shock is a term for the effects of an otherwise imperceptible electric current applied directly, or in very close proximity, to the heart muscle. The electric current is of sufficient strength, frequency, and duration to cause disruption of normal cardiac function.

Macro-shock is a term for the effects of an electric current passed through the body, usually via a skin to skin pathway. Electric shock is usually referring to macro-shock. More generally, the electric current during macro-shock is not applied directly through the heart muscle. The current in macro-shock events can vary widely from being imperceptible to being extremely destructive of tissue.

Subclause 201.7.9.2.2 c) and **d)**

The PATIENT needs to be protected from electrical impulses inadvertently introduced by making contact with the terminals of the NON-IMPLANTABLE PULSE GENERATOR, PATIENT CABLE and indwelling LEADS. Proper handling of the ME EQUIPMENT will reduce the chance of inadvertent shock while maintaining the clinically needed flexibility of connecting a variety of temporary

LEADS, permanent LEADS, and heartwires to the PATIENT CABLE, or directly to the NON-IMPLANTABLE PULSE GENERATOR.

Subclause 201.7.9.2.2 e)

Performance predictions, especially projections of life after the low battery indicator comes on, are dependent on an understanding of the depletion characteristics of the battery. Batteries with different physical dimensions can result in poor or intermittent contact.

Subclause 201.7.9.2.2 f)

Although believed to be, at best, a rare complication of pacing, there is a theoretical possibility that a static discharge to the NON-IMPLANTABLE PULSE GENERATOR or a PATIENT CABLE connected to it could transfer minimally sufficient energy to the PATIENT to produce cardiac depolarization. If this were to occur in an electrically unstable PATIENT during the vulnerable portion of the cardiac cycle, a potentially lethal arrhythmia might be induced. No documented cases or anecdotal reports of such an event are known. It should be noted that there are ways that one or more asynchronous PULSES can be delivered to the PATIENT (e.g. noise reversion, loss of sensing) all of which are much more likely and which typically are cautioned about in the labelling. While only rarely have these common occurrences precipitated an arrhythmia, medical literature leaves no doubt as to the potential for serious consequences. Therefore, a warning that care should be taken to discharge any static electricity that has accumulated on the attending health care professional or the PATIENT before touching the ME EQUIPMENT is appropriate.

Subclause 201.7.9.2.2 g)

The PULSE energy delivered to the PATIENT is a consequence of the setting of the NON-IMPLANTABLE PULSE GENERATOR and interaction of that output with a dynamic PATIENT/LEAD environment. The acute load presented by the temporary PATIENT/LEAD system can vary over a range of several hundred ohms. While much of this variation might be clinically inconsequential, "significant" departures from the pre-set level of energy output can occur. Since what constituted a "significant" departure from the pre-set level of energy output will vary widely from PATIENT to PATIENT depending on many factors, including the pre-set margin of safety for capture, selecting a limit that could be monitored by the ME EQUIPMENT and that would apply to all PATIENTS would necessarily leave other PATIENTS largely unprotected. The output circuitry cannot readily determine if the output resulted in capture of the heart.

Subclause 201.7.9.2.4 – Electrical power source

Well-made PRIMARY BATTERIES do not leak under the recommended conditions of storage and use. All batteries, however, have a tendency to leak under some conditions. A leaking battery can result in damage to the ME EQUIPMENT. Good practice would indicate that the battery should be removed if the ME EQUIPMENT is to be stored or left for a period without use.

This edition of the standard is disallowing rechargeable batteries as the power source for the following additional RISK associated with their use.

- Rechargeable batteries cannot be recharged indefinitely.
- Eventually, depending on battery chemistry and the pattern of charging and discharging, a rechargeable battery would no longer retain sufficient energy to meet the service life specified by the MANUFACTURER.
- A MANUFACTURER that specifies the use of rechargeable batteries would be required to provide instructions that enable the RESPONSIBLE ORGANIZATION to determine when the battery will no longer hold sufficient energy to meet the specified service life.

Service life estimate is based on batteries which are fully charged. PRIMARY BATTERIES should be fresh and fully charged as defined by the battery MANUFACTURER or supplier.

An understanding of the service life of the ME EQUIPMENT after the onset of the low battery condition is important for establishing the urgency of replacing the power source when the low battery indicator is activated.

There is a wide variety of PRIMARY BATTERIES, especially of the 9 V alkaline type, available. Use of batteries with different chemical characteristics from that recommended by the MANUFACTURER can result in: 1) a short battery life after onset of the low battery indicator; 2) degraded NON-IMPLANTABLE PULSE GENERATOR performance; and/or 3) overall reduced battery life. Although IEC 60086-1 [4] gives recognized dimensions for 9 V batteries, there are many commonly available batteries which vary in size and terminal configuration. Use of batteries other than the ones specified by the MANUFACTURER can result in erratic or no pacing.

Subclause 201.7.9.2.5 – ME EQUIPMENT description

Subclause 201.7.9.2.5 a)

Knowledge of NON-IMPLANTABLE PULSE GENERATOR features and characteristics is necessary when selecting an EXTERNAL PACEMAKER for use on a PATIENT. Choosing between these features and characteristics requires that they be comparable, i.e. that they are based on common measurement techniques or common assumptions.

Subclause 201.7.9.2.5 b)

NON-IMPLANTABLE PULSE GENERATORS and PATIENT CABLES are connected to a variety of LEADS with different LEAD connector pin configurations. The connector assembly grips the LEAD connector pin(s) with sufficient force to provide good electrical and mechanical connection. Knowledge of the design limits of the device can help prevent damage to the ME EQUIPMENT and failure to pace due to an inadequate connection.

Subclause 201.7.9.2.5 c)

The electrical characteristics follow the outline established in 28.8.2 of ISO 14708-2:2019 for IMPLANTABLE PULSE GENERATORS. The test load of 500 Ω ± 1 % is the same value specified in ISO 14708-2 for IMPLANTABLE PULSE GENERATORS.

Microphonics refers to the creation of electrical noise induced into the sensing electronics as a result of motion or vibration of the EXTERNAL PACEMAKER or LEAD.

This edition specifies particular environmental conditions for some requirements and tests.

Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

The operating temperature of 20 °C ± 2 °C is the temperature under which PRIMARY BATTERY discharge tests are to be carried out as specified in 6.2 of IEC 60086-1:2015 [4].

Subclause 201.7.9.2.5 d)

This requirement was taken from 28.19 d) of ISO 14708-2:2019 for IMPLANTED PULSE GENERATORS.

Subclause 201.7.9.2.8 – Start-up PROCEDURE

Adverse environmental conditions immediately prior to use can affect the reliable operation of the ME EQUIPMENT.

Subclause 201.7.9.2.13 – Maintenance

As reliable functioning of the ME EQUIPMENT is essential for the PATIENT's safety, these maintenance items are regarded as important.

Subclause 201.8.5.5.1 – Defibrillation protection

Rationale for a 900 V/50 J requirement

While defibrillating on the chest using an external defibrillator, only a small fraction of the initial defibrillation voltage (and energy) reaches the heart and appears between the LEADS of an EXTERNAL PACEMAKER, stressing its outputs. A much higher stress to an EXTERNAL PACEMAKER, however, is provided by an internal defibrillator, which is often used during an open-heart surgery. Defibrillation electrodes (e.g. paddles) of an internal defibrillator are applied directly to the heart muscle, thus an attached EXTERNAL PACEMAKER sees only a slightly diminished voltage (energy) compared with the actual output voltage (energy) of the internal defibrillator waveform.

Previous testing of defibrillation protection (according to ISO 14117) took only the conditions arising during external defibrillation into account. In this case, the high voltage applied to the chest of the PATIENT is strongly reduced, when it arrives at the heart of the PATIENT.

The high voltage standoff requirement for EXTERNAL PACEMAKERS is determined by the maximum voltage between any two electrodes during epicardial (internal) defibrillation. The maximum energy used for epicardial (internal) defibrillation is limited to 50 J by IEC 60601-2-4 [5].

For example, a typical epicardial (internal) defibrillator (Lifepak 12®[3]) can be considered in the use condition with epicardial defibrillation electrodes. In this use case, higher output voltages are used with monophasic vs biphasic defibrillation PULSES, so monophasic waveforms represent the worst-case defibrillation waveform. The maximum voltage delivered during a 50 J monophasic delivery from a Lifepak 12 into a 50 Ω load is approximately 1 029 V. A reasonable minimum expected implant depth of the EXTERNAL PACEMAKER electrodes is 2,5 mm, which would result in a combined voltage drop from the defibrillation electrodes to the two EXTERNAL PACEMAKER electrodes of 5 mm x 28 V/mm or 140 V. As a percentage of the 1 kV applied defibrillation PULSE, this would be 86 % to the EXTERNAL PACEMAKER electrodes. Multiplying this by the maximum monophasic defibrillation PULSE voltage of 1 029 V will result in a theoretical maximum voltage delivered to the EXTERNAL PACEMAKER electrodes of 884 V. Given the EXTERNAL PACEMAKER electrodes would typically not be located on opposite sides of the shortest dimension of the heart, there is additional margin provided by worst case electrode assumption used.

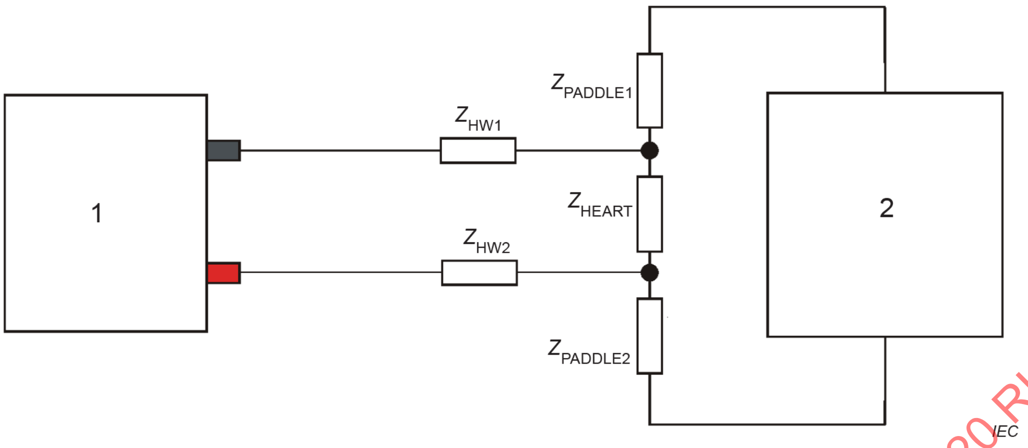
For the reasons described above, the defibrillation test voltage should be set to 900 V and the defibrillation waveform should have the energy of 50 J.

