SLOVENSKI STANDARD
SIST EN 60601-2-31:2008/A1:2011

01-oktober-2011

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 Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von externen Schrittmachern mit interner 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: **EN 60601-2-31:2008/A1:2011**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-2-31:2008/A1:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-31/A1

August 2011

ICS 11.040.01

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/A1:2011)

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/A1:2011)

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/A1:2011)

This amendment A1 modifies the European Standard EN 60601-2-31:2008; it was approved by CENELEC on 2011-08-03. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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.

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CENELEC

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

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Foreword

The text of document 62D/918/FDIS, future amendment 1 to IEC 60601-2-31:2008, 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 amendment A1 to EN 60601-2-31:2008 on 2011-08-03.

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

The following dates were fixed:

– latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-05-03
– latest date by which the national standards conflicting with the amendment have to be withdrawn	(dow)	2014-08-03

Endorsement notice

The text of amendment 1:2011 to the International Standard IEC 60601-2-31:2008 was approved by CENELEC as an amendment to the European Standard without any modification.

IEC 60601-2-31

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

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

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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/918/FDIS	62D/931/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this publication will remain unchanged until the stability 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 purpose of this amendment is to address comments received during the process of harmonizing the standard in Europe, update several references to defined terms that were not printed in SMALL CAPS, and improve terminology usage.

INTRODUCTION

*Replace the term "*IMPLANTABLE*" in the first and third lines of the third paragraph with the same term in normal case*

Replace the defined terms "pacemaker" and "patient" in the fourth line of the fifth paragraph with the same terms in SMALL CAPS.

201.1.1 Scope

Replace the second paragraph with:

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

Delete the third paragraph.

In the fifth paragraph, replace the defined term "active implantable medical devices" with the same term in SMALL CAPS.

201.1.2 Object

Replace "AS DEFINED IN" in the second line with the same words in normal case.

Replace definition 201.3.105 with:

201.3.105
EXTERNAL PACEMAKER
CARDIAC PACEMAKER consisting of a NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE(S) (if used)

201.3.106

Replace the defined term "patient's" in the second line with the same term in SMALL CAPS.

Replace definition 201.3.107 with:

201.3. 107
MAXIMUM TRACKING RATE
maximum PULSE RATE at which the NON-IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

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

201.3.108

Replace the defined term "pulse" in the second line of the definition with the same term in small caps.

201.4.3.101

Replace "PERFORMACNE" with "PERFORMANCE".

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Replace the defined term "Supply mains" in the title with the same term in SMALL CAPS.

201.7.9.2.2 * Warning and SAFETY notices

Replace the term "pulse generator" with "NON-IMPLANTABLE PULSE GENERATOR" in three places in item 201.7.9.2.2 aa).

Replace the term "external pulse generator" with "NON-IMPLANTABLE PULSE GENERATOR" in item 201.7.9.2.2 ff).

Replace the defined terms "patient", "lead", "leakage current", "manufacturer", " non-implantable pulse generator", "patient cable" and "supply mains" with same terms formatted in SMALL CAPS in items 201.7.9.2.2 bb), cc), dd), ee), ff) and gg).

201.7. 9.2.4 * Electrical power source

*Replace the defined term "*primary battery*" in the second paragraph with the same term in SMALL CAPS.*

201.7.9.2.13 Maintenance

*Replace the term "*EQUIPMENT*" in the final dashed item with "ME EQUIPMENT".*

201.8.5.5 Defibrillation-proof applied parts

Replace the subclause title with:

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1

Add Note:

NOTE ANSI/AAMI PC69:2007 is being adopted as ISO 14117.

201.8.7.3 * Allowable values

*In the requirement, replace "*for both d.c. and a.c.*" with "*for d.c.*".*

Add note:

NOTE Where the a.c. component of the current is intended to produce a physiological effect, it is therefore outside the definition of PATIENT AUXILIARY CURRENT.

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Replace test method with the following text:

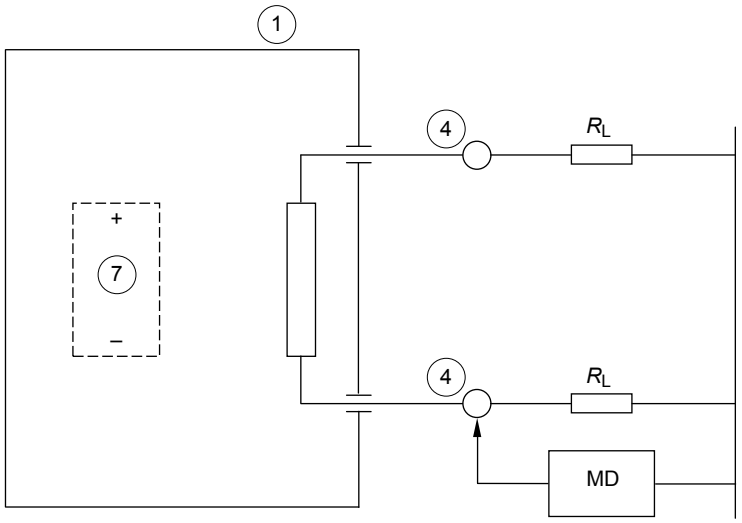
For measurement of the PATIENT AUXILIARY CURRENT, the ME EQUIPMENT is connected as shown in Figure 201.101. Each PATIENT CONNECTION is connected to a common bus through a 500 Ω ± 1% load resistor (R_L). Using a measuring device (MD) consisting of a DC voltmeter, resolution better than 2 μV, fed through a low pass filter with a time constant of at least 10 s, measure the average direct voltage across each low resistor. Steady state condition shall be reached before the measurement is made.

The NON-IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the manufacturer (i.e., the factory recommended settings) but with the PULSE AMPLITUDE and PULSE DURATION programmed to the highest available settings.

NOTE The low pass filter can be implemented by a four-element RC filter with elements built from 1 MΩ resistors and 10 μF metalized polypropylene capacitors. The input resistance of the dc voltmeter should be ≥ 400 MΩ.

Figure

Replace the existing Figure 201.101 with the following:



Legend

(1)	ME EQUIPMENT ENCLOSURE
(4)	PATIENT CONNECTIONS
(7)	INTERNAL ELECTRICAL POWER SOURCE
R_L	Load resistor
MD	Measuring device (see 201.8.7.4.8)

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Replace the requirement with:

The ME EQUIPMENT shall be so constructed that the ingress of liquids (accidental wetting), shall not result in an unacceptable RISK.

201.12.1.101 * ME EQUIPMENT PARAMETERS

Replace the defined term "pulse" in two places in the fifth paragraph with the same term in SMALL CAPS.

201.12.4.1 * Intentional exceeding of safety limits

*In the requirement, replace the reference to "*12.4.103*" by "*201.12.4.103*".:*

201.12.4.102 * Protection against a low battery condition

Replace the term "EQUIPMENT" in the first line of the first paragraph with ME EQUIPMENT.