

Australian/New Zealand Standard™

Medical electrical equipment

**Part 2.31: Particular requirements for
the basic safety and essential
performance of external cardiac
pacemakers with internal power source**



AS/NZS IEC 60601.2.31:2016

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Australian Society of Anaesthetists
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College of Biomedical Engineering Engineers Australia
Department of Defence
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Originated as AS/NZS 3200.2.31:1996.
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.31:1996, *Medical electrical equipment, Part 2.31: Particular requirements for safety—External cardiac pacemakers with internal power source*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for external pacemakers.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015. This Standard is identical with, and has been reproduced from IEC 60601-2-31, Ed.2.1 (2011), *Medical electrical equipment, Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source*. This IEC document comprises the 2008 second edition and incorporates its amendment 1 (2011). A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

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FOREWORD

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.

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~~ implantable PACEMAKERS and EXTERNAL PACEMAKERS. EXTERNAL PACEMAKERS are used to pace PATIENTS temporarily prior to implanting an ~~IMPLANTABLE~~ 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~~ PACEMAKER will perform in a specific ~~patient~~ 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.

INTRODUCTION (to amendment 1)

The purpose of this amendment is to address comments received during the process of harmonizing the standard in Europe, update several references to defined terms that were not printed in SMALL CAPS, and improve terminology usage.

NOTES

AUSTRALIAN/NEW ZEALAND 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 standard¹⁾ 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.~~

This standard applies to PATIENT CABLES as defined in 201.3.109, but does not apply to LEADS as defined in 201.3.106.

~~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~~ 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~~ as defined in 201.3.103.

201.1.3 Collateral standards

Addition:

¹⁾ The general standard is IEC 60601-1:2005.

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.

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 36.

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~~ consisting of 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~~ PATIENT'S heart

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

201.3.107**MAXIMUM TRACKING RATE**

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

[ISO 14708-2:2005, definition 3.3.18 modified]

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~~ 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 BATTER 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~~ 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: