

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

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

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

<https://standards.iteh.ai/en/standards/iec/198659af-c8d9-4d13-b6d0-1768e68aa6ce/iec-60601-2-31-2008>

WILSON



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IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland  
Email: [inmail@iec.ch](mailto:inmail@iec.ch)  
Web: [www.iec.ch](http://www.iec.ch)

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Email: [csc@iec.ch](mailto:csc@iec.ch)

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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International standard IEC 60601-2-31 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994 and its Amendment 1 (1998). This edition constitutes a technical revision.

This second edition of IEC 60601-2-31 is aligned with IEC 60601-1:2005, and contains minimal technical revisions from the first edition.

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

Enquiry draft	Report on voting
62D/603/CDV	62D/667/RVC

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

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

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

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## INTRODUCTION

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

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

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

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

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in selecting 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 (third edition, 2005): *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 standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.



## 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<sup>1)</sup> applies, except as follows:

##### 201.1.1 \* Scope

*Replacement:*

This International Standard 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 standard applies to PATIENT CABLES as defined in 201.3. 109.

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

NOTE See also 4.2 of the general standard.

This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1 This standard does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This standard 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.

##### 201.1.3 Collateral standards

*Addition:*

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

<sup>1)</sup> The general standard is IEC 60601-1:2005.

IEC 60601-1-3 does not apply.

#### 201.1.4 Particular standards

##### *Replacement:*

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

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

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

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

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

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

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

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

#### 201.2 Normative references

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

##### *Replacement:*

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

*Addition:*

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

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.

### **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:

NOTE An index of defined terms is found beginning on page 35.

*Addition:*

#### **201.3.101**

##### **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

[ISO 14708-1:2000, definition 3.3]

#### **201.3.102**

##### **BATTERY DEPLETION INDICATOR**

means of indicating when the battery should be replaced

#### **201.3.103**

##### **CARDIAC PACEMAKER**

ME EQUIPMENT intended to treat bradyarrhythmias

#### **201.3.104**

##### **DUAL CHAMBER**

relating to both atrium and ventricle

#### **201.3.105**

##### **EXTERNAL PACEMAKER**

CARDIAC PACEMAKER with a NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE(S) (if used)

#### **201.3.106**

##### **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

[ISO 14708-1:2000, definition 3.5 modified]

**201.3.107**

**MAXIMUM TRACKING RATE**

maximum PULSE RATE at which the IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

[ISO 14708-2:2005, definition 3.3.18]

**201.3.108**

**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**

**PATIENT CABLE**

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

**201.3.110**

**POST-VENTRICULAR ATRIAL REFRACTORY PERIOD**

**PVARP**

atrial refractory period minus the AV delay

**201.3.111**

**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

[IEC 60050-482:2004, definition 482-01-04 modified]

**201.3.112**

**SINGLE CHAMBER**

relating to either atrium or ventricle

**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 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 electrical interference	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  $500 \Omega \pm 1 \%$ . 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  $500 \Omega \pm 1 \%$ .

**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 of ISO 14708-2:2005.