Characteristics for modelling internal defibrillation on open heart

Impedance of the heart

Figure AA.1 shows a possible model of internal defibrillation during open heart surgery. The brief investigation presented below describes the impedances specified in this model.

3 Lifepak 12 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of this product.



Key

①	EXTERNAL PACEMAKER (only one chamber is shown)
②	epicardial defibrillator (max. 50 J according to IEC 60601-2-4)
$Z_{PADDLE1}$	impedance of epicardial defibrillation paddles and impedance of tissue transition
$Z_{PADDLE2}$	impedance of epicardial defibrillation paddles and impedance of tissue transition
Z_{HEART}	heart impedance seen by epicardial defibrillator
Z_{HW1}	impedance of heart wire and impedance of tissue transition
Z_{HW2}	impedance of heart wire and impedance of tissue transition

Figure AA.1 – Simple model of a SINGLE CHAMBER EXTERNAL PACEMAKER during defibrillation

Schwarz [6] compares biphasic shocks with monophasic sine wave shocks for direct epicardial defibrillation during open chest cardiothoracic surgery. The monophasic shocks were generated by a Lifepak 12 defibrillator/monitor (50 µF capacitance, 21 mH inductance with internal resistance of 11 Ω). The biphasic shocks were delivered by a biphasic Lifepak 12 defibrillator/monitor. Regarding the biphasic PULSE shape, the publication [7] was referenced, where a 200 µF capacitor without inductor was used to generate the biphasic PULSES for external defibrillation. In most cases, 5,1 cm-diameter internal paddles were used.

We find in [6]:

"The mean delivered peak current for the biphasic shock group was calculated to be 5,6 A at the mean threshold energy (6,8 J) and the mean measured defibrillation impedance of ***45 Ω ± 9 Ω*** *(range,* ***30 Ω – 79 Ω****). The mean delivered peak current for the monophasic shock group was 10,6 A at the mean threshold energy (11,0 J). This mean current was estimated by assuming that the monophasic shock group had the same mean impedance as that measured for the biphasic shock group."*

It seems that the impedance in this study was measured by the biphasic defibrillator directly. Due to this fact, we have to assume that the measured defibrillation impedance includes both the impedance of the heart and of both internal paddles as given by Formula (AA.1):

$$Z_{DEFIB} = Z_{HEART} + Z_{PADDLE1} + Z_{PADDLE2} \qquad (AA.1)$$

The maximum measured value would be according to Formula (AA.2) as found in [6]:

$$Z_{DEFIB,MAX} = 79\ \Omega \tag{AA.2}$$

In [8], the heart impedance was explicitly measured on pigs[4]. Experimental series special defibrillation electrodes for open heart were used. All measurements were done using Gurvich-Venin bipolar quasi-sinusoidal defibrillation PULSES. Figure 6 in [8] shows a detailed diagram of measured heart impedance. It could be meant that only Z_{HEART} is presented in this figure. According to the test setup shown in [8], the measured value according to Formula (AA.1) appears to have been measured with respect to the defibrillation current. For values of the defibrillation current in the range between 0 A to 3 A, there is a region where the defibrillation impedance can change quite a lot with the highest value being about 31 Ω. However, for higher defibrillation currents, Z_{DEFIB} seems to be quite stable and was measured in a range between 20 Ω to 23 Ω. These are fairly lower impedance values than those obtained by [8].

From [6] and [8], we conclude that only the impedance represented by Formula (AA.1) was obtained, so we still cannot differentiate between Z_{HEART}, $Z_{PADDLE1}$ and $Z_{PADDLE2}$.

For tests of defibrillation protection of EXTERNAL PACEMAKERS, the heart impedance could be set to Z_{HEART} = 50 Ω as higher value of the heart impedance is not expected. As the paddles introduce a voltage dividing behaviour into the entire defibrillation protection configuration, the impedance of them could be neglected and thus set to 0 Ω.

Impedance of heart wires

Heart wires are intended for temporary stimulation of the heart during and after cardiac surgery. The stimulation is used to maintain a certain heart rhythm and/or to treat arrhythmia occurring intra- and/or postoperatively.

Heart wires are temporarily implanted epicardial electrodes at the ventricle and/or atrium. The fixation on the epicardium is achieved by special electrode anchor mechanisms. The distal end of heart wires can be equipped with small heart needles for implantation into the epicardium or are attached with sutures. The proximal end is equipped with a thorax needle for puncturing the chest and leading the wire out of the thorax. Heart wires are connected to EXTERNAL PACEMAKERS and have to be explanted after 5 to 7 days by pulling gently on the wire in a certain way. Heart wires are often called "temporary myocardial electrodes" (TME).

If the internal defibrillation paddles had a direct contact with the heart wires, then the heart wire impedance would have to have an impedance Z_{HW} somewhere between 10 Ω and 150 Ω. In this case, the impedance of electrode/tissue transition is omitted. It is unlikely, however, that both defibrillator paddles will contact the heart wires.

Normally, the total impedance seen by an EXTERNAL PACEMAKER is well within the range 200 Ω to 1 000 Ω specified in IEC 60601-2-31:2008 in 201.12.1.102[5]. There can be much lower impedance than 200 Ω achieved. However, this case does not represent a correct application of heart wire.

Taking all this information presented above into account and having in mind that a defibrillation-protection test should use a reasonably foreseeable worst-case condition, we consider the case in which one heart wire is directly connected with the internal defibrillation paddle, with the second internal paddle not being in any direct contact with the second heart wire. The Z_{HW}

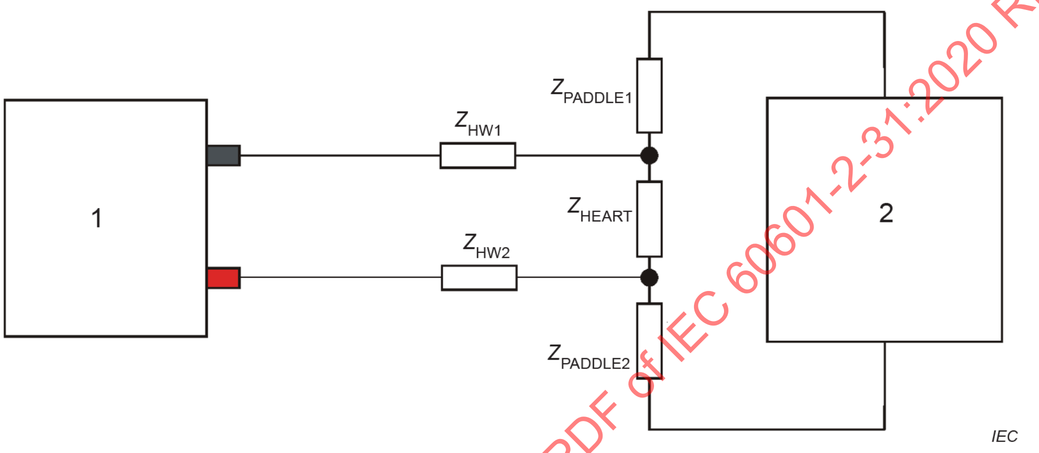
4 Pig heart is regarded to be very similar to that of a human.

5 For impedance smaller than 200 Ω the accuracy of PACEMAKER pulses would get worse. Eventually, a short condition would occur to the PACEMAKER, which would be considered as a fault condition.

would then be roughly 200 Ω/2 ≈ 100 Ω. This value could be lowered to 80 Ω to take any inequality in electrode/tissue impedance into account.

Example test meeting the requirements

Z_{HEART} would unlikely be more than 50 Ω, which should already be treated as an extreme value. Z_{HEART} ≈ 50 Ω would be a good value for a worst case in defibrillation model. For an easy test setup, the impedance of internal paddles $Z_{PADDLE1}$ and $Z_{PADDLE2}$ could actually be set to 0 Ω, since these elements only divide the output voltage of the defibrillator before it appears at Z_{HEART}. The test voltage could then be directly adjusted to 900 V.



