SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-31:2024

01-september-2024

Medicinska električna oprema - 2-31. del: Posebne zahteve za osnovno varnost in bistvene lastnosti zunanjih srčnih spodbujevalnikov z vgrajenim napajalnim virom

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

Medizinische elektrische Geräte - Teil 2-31: Besondere Anforderungen an die Basissicherheit einschließlich der wesentlichen Leistungsmerkmale von externen Herzschrittmachern mit geräteeigener Stromversorgung

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

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-31:2024**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

oSIST prEN IEC 80601-2-31:2024 **en**

62D/2136/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-31 ED1**	
DATE OF CIRCULATION: **2024-06-28**	CLOSING DATE FOR VOTING: **2024-09-20**
SUPERSEDES DOCUMENTS: **62D/2040/CD, 62D/2061A/CC**	

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 CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

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.

Recipients of this document are invited to submit, with their comments, notification of any relevant "In Some Countries" clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2029

NOTE FROM TC/SC OFFICERS:

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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. It is an International Standard.

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:

Draft	Report on voting
62D/XX/FDIS	62D/XX/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 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can b 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 webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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 document 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 sense and maintain 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 performanc*, 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 standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of EXTERNAL PACEMAKERS powered by an INTERNAL ELECTRICAL POWER SOURCE, hereafter referred to as ME EQUIPMENT.

This document applies to PATIENT CABLES as defined in 201.3.209, but does not apply to LEADS as defined in 201.3.206.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document does not apply to the implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES covered by ISO 14708-1. This document does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This document does not apply to transthoracic and oesophageal pacing ME EQUIPMENT and antitachycardia ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS as defined in 201.3.205.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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:

[1] The general standard is IEC 60601-1:2005, 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.*

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-: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 53.

Addition:

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

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

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

201.3.203
CARDIAC PACEMAKER
ME EQUIPMENT intended to treat bradyarrhythmias

201.3.204
DUAL CHAMBER
relating to both atrium and ventricle

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

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

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

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

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

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

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

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

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

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

[SOURCE: IEC 60050-482:2004 + 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 polarity of the connector terminals (if used) shall be conspicuously marked positive (+) and negative (–).