

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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-31:2008 sisaldab Euroopa standardi EN 60601-2-31:2008 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 19.08.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 60601-2-31:2008 consists of the English text of the European standard EN 60601-2-31:2008.

This standard is ratified with the order of Estonian Centre for Standardisation dated 19.08.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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Võtmesõnad: electro medical equipment, equipment, external cardiac pacemaker, safety requirements, specifications, test

Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
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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 60601-2-31:2008)**

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
(CEI 60601-2-31:2008)

Medizinische elektrische Geräte -
Teil 2-31: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von externen Schrittmachern
mit interner Stromversorgung
(IEC 60601-2-31:2008)

This European Standard was approved by CENELEC on 2008-06-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/603/CDV, future edition 2 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 was approved by CENELEC as EN 60601-2-31 on 2008-06-01.

This European Standard supersedes EN 60601-2-31:1995 + A1:1998.

EN 60601-2-31:2008 is aligned with EN 60601-1:2006, and contains minimal technical revisions from EN 60601-2-31:1995.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2009-03-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2011-06-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-31:2008 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 60086-1	NOTE Harmonized as EN 60086-1:2007 (not modified).
IEC 60086-2	NOTE Harmonized as EN 60086-2:2007 (not modified).

Annex ZA
(normative)**Normative references to international publications
with their corresponding European publications****Replacement** in Annex ZA of EN 60601-1:2006:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007

Addition to Annex ZA of EN 60601-1:2006:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	8
201.3 Terms and definitions.....	9
201.4 General requirements.....	10
201.5 General requirements for testing ME EQUIPMENT.....	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	15
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	16
201.10 Protection against unwanted and excessive radiation HAZARDS.....	16
201.11 Protection against excessive temperatures and other HAZARDS.....	16
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	17
201.13 HAZARDOUS SITUATIONS and fault conditions.....	21
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	21
201.15 Construction of ME EQUIPMENT	21
201.16 ME SYSTEMS	21
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	21
202 Electromagnetic compatibility – Requirements and tests	21
Annexes	23
Annex AA (informative) Particular guidance and rationale.....	24
Bibliography.....	34
Index of defined terms used in this particular standard.....	35
Figure 201.101 – Measuring circuit for the PATIENT AUXILIARY CURRENT for ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE.....	16
Figure 201.102 – Measuring circuit for the MAXIMUM TRACKING RATE	19
Figure 201.103 – Initial oscilloscope display when measuring MAXIMUM TRACKING RATE	19
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	11
Table 201.102 – DUAL CHAMBER connector terminal marking	12
Table 201.103 – Measurement method accuracy	18
Table 202.101 – Static discharge requirements.....	22
Table AA.1 – EXTERNAL PACEMAKER HAZARD inventory	25

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

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

INTRODUCTION

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

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

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

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

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in selecting and applying these devices. It is through these aspects of standardization that the central role of clinical experience should be, or has been, acknowledged. The ability to predict how a pacemaker will perform in a specific patient based on testing of a device to a set of technical criteria is limited.

This particular standard does not take into consideration the specific safety aspects of EXTERNAL PACEMAKERS that are connected to a SUPPLY MAINS while simultaneously connected to the PATIENT.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard (see 1.4).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

An inventory of the PATIENT's safety posed by EXTERNAL PACEMAKERS and a rationale for the safety requirements contained in this particular standard are given in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general 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.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

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

NOTE See also 4.2 of the general standard.

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

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS AS DEFINED IN 201.3. 103.

201.1.3 Collateral standards

Addition:

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

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

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

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

Replacement:

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

Addition:

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

ANSI/AAMI PC69:2007, *Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

NOTE Informative references are listed in the bibliography on page 34.

201.3 * Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and ISO 14708-2:2005 apply, except as follows:

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

Addition:

201.3.101

ACTIVE IMPLANTABLE MEDICAL DEVICE

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

[ISO 14708-1:2000, definition 3.3]

201.3.102

BATTERY DEPLETION INDICATOR

means of indicating when the battery should be replaced

201.3.103

CARDIAC PACEMAKER

ME EQUIPMENT intended to treat bradyarrhythmias

201.3.104

DUAL CHAMBER

relating to both atrium and ventricle

201.3.105

EXTERNAL PACEMAKER

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

201.3.106

LEAD

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

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