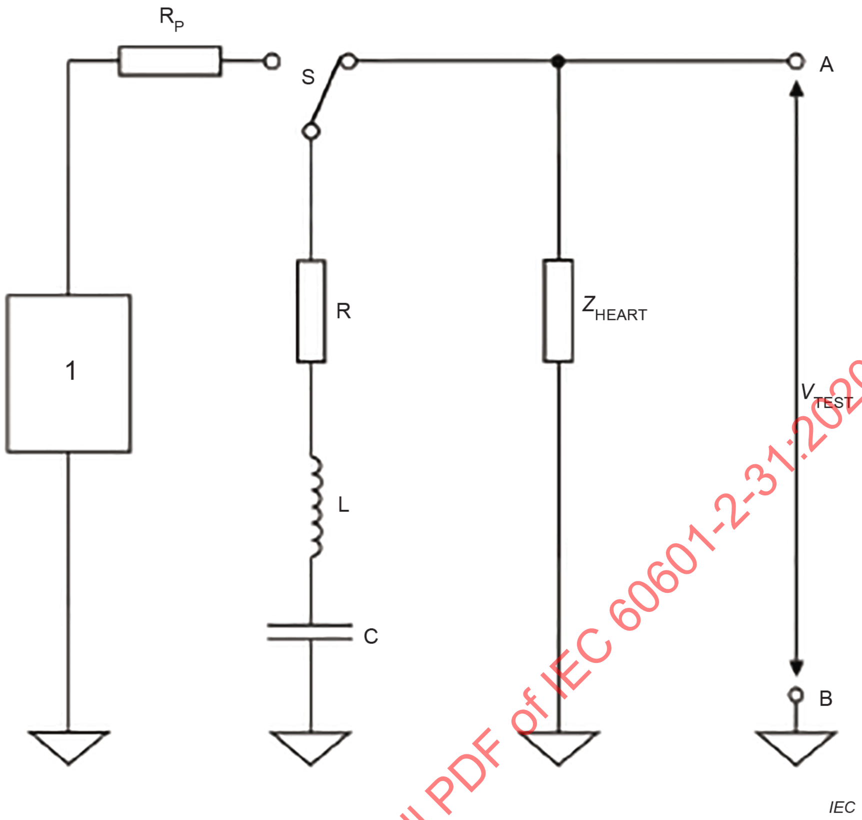
Key

①	SINGLE CHAMBER EXTERNAL PACEMAKER
②	epicardial defibrillator (max. 50 J according to IEC 60601-2-4)
$Z_{PADDLE1}$	impedance of epicardial defibrillation paddles and impedance of tissue transition; *R* = 0 Ω
$Z_{PADDLE2}$	impedance of internal defibrillation paddles and impedance of tissue transition; *R* = 0 Ω
Z_{HEART}	heart impedance seen by epicardial defibrillator; *R* = 50 Ω
Z_{HW1}	impedance of heart wire and impedance of tissue transition; *R* = 0 Ω
Z_{HW2}	impedance of heart wire and impedance of tissue transition; *R* = 80 Ω

Figure AA.2 – First proposal for a defib-protection test of SINGLE CHAMBER EXTERNAL PACEMAKER

Defibrillation test voltage generator

Figure AA.3 represents an example circuit for generation of the defibrillation test voltage. In practice, component tolerances used to construct this circuit will affect the energy delivered to the EUT. Therefore, an analysis of the effects of tolerances was undertaken to arrive at a set of component values that would minimally meet the needs for this test under foreseeable tolerance combinations. Figure AA.4 shows the variation in delivered PULSE waveform timing for a range of value for capacitor C.



Key

1	voltage generator
R	resistor in series with L and C
L	inductance
C	capacitor
R_P	current limiting resistor
Z_{HEART}	heart impedance seen by epicardial defibrillator; R = 50 Ω; simulated with an ohmic resistor
V_{TEST}	test voltage
A, B	output terminals of the defibrillator test voltage generator

Figure AA.3 – Circuit for a defibrillation test generator for defibrillation test according to conditions during open heart surgery

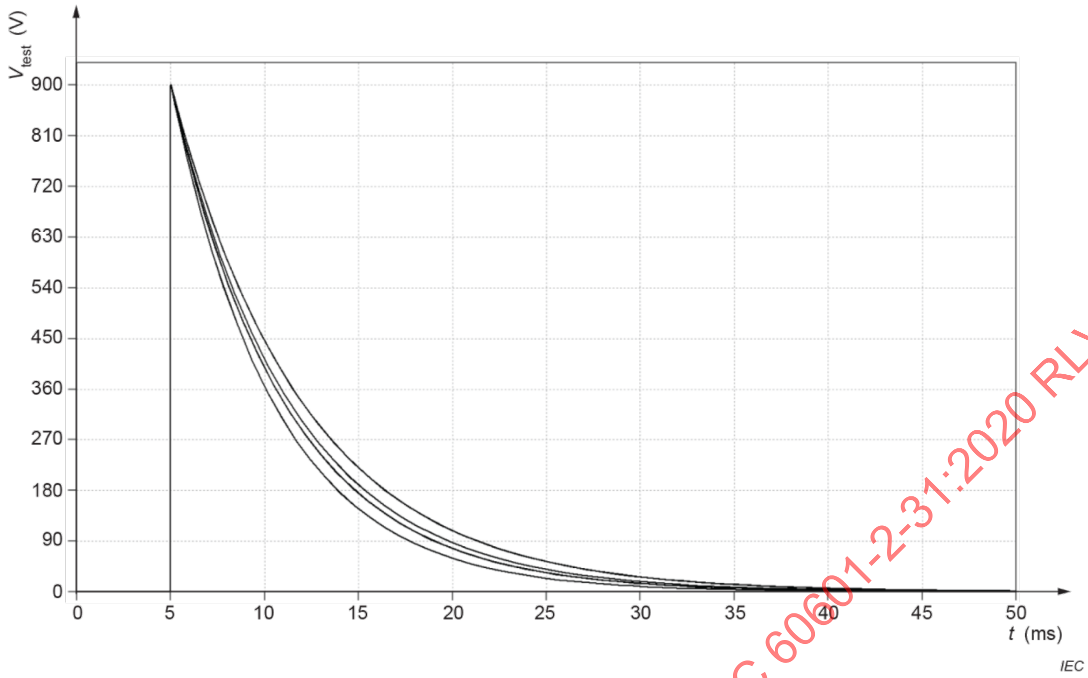


Figure AA.4 – Defibrillation PULSE generated by the defibrillation test generator from Figure AA.3

Z_{HEART}, in the example circuit of Figure AA.3 simulated with an ohmic resistor, is assumed to be 50 Ω ± 5 %. The test generator should provide output PULSES having 50 J. The energy delivered by the generator mainly depends on the value of the used capacitor. The rise time of the generated PULSE is mainly dependent on the applied inductor L. IEC 60601-2-4 [5] provides a test circuit for immunity of pacing circuitry to defibrillation pulses. The circuit specifies a series inductance of 500 µH. For the purposes of this document, a series inductance of 25 µH is used, thereby leading to a more challenging rise time test.

Calculations of the rise time show that the rise time t_r very well fits into the interval of 1 µs < t_r < 5 µs. Please see Figure AA.5 for the calculated rise times for components with applied tolerances. It should be noted that for those calculations the range of capacitance values was extended to include the range of 114 µF to 132,63 µF to take the three capacitance values proposed below and their tolerances of ±5 % into account. Looking at Figure AA.5, we see that the value of t_r(taken the definition of a rise time between 10 % and 90 % of the slope) is about 1 µs to 1,25 µs. It should however be noted here that the calculated rise times do not take any further damping factors, like the inductance of internal connections or cables into account. The real PULSE rise times are expected to be somewhat longer.

The resistance R should be chosen in such a way that $R + RL$ = 1 Ω with a tolerance of ±5 %.

The calculations below (see Tables AA.2, AA.3 and AA.4) show the dependence of output PULSE energy for a capacitance tolerance of ±5 % for three different capacitance values: 120 µF, 122 µF and 126,32 µF. On the one hand, only for the largest values, all PULSE energies are greater than 50 J. On the other hand, 122 µF can easily be built of two capacitors: 100 µF + 22 µF.

Table AA.2 – PULSE energies calculated for C = 120 µF ± 5 %

V_{set} = 925 V					
C = 120 µF ± 5 %		L = 25 µH ± 5 %		$R + RL$ = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	**C**	**L**	**Z_{HEART}**	**V_{out}**	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	114	23,75	47,5	903	**47,7**
2	120	23,75	47,5	903	**50,2**
3	126	23,75	47,5	903	**52,7**
4	114	25,00	47,5	903	**47,7**
5	120	25,00	47,5	903	**50,2**
6	126	25,00	47,5	903	**52,7**
7	114	26,25	47,5	903	**47,7**
8	120	26,25	47,5	903	**50,2**
9	126	26,25	47,5	903	**52,7**
10	114	23,75	50,0	903	**47,8**
11	120	23,75	50,0	903	**50,2**
12	126	23,75	50,0	903	**52,7**
13	114	25,00	50,0	903	**47,8**
14	120	25,00	50,0	903	**50,2**
15	126	25,00	50,0	903	**52,7**
16	114	26,25	50,0	903	**47,8**
17	120	26,25	50,0	903	**50,2**
18	126	26,25	50,0	903	**52,7**
19	114	23,75	52,5	903	**47,8**
20	120	23,75	52,5	903	**50,3**
21	126	23,75	52,5	903	**52,8**
22	114	25,00	52,5	903	**47,8**
23	120	25,00	52,5	903	**50,3**
24	126	25,00	52,5	903	**52,8**
25	114	26,25	52,5	903	**47,8**
26	120	26,25	52,5	903	**50,3**
27	126	26,25	52,5	903	**52,8**

Table AA.3 – PULSE energies calculated for C = 122 µF ± 5 %

V_{set} = 925 V					
C = 122 µF ± 5 %		L = 25 µH ± 5 %		$R + RL$ = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	***C***	***L***	Z_{HEART}	V_{out}	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	115,9	23,75	47,5	903	**48,5**
2	122,0	23,75	47,5	903	**51,0**
3	128,1	23,75	47,5	903	**53,5**
4	115,9	25,00	47,5	903	**48,5**
5	122,0	25,00	47,5	903	**51,0**
6	128,1	25,00	47,5	903	**53,5**
7	115,9	26,25	47,5	903	**48,5**
8	122,0	26,25	47,5	903	**51,0**
9	128,1	26,25	47,5	903	**53,5**
10	115,9	23,75	50,0	903	**48,5**
11	122,0	23,75	50,0	903	**51,1**
12	128,1	23,75	50,0	903	**53,6**
13	115,9	25,00	50,0	903	**48,5**
14	122,0	25,00	50,0	903	**51,1**
15	128,1	25,00	50,0	903	**53,6**
16	115,9	26,25	50,0	903	**48,5**
17	122,0	26,25	50,0	903	**51,1**
18	128,1	26,25	50,0	903	**53,6**
19	115,9	23,75	52,5	903	**48,6**
20	122,0	23,75	52,5	903	**51,1**
21	128,1	23,75	52,5	903	**53,6**
22	115,9	25,00	52,5	903	**48,6**
23	122,0	25,00	52,5	903	**51,1**
24	128,1	25,00	52,5	903	**53,6**
25	115,9	26,25	52,5	903	**48,6**
26	122,0	26,25	52,5	903	**51,1**
27	128,1	26,25	52,5	903	**53,6**

