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Elektrisk utrustning för medicinskt bruk – Del 2-31: Särskilda fordringar på säkerhet och väsentliga prestanda för externa hjärtstimulatorer med intern energikälla

Medical electrical equipment –

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

Som svensk standard gäller europastandarden EN IEC 60601-2-31:2020. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 60601-2-31:2020.

Nationellt förord

Europastandarden EN IEC 60601-2-31:2020

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-31, Third edition, 2020 - Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2.1, 2013.

Tidigare fastställd svensk standard SS-EN 60601-2-31, utgåva 2, 2008 och SS-EN 60601-2-31/A1, utgåva 1, 2011, gäller ej fr o m 2023-04-03.

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English Version

**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)**

Appareils électromédicaux - Partie 2-31: Exigences
particulières pour la sécurité de base et les performances
essentielles des stimulateurs cardiaques externes à source
d'énergie interne
(IEC 60601-2-31:2020)

Medizinische elektrische Geräte - Teil 2-31: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von externen
Schrittmachern mit interner Stromversorgung
(IEC 60601-2-31:2020)

This European Standard was approved by CENELEC on 2020-01-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1719/FDIS, future edition 3 of IEC 60601-2-31, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-31:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

This document supersedes EN 60601-2-31:2008 and all of its amendments and corrigenda (if any).

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

Endorsement notice

The text of the International Standard IEC 60601-2-31:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60086-2:2015	NOTE	Harmonized as EN 60086-2:2016 (not modified)
IEC 61000-4-2:2008	NOTE	Harmonized as EN 61000-4-2:2009 (not modified)
IEC 60086-1:2015	NOTE	Harmonized as EN 60086-1:2015 (not modified)
IEC 60601-2-4:2010	NOTE	Harmonized as EN 60601-2-4:2011 (not modified)

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<u>Replace</u>				
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	EN 60601-1-2	2015
<u>Addition</u>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-2010	
			1:2006/corrigendum	
			Mar. 2010	
			+AC	2014
			+A11	2011
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		-

CONTENTS

FOREWORD	4
INTRODUCTION	7
201.1 Scope, object and related standards	8
201.2 Normative references	10
201.3 * Terms and definitions	10
201.4 General requirements	12
201.5 General requirements for testing ME EQUIPMENT	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	13
201.7 ME EQUIPMENT identification, marking and documents	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	17
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	23
201.10 Protection against unwanted and excessive radiation HAZARDS	23
201.11 Protection against excessive temperatures and other HAZARDS	23
201.12 Accuracy of controls and instruments and protection against hazardous outputs	24
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	29
201.15 Construction of ME EQUIPMENT	29
201.16 ME SYSTEMS	29
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	29
202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests	29
Annexes	31
Annex I Identification of IMMUNITY pass/fail criteria	31
Annex AA (informative) Particular guidance and rationale	32
Bibliography	52
Index of defined terms used in this particular standard	53
Figure 201.101 – Test waveform V_{test} implemented by example RCL circuit using $C = 120 \mu\text{F}$, $L = 25 \mu\text{H}$, $RL + R = 1 \Omega$	18
Figure 201.102 – Example circuit of defibrillation test voltage generator for generating a decaying exponential waveform	19
Figure 201.103 – Test setup for a SINGLE CHAMBER external CARDIAC PACEMAKER	20
Figure 201.104 – Test setup for a DUAL CHAMBER external CARDIAC PACEMAKER	20
Figure 201.105 – Test setup for a triple chamber external CARDIAC PACEMAKER, e.g. bi-ventricular external CARDIAC PACEMAKER	21
Figure 201.106 – Timing sequence	21
Figure 201.107 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE	23
Figure 201.108 – Measuring circuit for the MAXIMUM TRACKING RATE	26
Figure 201.109 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE	27
Figure AA.1 – Simple model of a SINGLE CHAMBER EXTERNAL PACEMAKER during defibrillation	39

Figure AA.2 – First proposal for a defib-protection test of SINGLE CHAMBER EXTERNAL PACEMAKER.....	41
Figure AA.3 – Circuit for a defibrillation test generator for defibrillation test according to conditions during open heart surgery	42
Figure AA.4 – Defibrillation PULSE generated by the defibrillation test generator from Figure AA.3	43
Figure AA.5 – Rise times of a defibrillation PULSE according to the circuit proposed in Figure AA.3	47
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	12
Table 201.102 – DUAL CHAMBER connector terminal marking.....	14
Table 201.103 – ME EQUIPMENT parameters.....	25
Table 202.101 – Static discharge requirements.....	30
Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory	33
Table AA.2 – PULSE energies calculated for $C = 120 \mu\text{F} \pm 5 \%$	44
Table AA.3 – PULSE energies calculated for $C = 122 \mu\text{F} \pm 5 \%$	45
Table AA.4 – PULSE energies calculated for $C = 126,32 \mu\text{F} \pm 5 \%$	46

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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- 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.

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 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, *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*