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Interested committees:

Title: BS EN IEC 80601-2-31 Medical electrical equipment

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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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THIS DRAFT IS NOT CURRENT BEYOND 3 May 2023**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2040/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
IEC 80601-2-31 ED1

DATE OF CIRCULATION:
2023-04-07

CLOSING DATE FOR COMMENTS:
2023-06-02

SUPERSEDES DOCUMENTS:
62D/2008/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:
United States of America

SECRETARY:
Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

NOTE FROM TC/SC OFFICERS:

In accordance with IEC directives concerning standards developed jointly with ISO, the numbering of this particular standard has been changed from IEC 60601-2-31 to IEC 80601-2-31. This document constitutes the first edition of IEC 80601-2-31.

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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

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 80601-2-31 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 first edition of IEC 80601-2-31 cancels and replaces the third edition of IEC 60601-2-31 published in 2020. This edition constitutes a technical revision.

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

- The requirements regarding essential performance have been simplified;

- The allowed colours for indicators have been modified from those specified in the general standard;
- Requirements for terminal markings have been clarified;
- The required instructions for use regarding estimated service time for a fully charged BATTERY have been modified;
- The test for saline exposure has been clarified as an additional test;
- The requirements related to immunity from ELECTROSTATIC DISCHARGE have been modified;
- Additional rationale for all changes.

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

FDIS	Report on voting

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 TBD P members out of TBD 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.

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

159 The committee has decided that the contents of this document will remain unchanged until the
160 stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to
161 the specific document. At this date, the document will be

- 162 • reconfirmed,
- 163 • withdrawn,
- 164 • replaced by a revised edition, or
- 165 • amended.

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

171

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.

172

173

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 pre-set 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 and IEC 60601-1:2005/AMD2:2020, *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.

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.

In accordance with IEC directives concerning standards developed jointly with ISO, the numbering of this particular standard has been changed from IEC 60601-2-31 to IEC 80601-2-31. This document constitutes the first edition of IEC 80601-2-31.

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 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 and IEC 60601-1:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 +AMD1:2020 applies as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-1-12 do 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 and IEC 60601-1:2005/AMD2:2020 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 3.154, 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* IEC 60601-1-2:2014/AMD1:2020

Addition:

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

IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020

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 and IEC 60601-1:2005/AMD2:2020, 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 55.

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 +AMD1:2016+AMD2:2020, 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

Pacing is considered as essential performance. During intended use, pacing output shall not be interrupted for a period exceeding two pre-set pacing intervals.

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) for each channel shall be marked as follows:

a) The polarity of each terminal shall be marked as positive (+) and negative (–).

b) The channels shall be marked as follows:

– The terminals associated with the atrial channel shall be marked “A”.

– The terminals associated with the ventricular channel shall be marked “V”.

A single letter may be used to indicate the channel for a pair of terminals where it is not ambiguous as to which terminals are associated with the channel (e.g. by grouping or colour coding).

201.7.2.103 ME EQUIPMENT intended for bi-ventricular application

If the ME EQUIPMENT is intended for bi-ventricular application, the connector terminals (if used) for each channel shall be marked as follows:

a) The polarity of each terminal shall be marked as positive (+) and negative (–).

b) The channels shall be marked as follows:

– The terminals associated with the atrial channel shall be marked “A”.

– The terminals associated with the right ventricular channel shall be marked “RV”.

– The terminals associated with the left ventricular channel shall be marked “LV”.

A single marking using letters may be used to indicate the channel for a pair of terminals where it is not ambiguous as to which terminals are associated with the channel (e.g. by grouping or colour coding).

201.7.2.104 Bipolar connectors

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

201.7.2.105 * 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 C of ISO 14708-2:2019.

201.7.8.1 * Colours of indicator lights

Additional subclause:

In the case of indicators specifically required for EXTERNAL PACEMAKERS, the indicated colours and their meanings are permitted as defined in Table 201.101:

Table 201.101 – Colours and meanings of indicators lights for EXTERNAL PACEMAKERS

Name	On when	Indicator light	Accompanied by sound	Operator requirement
Battery Depletion Indicator	Defined in 201.11.8	Red (flashing or not flashing)	Optional	As described in Instructions for Use
Output Indicator	Defined in 201.15.101	Yellow or Green flash per pace pulse	Optional	As described in Instructions for Use
Input Indicator	Defined in 201.15.102	Blue or green flash per sensed beat	Optional	As described in Instructions for Use

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, and the operating conditions upon which the estimate is based.

The instructions for use shall contain the estimated service time following activation of the BATTERY DEPLETION INDICATOR and the operating conditions upon which the estimate is based.

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.

- 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 $500\ \Omega \pm 1\%$ 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.

² Numbers in square brackets refer to the Bibliography.