Table AA.4 – PULSE energies calculated for *C* = 126,32 µF ± 5 %

V_{set} = 925 V					
C = 126,32 µF ± 5 %		*L* = 25 µH ± 5 %		*R* + *RL* = 1 Ω (nominal)	
Z_{HEART} = 50 Ω ± 5 %					
Calc. No	***C***	***L***	Z_{HEART}	V_{out}	**Energy**
	[µF]	[µH]	[Ω]	[V]	[J]
1	120,00	23,75	47,5	903	**50,2**
2	126,32	23,75	47,5	903	**52,8**
3	132,63	23,75	47,5	903	**55,4**
4	120,00	25,00	47,5	903	**50,2**
5	126,32	25,00	47,5	903	**52,8**
6	132,63	25,00	47,5	903	**55,4**
7	120,00	26,25	47,5	903	**50,2**
8	126,32	26,25	47,5	903	**52,8**
9	132,63	26,25	47,5	903	**55,4**
10	120,00	23,75	50,0	903	**50,2**
11	126,32	23,75	50,0	903	**52,8**
12	132,63	23,75	50,0	903	**55,4**
13	120,00	25,00	50,0	903	**50,2**
14	126,32	25,00	50,0	903	**52,8**
15	132,63	25,00	50,0	903	**55,4**
16	120,00	26,25	50,0	903	**50,2**
17	126,32	26,25	50,0	903	**52,8**
18	132,63	26,25	50,0	903	**55,4**
19	120,00	23,75	52,5	903	**50,3**
20	126,32	23,75	52,5	903	**52,9**
21	132,63	23,75	52,5	903	**55,5**
22	120,00	25,00	52,5	903	**50,3**
23	126,32	25,00	52,5	903	**52,9**
24	132,63	25,00	52,5	903	**55,5**
25	120,00	26,25	52,5	903	**50,3**
26	126,32	26,25	52,5	903	**52,9**
27	132,63	26,25	52,5	903	**55,5**

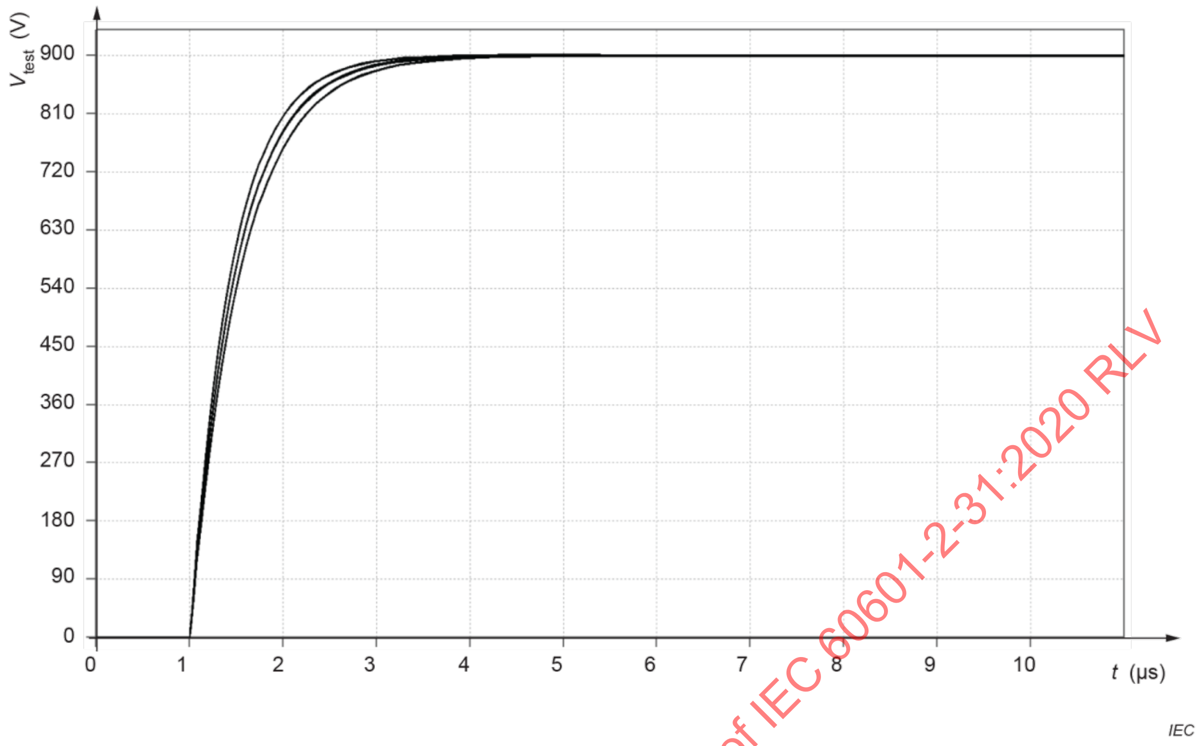


Figure AA.5 – Rise times of a defibrillation PULSE according to the circuit proposed in Figure AA.3

Subclause 201.8.5.5.2 – Energy reduction test

The applicability of the energy reduction clause was considered at length during the development of the third edition of this document.

There are two primary pathways by which energy reduction might occur. The first of these might be from the thorax to an earth grounded piece of equipment.

EXTERNAL PACEMAKERS within the scope of this particular standard differ from the ME EQUIPMENT considered in the general standard, in that they are not mains connected, and therefore cannot provide a shunting pathway to earth that would lead to an energy reduction.

A second pathway for energy reduction would be through the external PULSE generator itself by way of the attached heart wires. This might occur during the use of either internally or externally applied paddles. This effect is addressed primarily by the defibrillation protection clause.

Furthermore, these two scenarios were presented to a group of clinicians during a meeting of the AAMI CRMD committee in 2017. Their conclusion as to the need for a test of the effect of energy reduction effect caused by the presence of the EXTERNAL PACEMAKER was that it would be unnecessary. None of the physicians responded that they had seen the effect, and they further explained that even if there were an effect, that they would simply increase defibrillation energy, make repeated defibrillation attempts, or go so far as to remove the EXTERNAL PACEMAKER or LEAD connections in order to ensure the safety of the PATIENT.

Subclause 201.8.7.3 – Allowable values

A net direct current between electrodes in the body can result in damage to the tissue and the electrodes. Subclause 16.2 of ISO 14708-2:2019 requires that no PATIENT AUXILIARY CURRENT of more than 0,1 µA shall be detected in any current pathway. Since NON-IMPLANTABLE PULSE GENERATORS are used for relatively short periods of time, a higher level of PATIENT AUXILIARY CURRENT should be tolerated both under NORMAL (1 µA) and SINGLE FAULT (5 µA) conditions.

Where the AC component of the current is intended to produce a physiological effect, it is therefore outside the definition of PATIENT AUXILIARY CURRENT.

Subclause 201.8.7.4.1 – General

Subclause 201.8.7.4.1 aa)

Due to capacitive coupling between the APPLIED PART and other parts, a certain amount of LEAKAGE CURRENT is unavoidable. During the pacing PULSE, LEAKAGE CURRENTS can be higher, but will be much smaller than the intended pacing PULSE current and will not present a HAZARD to the PATIENT and the OPERATOR.

Subclause 201.8.7.4.8 – Measurement of the PATIENT AUXILIARY CURRENT

The test PROCEDURE is based on the one in 16.2 of ISO 14708-2:2019.

Subclause 201.11.6.5 – Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

The ME EQUIPMENT is likely to be used in close proximity to liquids which could be inadvertently spilled on the device while in operation, e.g. food and drink, urine, intravenous solutions, etc. The ME EQUIPMENT also has the potential to be carried and used outside medically used rooms. Therefore, a certain degree of protection against spillage and rainfall was deemed to be necessary.

Saline solution with a concentration of 9 g/l was selected as a worst-case solution simulating body fluids. 400 ml was selected to simulate a filled large glass or coffee cup. Wiping the ME EQUIPMENT dry after 30 s would be a normal response to a spill. The ME EQUIPMENT should continue to operate normally during and after the spill.

If saline penetrates the electronic compartment, undesired conduction paths or dendrites might develop within the circuitry. A 24 h delay between the solution exposure and the inspection was selected, so that sufficient time would pass for any saline that had entered the electronic compartment to migrate within the electronic compartment, and/or dendrites to develop.

Therefore, the integrity of the liquid ingress protection is assessed in two ways:

1) by assuring that the device function is not impaired during the spill (undesired conduction paths bridging intended conduction paths); and
2) visually by ensuring that no liquid, dendrites or stains are found in the electronics after the saline has had time to seep into and migrate within the electronic compartment.

Subclause 201.11.8 – Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

The requirement for a BATTERY DEPLETION INDICATOR is essential to avoid unexpected change in characteristics or function caused by depletion of the battery.

Subclause 201.12.1.101 – ME EQUIPMENT parameters

The purpose of the test methods in 6.1 of ISO 14708-2:2019 are to allow overall assessment of NON-IMPLANTABLE PULSE GENERATOR function without elaborate instrumentation or equipment.

The intention is that compliance be measured using the test similar to those specified in 6.1 of ISO 14708-2:2019 with fully charged batteries.

This edition specifies particular environmental conditions for some requirements and tests.

Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

To test the parameter stability at different rates settings, values of 60 PULSES and 120 PULSES per minute were selected as typical.

The test method for MAXIMUM TRACKING RATE is patterned on the test methods and uses the test apparatus and terminology described in 6.1 of ISO 14708-2:2019.

Subclause 201.12.1.102 – PULSE AMPLITUDE

Experience has shown that 200 Ω to 1 000 Ω represents the range of LEAD impedances, including the heart tissue, which are likely to be encountered in temporary pacing. 500 Ω is the typical value. Variation due to changing load is to be measured at a fixed pacing rate. A rate of 70 PULSES per minute was selected as a common rate available in all devices.

Subclause 201.12.4.1 – Intentional exceeding of safety limits

If high pacing rates are used in specific circumstances, extra precautions should be taken to prevent accidental high rate stimulation and to prevent the ME EQUIPMENT from being inadvertently left with the runaway rate protection feature disabled.

Subclause 201.12.4.101 – Protection against accidental change of controls and tampering

Maladjustment of the controls can result in a HAZARDOUS SITUATION; therefore, appropriate steps should be taken to reduce this possibility.

Subclause 201.12.4.102 – Protection against a low battery condition

The published tolerances listed in 201.7.9.2.5 c) are intended to extend over the service life of the power source, from fully charged to the detection of the low battery condition. If the ME EQUIPMENT changes its behaviour or is unable to maintain the tolerances listed in 201.7.9.2.5 c), the new behaviour is described in 201.7.9.2.5 d) and tested using the same test methods as those used to characterize the electrical parameters listed in 201.7.9.2.5 c).

Subclause 201.12.4.103 – Rate limit (runaway protection)

This feature is required in order to prevent unexpected and dangerously high pacing rates from occurring in the event of a SINGLE FAULT CONDITION.

Subclause 201.12.4.104 – Interference reversion

The ME EQUIPMENT during NORMAL USE might be used in areas where strong continuous electrical ELECTROMAGNETIC DISTURBANCE is present. For maximum safety under these conditions, the ME EQUIPMENT should revert to a stated mode of operation.

Subclause 201.12.4.105 – MAXIMUM TRACKING RATE

If DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing are available in the ME EQUIPMENT, a means should be provided to limit the ventricular pacing rate in response to sensed atrial activity to prevent deterioration of the haemodynamic state of the PATIENT. This value is independent of the runaway limit which is intended to prevent an excessively high pacing rate in the event of a SINGLE FAULT CONDITION.

Subclause 201.15.101 – Output indicator

An output indicator is a quick non-invasive indication of device operation. However, a circuit which monitors the actual output PULSE cannot readily determine if that output resulted in capture of the heart. Determining proper ME EQUIPMENT function and capture of the heart requires expert examination of the electrocardiogram.

Subclause 201.15.102 – Input indicator

An input indicator provides an indication that the device has detected the electrical activity of the heart and will react to the signal as specified by the MANUFACTURER for the selected pacing mode and other operational characteristics of the ME EQUIPMENT.

Subclause 202.8.9 – IMMUNITY TEST LEVELS

EXTERNAL PACEMAKERS are used in a professional healthcare facility environment, for example, physician offices, hospitals (emergency rooms, PATIENT rooms, intensive care, and surgery rooms).

Because EXTERNAL PACEMAKERS are used in conjunction with pacing LEADs which provide a low-impedance pathway to the heart, it is a standard of care and a recommended practice that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface before touching the PATIENT, the cable, the LEADS, or the EXTERNAL PACEMAKER. Also, static electricity from the PATIENT should be neutralized by touching the PATIENT away from (i.e., distal to) the LEADS.

In these conditions, the ME EQUIPMENT is less likely than in a HOME HEALTHCARE ENVIRONMENT to be exposed to static discharges which could damage an unprotected device. Severity level 4 was chosen as the maximum test level because 15 kV is a practically achievable value for the electrostatic voltage to which the OPERATOR might be charged. See Figure A.1 in IEC 61000-4-2:2008 [3].

Multiple discharges are needed to test ESD effects on timing sequences within the device, especially where microprocessors and software are involved. Subclause 8.3.2 of IEC 61000-4-2:2008 [3] recommends at least ten single discharges. Because the probability of the higher voltages is lower, some temporary degradation requiring OPERATOR intervention or system reset is allowed at severity levels 3 and 4.

OPERATOR intervention is acceptable, given that external pacing is performed under highly monitored conditions, with the EXTERNAL PACEMAKER secured out of the reach of the PATIENT and the PATIENT in a non-ambulatory state. Intervention with the accessibility of a back-up within a reasonable time is considered a standard of care. For example, it is standard practice for the user to monitor the PATIENT's ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during evaluation of stimulation and sensing thresholds, EXTERNAL PACEMAKER and pacing LEAD connections and adjustments, and atrial high-rate burst pacing therapy.

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Index of defined terms used in this particular standard

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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

1) La Commission électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

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.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– "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.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
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- amendé.

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IMPORTANT – Le logo "*colour inside*" qui se trouve sur la page de couverture de cette publication indique qu'elle contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer ce document en utilisant une imprimante couleur.

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.

[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*

201.3 * Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, l'ISO 14117:2019 et l'ISO 14708-2:2019, ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

NOTE Un index des termes définis est donné à partir de la page 109.

Addition:

201.3.201
DISPOSITIF MEDICAL IMPLANTABLE ACTIF
dispositif médical actif qui est conçu pour être implanté dans le corps humain, en totalité ou en partie, par une intervention chirurgicale ou médicale, ou dans un orifice naturel par une intervention médicale, et pour demeurer en place après l'intervention

[SOURCE: En anglais, ISO 14708-1:2014, 3.2]

201.3.202
INDICATEUR D'EPUISEMENT DE LA BATTERIE
moyen indiquant qu'il convient de remplacer la BATTERIE

201.3.203
STIMULATEUR CARDIAQUE
APPAREIL EM destiné à traiter les bradyarythmies

201.3.204
DOUBLE CHAMBRE
concerne à la fois l'oreillette et le ventricule

201.3.205
STIMULATEUR EXTERNE
STIMULATEUR CARDIAQUE constitué d'un GENERATEUR D'IMPULSIONS NON IMPLANTABLE et d'un ou des CABLE(S) PATIENT (le cas échéant)

201.3.206
DERIVATION
tube souple abritant un ou plusieurs conducteurs électriques isolés destinés à transférer l'énergie électrique entre le STIMULATEUR EXTERNE et le cœur du PATIENT

[SOURCE: En anglais, ISO 14708-1:2014, 3.13]

201.3.207
FREQUENCE MAXIMALE DE REPONSE
FRÉQUENCE D'IMPULSION maximale pour laquelle le GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE multichambre répondra 1:1 à un signal auriculaire détecté

[SOURCE: ISO 14708-2:2019, 3.30, modifié – Le mot "IMPLANTABLE" a été remplacé par "NON IMPLANTABLE multichambre" et le mot "déclenchement" par "auriculaire détecté".]

201.3.208
GENERATEUR D'IMPULSIONS NON IMPLANTABLE
APPAREIL EM à SOURCE ÉLECTRIQUE INTERNE destiné à être utilisé à l'extérieur du corps et qui produit une IMPULSION électrique périodique pour stimuler le cœur par l'intermédiaire d'une DÉRIVATION (ou d'une combinaison d'une DÉRIVATION et d'un CÂBLE PATIENT)

201.3.209
CABLE PATIENT
câble utilisé pour allonger la distance entre le GENERATEUR D'IMPULSIONS NON IMPLANTABLE et la DÉRIVATION de stimulation

201.3.210
PERIODE REFRACTAIRE AURICULAIRE POST-VENTRICULAIRE
PVARP
période réfractaire dans le canal auriculaire après un événement stimulé ou détecté dans le canal ventriculaire, utilisée dans les modes à DOUBLE CHAMBRE

Note 1 à l'article: L'abréviation "PVARP" est dérivée du terme anglais développé correspondant "post-ventricular atrial refractory period".

201.3.211
BATTERIE
un ou plusieurs éléments qui ne sont pas conçus pour être rechargés électriquement et qui sont équipés des dispositifs nécessaires pour l'emploi, par exemple boîtier, bornes, marquage et dispositifs de protection

[SOURCE: IEC 60050-482:2004, 482-01-04, modifié – Ajout de "qui ne sont pas conçus pour être rechargés électriquement.]

201.3.212
CHAMBRE UNIQUE
concerne soit l'oreillette soit le ventricule

201.3.213
FREQUENCE DE BASE
FREQUENCE D'IMPULSION d'un GENERATEUR D'IMPULSIONS NON IMPLANTABLE, qu'il soit auriculaire ou ventriculaire, non modifiée par une influence cardiaque détectée ou toute autre influence électrique

[SOURCE: En anglais, ISO 14708-2:2019, 3.26]

201.3.214
INTERVALLE D'ECHAPPEMENT
temps qui s'écoule entre la détection d'un BATTEMENT spontané et l'IMPULSION non déclenchée suivante d'un GENERATEUR D'IMPULSIONS NON IMPLANTABLE

[SOURCE: En anglais, ISO 14117:2019, 3.128]

201.3.215
FREQUENCE DES IMPULSIONS EN PRESENCE D'INTERFERENCE
FREQUENCE D'IMPULSION avec laquelle le GENERATEUR D'IMPULSIONS NON IMPLANTABLE répond lorsqu'il détecte une activité électrique qu'il reconnaît comme une interférence

[SOURCE: En anglais, ISO 14117:2019, 3.129]

201.4 Exigences générales

L'Article 4 de la norme générale s'applique, avec les exceptions suivantes:

201.4.3 PERFORMANCE ESSENTIELLE

Paragraphe complémentaire:

201.4.3.101 Exigences supplémentaires de PERFORMANCES ESSENTIELLES

Des exigences supplémentaires pour les PERFORMANCES ESSENTIELLES sont données dans les paragraphes dont la liste figure dans le Tableau 201.101.

Tableau 201.101 – Répartition des exigences pour les PERFORMANCES ESSENTIELLES

Exigence	Paragraphe
INDICATEUR D'EPUISEMENT DE LA BATTERIE	201.11.8
Stabilité de paramètre de l'APPAREIL EM	201.12.1.101
Stabilité d'AMPLITUDE D'IMPULSION	201.12.1.102
Désactivation de la protection contre l'emballement en fréquence	201.12.4.1
Action délibérée exigée pour modifier les réglages	201.12.4.101
Stabilité de paramètre au déclenchement de l'INDICATEUR D'ÉPUISEMENT DE LA BATTERIE	201.12.4.102
Protection contre les emballements	201.12.4.103
Action préventive en présence de PERTURBATIONS ELECTROMAGNETIQUES détectées ou de sources d'énergie électrique	201.12.4.104
Limite à laquelle le ventricule est stimulé en réponse à une activité auriculaire détectée	201.12.4.105

201.4.10.1 Source d'alimentation pour APPAREIL EM

Remplacement:

L'APPAREIL EM doit être alimenté par une BATTERIE.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.4.10.2 RESEAU D'ALIMENTATION pour APPAREILS EM et SYSTEMES EM

Ce paragraphe de la norme générale ne s'applique pas.

201.4.11 * Puissance absorbée

Ce paragraphe de la norme générale ne s'applique pas.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique, avec les exceptions suivantes:

201.6.2 * Protection contre les chocs électriques

Remplacement:

L'APPAREIL EM doit être classé comme APPAREIL EM ALIMENTE DE MANIERE INTERNE.

L'APPAREIL EM doit être reconnu comme étant un APPAREIL ALIMENTE DE MANIERE INTERNE uniquement s'il n'est équipé d'aucune connexion externe avec une source d'énergie électrique.

Les PARTIES APPLIQUEES doivent être classées comme des PARTIES APPLIQUEES DE TYPE CF. Les PARTIES APPLIQUEES doivent être classées comme des PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique, avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

Paragraphes complémentaires:

201.7.2.101 APPAREILS EM destinés à une application à CHAMBRE UNIQUE

Si l'APPAREIL EM est destiné à des applications à CHAMBRE UNIQUE, les bornes de connecteur (le cas échéant) doivent être marquées de manière bien visible (+) (borne positive) et (–) (borne négative).

201.7.2.102 * APPAREILS EM destinés à une application à DOUBLE CHAMBRE

Si l'APPAREIL EM est destiné à des applications à DOUBLE CHAMBRE, les bornes de connecteur (le cas échéant) doivent être marquées conformément au Tableau 201.102. Si des couleurs sont utilisées pour distinguer les canaux dans une application à DOUBLE CHAMBRE, alors il convient de marquer le canal ventriculaire en blanc et le canal auriculaire avec une couleur faisant contraste.

Tableau 201.102 – Marquage des bornes de connecteur en DOUBLE CHAMBRE

Canal	Symbole		Étiquette de la borne
	Borne positive	Borne négative	
Canal auriculaire	A+	A–	OREILLETTE
Canal ventriculaire	V+	V–	VENTRICULE

201.7.2.103 Connecteurs bipolaires

Lorsque des connecteurs bipolaires sont utilisés, ils doivent comporter des détrompeurs pour empêcher toute inversion accidentelle de la polarité.

201.7.2.104 * Compartiment des BATTERIES

Les moyens pour accéder au compartiment des BATTERIES doivent être aisément identifiables. Le compartiment des BATTERIES doit être marqué de manière claire et indélébile en utilisant la nomenclature de l'IEC concernant les BATTERIES, la tension et le type. Le compartiment des BATTERIES doit porter de manière claire et indélébile l'indication pour l'orientation correcte de la ou des BATTERIES.

201.7.4 Marquage des organes de commande et des instruments

Paragraphes complémentaires:

201.7.4.101 * Commande ou indicateur pour la valeur de sortie de stimulation

Si une sortie à courant constant est utilisée, la commande de sélection de la valeur de sortie de stimulation ou les moyens correspondants qui l'indiquent doivent être marqués avec le courant en milliampères (mA) à travers une charge résistive de 500 Ω ± 1 %. Si une sortie à tension constante est utilisée, la sortie de stimulation ou les moyens correspondants qui l'indiquent doivent être marqués en volts (V) à travers une charge résistive de 500 Ω ± 1 %.

201.7.4.102 * Commande ou indicateur pour la FREQUENCE D'IMPULSION

La commande de sélection de la FREQUENCE D'IMPULSION ou les moyens correspondants qui l'indiquent doivent être marqués en IMPULSIONS par minute.

201.7.4.103 * Commande pour la sélection du mode de stimulation

Si des moyens sont fournis pour choisir le mode de stimulation, l'APPAREIL EM doit indiquer les modes de stimulation possibles ainsi que le mode choisi en utilisant les codes décrits à l'Annexe C de l'ISO 14708-2:2019.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.2.2 * Avertissements et consignes de sécurité

Remplacement:

Les instructions d'utilisation doivent inclure tous les avertissements et toutes les consignes de sécurité.

Il convient de placer les avertissements et les consignes de sécurité d'ordre général dans une section spécialement identifiée des instructions d'utilisation. Il convient qu'un avertissement ou une consigne de sécurité qui s'applique uniquement à une instruction ou une action spécifique précède l'instruction à laquelle elle s'applique.

Les instructions d'utilisation doivent fournir à l'OPERATEUR ou à l'ORGANISME RESPONSABLE les avertissements concernant tout RISQUE significatif d'interférence réciproque se posant en présence de l'APPAREIL EM au cours d'examens ou de traitements spécifiques.

Les instructions d'utilisation doivent inclure ce qui suit.

a) * Des avertissements concernant les changements potentiels de comportement du GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE causés par les SOURCES DE PERTURBATIONS ÉLECTROMAGNÉTIQUES (par exemple, émetteurs de communication dans les hôpitaux et les véhicules de transport d'urgence, les téléphones cellulaires, etc.) et les effets des sources d'énergie utilisées en thérapie et en diagnostic (par exemple, cardioversion externe, diathermie, neurostimulateurs électriques transcutanés, appareils chirurgicaux à haute fréquence, imagerie à résonance magnétique ou sources similaires) sur ces GÉNÉRATEURS D'IMPULSIONS NON IMPLANTABLES. Ils doivent inclure des conseils pour reconnaître à quel moment le comportement du GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE est influencé par les sources de PERTURBATIONS ÉLECTROMAGNÉTIQUES externes ou des sources d'énergie électrique, ainsi que les mesures à prendre pour éviter les interférences.

b) * Un avertissement concernant le danger d'introduire par inadvertance un COURANT DE FUITE dans le cœur si un appareil alimenté par le RÉSEAU D'ALIMENTATION est relié à l'ensemble des DÉRIVATIONS.

c) * Un avertissement indiquant que le CÂBLE PATIENT doit être relié au GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE avant de relier les DÉRIVATIONS de stimulation au CÂBLE PATIENT.

d) * Un avertissement indiquant que, lorsque des DÉRIVATIONS à demeure sont manipulées, les broches d'extrémité ou le métal nu ne doivent pas être touchés ni entrer en contact avec les surfaces électriquement conductrices ou humides.

e) * Un avertissement quant aux dangers d'utilisation de BATTERIES autres que celles recommandées par le FABRICANT (par exemple, courte durée de vie de la BATTERIE après indication de son affaiblissement, performances diminuées de l'APPAREIL EM, durée de vie totale réduite de la BATTERIE, stimulation irrégulière ou inexistante).

f) * Un avertissement indiquant qu'avant de manipuler UN GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE, le CÂBLE PATIENT ou les dérivations à demeure, des mesures doivent être prises pour égaliser le potentiel électrostatique entre l'utilisateur et le PATIENT, par exemple en touchant le PATIENT à un emplacement éloigné des DÉRIVATIONS de stimulation.

g) * Une mise en garde stipulant que, lorsque cela est cliniquement indiqué, il convient d'envisager une surveillance supplémentaire du PATIENT.

201.7.9.2.4 * Source d'alimentation électrique

Remplacement:

Les instructions d'utilisation doivent comporter des conseils sur le retrait des BATTERIES si l'APPAREIL EM doit être stocké ou rester inutilisé pendant un temps prolongé.

Les instructions d'utilisation doivent indiquer la spécification recommandée pour la BATTERIE.

Les instructions d'utilisation doivent mentionner le temps de service estimé pour des BATTERIES à pleine charge, à la température ambiante de 20 °C, dans des conditions spécifiées de fonctionnement.

Les instructions d'utilisation doivent mentionner le temps de service estimé de l'INDICATEUR D'EPUISEMENT DE LA BATTERIE après le déclenchement, dans des conditions spécifiées de fonctionnement.

Les instructions d'utilisation doivent comporter des informations (y compris une référence à la BATTERIE appropriée spécifiée dans l'IEC 60086-2 [1] [2] identifiant les BATTERIES à utiliser.

201.7.9.2.5 * Description de l'APPAREIL EM

Addition:

Les instructions d'utilisation doivent inclure ce qui suit.

a) * Une description générale, une explication des fonctions possibles et une description de l'interaction cœur/GENERATEUR D'IMPULSIONS pour chaque mode de stimulation possible. Voir Article C.3 de l'ISO 14708-2:2019 pour la description des modes de stimulation.

b) * La configuration des connecteurs, la géométrie et/ou les dimensions des connecteurs de réception et les instructions pour relier la ou les DERIVATIONS ou le ou les CABLES PATIENT au GÉNÉRATEUR D'IMPULSIONS NON IMPLANTABLE.

c) * Les caractéristiques électriques suivantes (y compris les tolérances, si applicables) avec une charge de 500 Ω ± 1 %, à moins qu'une autre valeur ne soit fixée:
   - plages des FREQUENCES DE BASE, des INTERVALLES D'ECHAPPEMENT, des FREQUENCES MAXIMALES DE REPONSE et des FREQUENCES DES IMPULSIONS EN PRESENCE D'INTERFERENCE (le cas échéant);
   - AMPLITUDE(S) D'IMPULSION;
   - DUREE(S) D'IMPULSION;
   - plage de la SENSIBILITE à la fois pour les polarités négatives et les polarités positives (si la fonction de détection est mise en place);
   - période(s) d'inactivité de l'amplificateur de détection (si une fonction de détection est mise en place);
   - PERIODE(S) REFRACTAIRE(S) (stimulation et détection) et INTERVALLES A-V (le cas échéant);
   - mode opératoire en présence de PERTURBATIONS ELECTROMAGNETIQUES détectées ou de sources d'énergie électrique;
   - limite de fréquence (protection contre l'emballement), en IMPULSIONS par minute.

d) * les caractéristiques électriques répertoriées ci-dessous et indiquées en 201.7.9.2.5 c) après déclenchement de l'INDICATEUR D'EPUISEMENT DE LA BATTERIE, sauf si ces valeurs sont les mêmes que celles données précédemment:
   - la FREQUENCE DE BASE ou l'INTERVALLE ENTRE IMPULSIONS équivalent;
   - AMPLITUDE(S) D'IMPULSION;
   - DUREE(S) D'IMPULSION;
   - la SENSIBILITE (si une fonction de détection est mise en place);
   - le changement de mode (le cas échéant).

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2 Les chiffres entre crochets se réfèrent à la Bibliographie.

201.7.9.2.8 * PROCEDURE de démarrage

Addition:

Les instructions d'utilisation doivent contenir toute limitation environnementale concernant le stockage des APPAREILS EM immédiatement avant utilisation.

201.7.9.2.13 * Maintenance

Addition:

Les instructions d'utilisation doivent contenir des informations détaillées pour le remplacement de la BATTERIE et les moyens de vérifier que le remplacement est exigé.

Les instructions d'utilisation doivent contenir des informations attirant l'attention de l'ORGANISME RESPONSABLE sur la nécessité d'une maintenance périodique ou après tout dysfonctionnement ou tout accident de l'APPAREIL EM, que celui-ci soit ou non utilisé, en particulier:

- nettoyage et désinfection des CABLES PATIENT réutilisables;
- nettoyage et désinfection du GÉNÉRATEUR D'IMPULSIONS NON-IMPLANTABLE;
- examen des câbles et connexions pour détecter d'éventuels défauts, par exemple connexions desserrées, usure et détérioration dues, par exemple, aux mouvements du PATIENT;
- examen du GENERATEUR D'IMPULSIONS NON IMPLANTABLE et du CABLE PATIENT à la recherche de signes de dommages physiques ou de contamination, en particulier dommages ou contamination qui peuvent avoir un effet préjudiciable sur les propriétés d'isolation électrique de l'APPAREIL EM;
- vérifications des fonctions, étalonnage, manœuvre des clés, interrupteurs, etc. en particulier si l'APPAREIL EM a subi des chocs sérieux, par exemple, en tombant.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique, avec les exceptions suivantes:

201.8.5.5 PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION

201.8.5.5.1 * Protection contre la défibrillation

Remplacement:

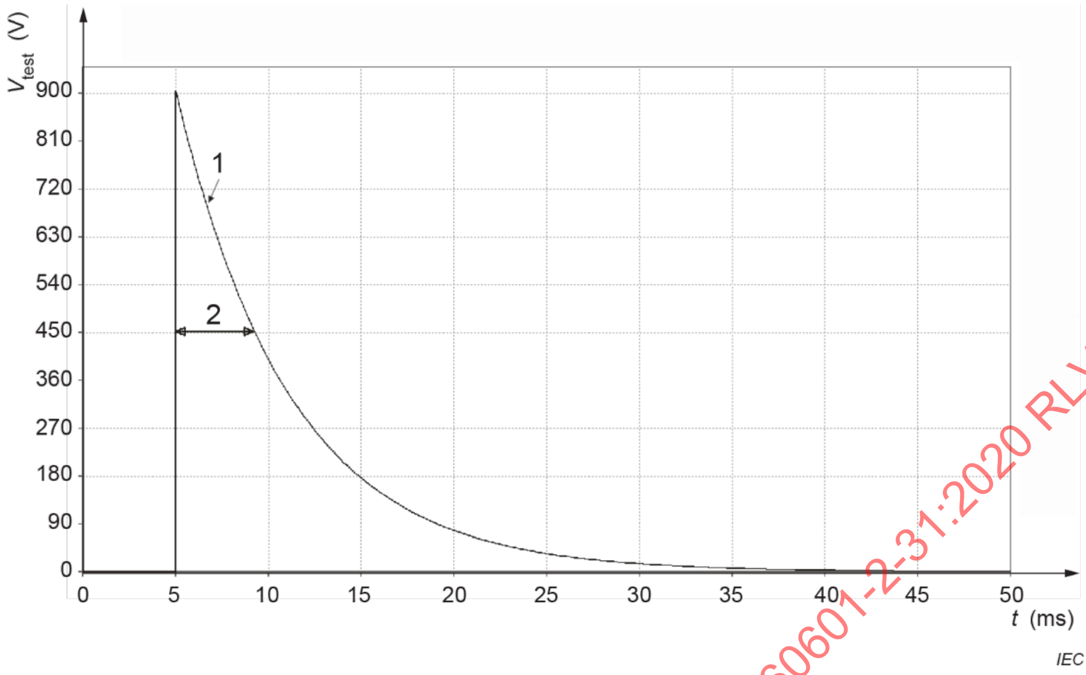
201.8.5.5.1.1 Exigences générales

L'APPAREIL EM doit être conçu de sorte que la défibrillation du PATIENT par un défibrillateur interne n'affecte pas irrémédiablement l'APPAREIL EM, à condition de placer les électrodes du défibrillateur interne conformément aux recommandations du FABRICANT de l'APPAREIL EM.

201.8.5.5.1.2 Essai de protection contre la défibrillation

Matériel d'essai: Utiliser un générateur de tension d'essai de défibrillation fournissant une forme d'onde exponentielle décroissante comme représentée à la Figure 201.101 avec les caractéristiques suivantes: une tension maximale V_{test} de 900 V $^{+2,5}_{-0}$ % et une énergie de 50 J à 55 J, avec T_{w50} = 4,05 ms à 4,6 ms, où T_{w50} est l'intervalle de temps pendant lequel la tension d'essai est supérieure à 50 % de la valeur maximale V_{test}, si elle est déchargée dans une résistance de charge R_{heart} = 50 Ω ± 1 %.

NOTE 1 La résistance R_{heart} = 50 Ω ± 1 % simule la résistance du cœur vue par un défibrillateur lors d'une opération à cœur ouvert.



Légende

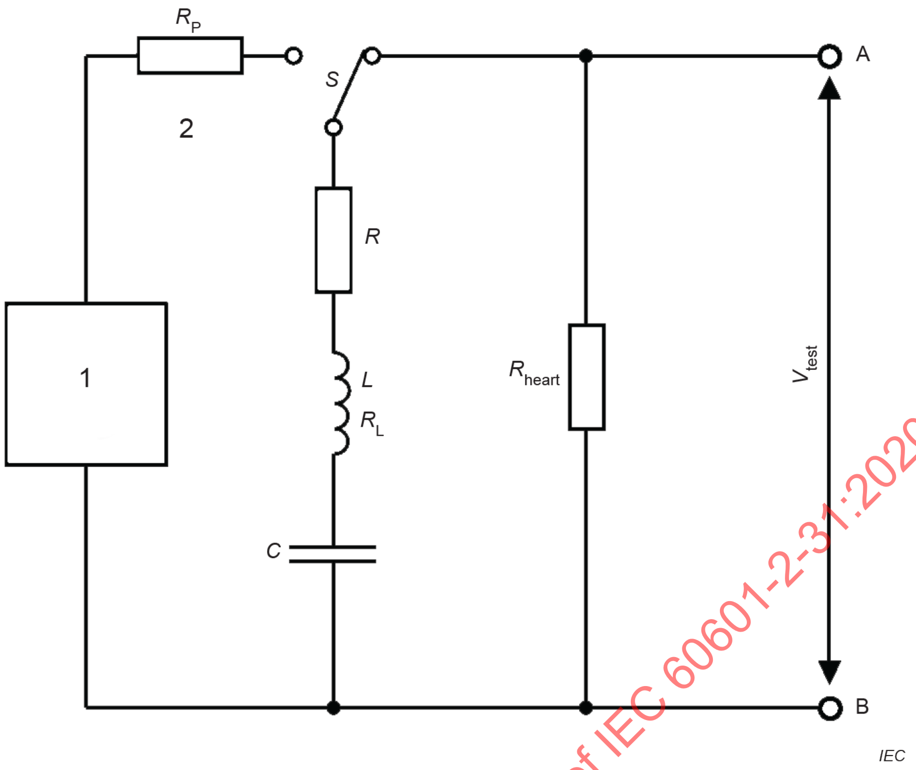
1 forme d'onde d'essai exponentielle décroissante

2 T_{w50} = 4,05 ms à 4,6 ms: intervalle de temps pendant lequel la tension d'essai est supérieure à 50 % de la valeur maximale V_{test}.

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

La Figure 201.102 représente un exemple schématique de générateur de tension d'essai de défibrillation avec C = 120 µF ± 5 % , L = 25 µH ± 5 %, $R_L + R$ = 1 Ω ± 5 %, où R_L est la résistance de l'inductance L et R et la résistance de sortie du générateur de tension d'essai de défibrillation.

NOTE 2 La résistance de limitation de courant R_P peut être utilisée pour protéger le générateur de tension lors de la charge du condensateur.



Légende

1	générateur de tension
2	résistance de limitation de courant
S	interrupteur pour appliquer la tension d'essai
L	inductance de 25 µh ± 5 %
R_L	résistance de l'inducteur
R	résistance en série avec *L* et *C*
C	condensateur de 120 µF ± 5 %
R_{heart}	résistance R_{heart} = 50 Ω ± 1 % qui simule la résistance du cœur vue par un défibrillateur lors d'une opération à cœur ouvert
V_{test}	tension d'essai
A,B	bornes de sorties du générateur de tension d'essai de défibrillation

Figure 201.102– Exemple de circuit de générateur de tension d'essai de défibrillation pour la génération d'une forme d'onde exponentielle décroissante

PROCÉDURE *d'essai:* Relier les bornes A et B de la sortie V_{test} au STIMULATEUR EXTERNE tel que décrit ci-dessous.

L'APPAREIL EM doit être classé dans un et/ou les deux groupes de STIMULATEURS EXTERNES selon le cas et relié comme suit:

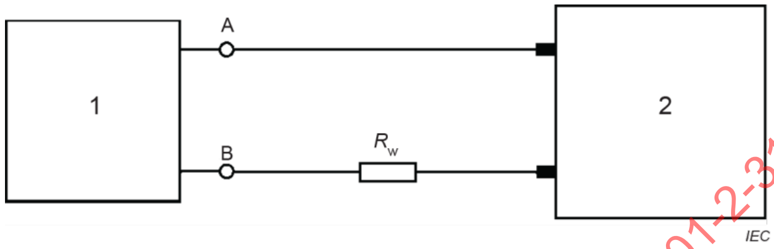
– STIMULATEUR EXTERNE A CHAMBRE UNIQUE:

La tension d'essai V_{test} est appliquée entre une CONNEXION PATIENT du STIMULATEUR EXTERNE reliée à la borne A du générateur de tension d'essai de défibrillation, et la seconde connexion du STIMULATEUR EXTERNE reliée à la borne B du générateur de tension d'essai de défibrillation par une résistance de 80 Ω. Le montage d'essai correspondant est représenté à la Figure 201.103.

– STIMULATEUR EXTERNE multichambre:

La tension d'essai V_{test} est appliquée à chaque CONNEXION PATIENT du STIMULATEUR EXTERNE reliée à la borne A du générateur de tension d'essai de défibrillation et tour à tour à toutes les connexions PATIENT du STIMULATEUR EXTERNE restantes reliées ensemble à la borne B du générateur de tension d'essai de défibrillation au moyen des résistances de 80 Ω.La Figure 201.104 représente le montage d'essai d'un STIMULATEUR CARDIAQUE EXTERNE à DOUBLE CHAMBRE, et la Figure 201.105 représente le montage d'essai d'un STIMULATEUR EXTERNE à triple chambre (par exemple, biventriculaire).

NOTE 3 Les résistances de 80 Ω représentées dans les montages d'essai ci-dessous simulent l'impédance des électrodes cardiaques appliquées et du tissu entre le défibrillateur interne et les bornes du STIMULATEUR EXTERNE.



Légende

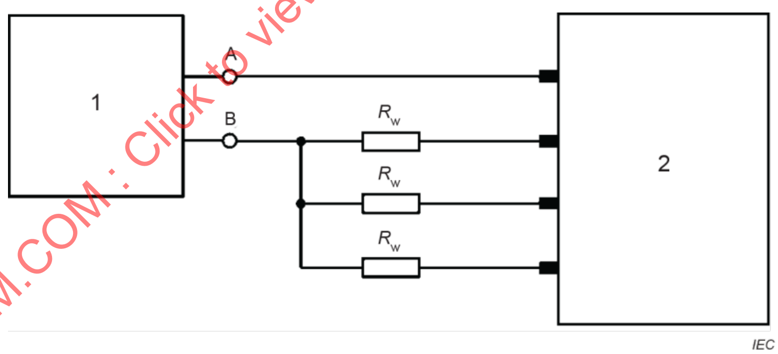
1 générateur de tension d'essai de défibrillation

2 STIMULATEUR EXTERNE A CHAMBRE UNIQUE:

R_w résistance de 80 Ω ± 1 % qui simule l'impédance des électrodes cardiaques et du tissu entre le défibrillateur et le STIMULATEUR EXTERNE

A,B bornes de sorties du générateur de tension d'essai de défibrillation

Figure 201.103 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à CHAMBRE UNIQUE



Légende

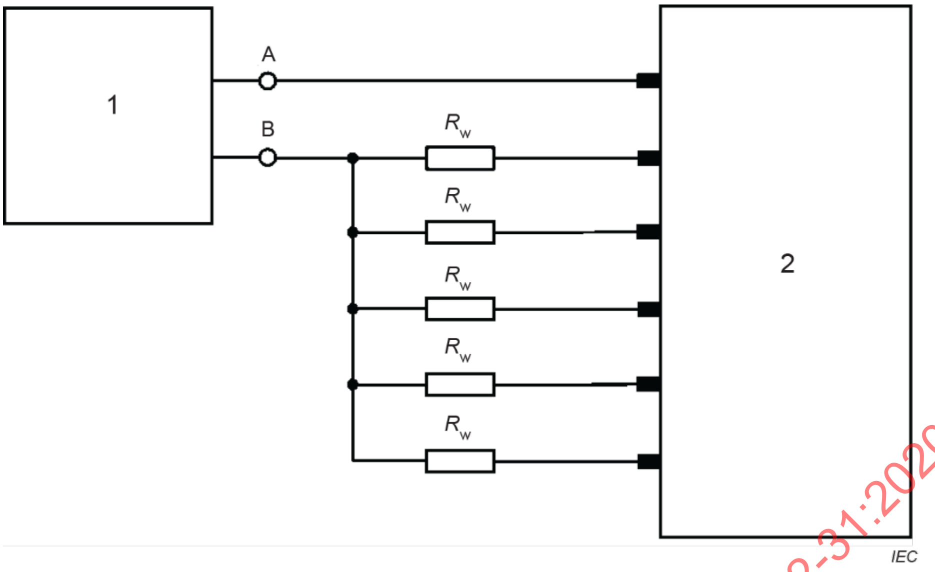
1 générateur de tension d'essai de défibrillation

2 STIMULATEUR EXTERNE A DOUBLE CHAMBRE

R_w résistance de 80 Ω ± 1 % qui simule l'impédance des électrodes cardiaques et du tissu entre le défibrillateur et le STIMULATEUR EXTERNE

A,B bornes de sorties du générateur de tension d'essai de défibrillation

Figure 201.104 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à DOUBLE CHAMBRE



Légende

1 générateur de tension d'essai de défibrillation

2 STIMULATEUR EXTERNE multichambre, par exemple STIMULATEUR EXTERNE biventriculaire avec trois chambres de stimulation

R_w résistance de 80 Ω ± 1 % qui simule l'impédance des électrodes cardiaques et du tissu entre le défibrillateur et le STIMULATEUR EXTERNE

A,B bornes de sorties du générateur de tension d'essai de défibrillation

Figure 201.105 – Montage d'essai d'un STIMULATEUR CARDIAQUE externe à triple chambre, par exemple un STIMULATEUR CARDIAQUE externe biventriculaire

Commencer l'essai en appliquant une séquence de trois tensions de choc à polarité positive à des intervalles de 20 s à 25 s. Puis, après un intervalle de 60 s (minimum), répéter l'essai avec des tensions de choc à polarité négative (voir la Figure 201.106).

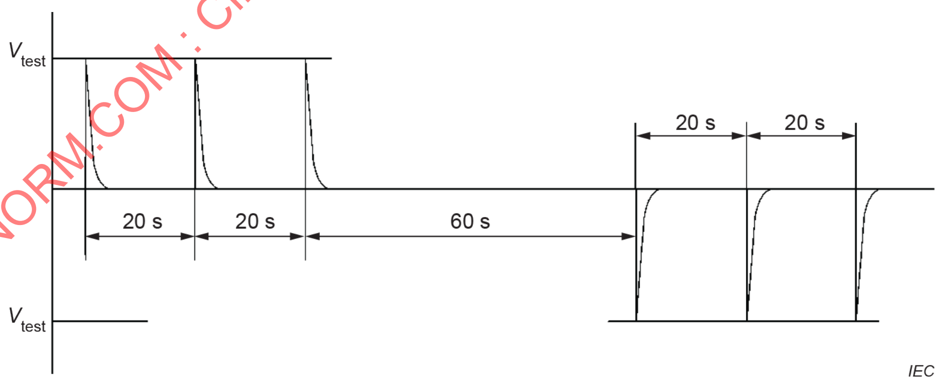


Figure 201.106 – Séquences de synchronisation

La conformité doit être confirmée si, après achèvement de la PROCÉDURE d'essai, l'APPAREIL EM continue d'assurer la SECURITE DE BASE et la PERFORMANCE ESSENTIELLE.

201.8.5.5.2 * Essai de réduction de l'énergie

Ce paragraphe de la norme générale ne s'applique pas.

201.8.7.3 * Valeurs admissibles

Amendement:

Dans le Tableau 3 de l'IEC 60601-1:2005, remplacer les valeurs pour le COURANT AUXILIAIRE PATIENT pour les PARTIES APPLIQUEES DE TYPE CF pour le courant continu par 1 µA en CONDITION NORMALE (normal condition (NC)) et 5 µA en CONDITION DE PREMIER DEFAUT (SFC, single fault condition).

201.8.7.4 Mesures

201.8.7.4.1 * Généralités

Addition:

aa) * Il convient, si possible, de désactiver la sortie du GÉNÉRATEUR D'IMPULSIONS NON-IMPLANTABLE pendant l'essai de COURANT DE FUITE. Si la sortie doit être active, il convient de ne pas considérer sa contribution comme une partie du COURANT DE FUITE.

201.8.7.4.8 * Mesure du COURANT AUXILIAIRE PATIENT

Remplacement:

Pour mesurer le COURANT AUXILIAIRE PATIENT, l'APPAREIL EM est relié comme représenté à la Figure 201.107. Chaque CONNEXION PATIENT est reliée à un bus commun par une résistance de charge (R_L) de 500 Ω ± 1 %. Mesurer la tension continue moyenne qui traverse chaque résistance de charge en utilisant un appareil de mesure (measuring device – MD) constitué d'un voltmètre à courant continu, dont la résolution est supérieure à 2 µV, alimenté par l'intermédiaire d'un filtre passe-bas avec une constante de temps d'au moins 10 s. Les conditions stables doivent être atteintes avant de réaliser le mesurage.

Le GENERATEUR D'IMPULSIONS NON IMPLANTABLE doit être réglé sur les valeurs nominales recommandées par le FABRICANT (c'est-à-dire, les réglages usine recommandés) mais avec l'AMPLITUDE D'IMPULSION et la DUREE D'IMPULSION programmées aux réglages disponibles les plus élevés.

Le filtre passe-bas peut être mis en œuvre par un filtre RC à quatre éléments constitués de résistances de 1 MΩ et de condensateurs en polypropylène métallisé de 10 µF. Il convient que la résistance d'entrée du voltmètre à courant continu soit ≥ 400 MΩ.