SLOVENSKI STANDARD
SIST EN 60601-2-31:2008

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Nadomešča:
SIST EN 60601-2-31:1995
SIST EN 60601-2-31:1995/A1:1998

Medicinska električna oprema - 2-31. del: Posebne zahteve za osnovno varnost in bistvene lastnosti zunanjih srčnih spodbujevalnikov z vgrajenim napajalnim virom (IEC 60601-2-31:2008)

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

Appareils électromédicaux - Partie 2-31: Regles particulieres de sécurité de base et de performances essentielles des stimulateurs cardiaques externes a source d'énergie interne (CEI 60601-2-31:2008)

Ta slovenski standard je istoveten z: **EN 60601-2-31:2008**

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11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-2-31:2008 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-31

July 2008

ICS 11.040.01

Supersedes EN 60601-2-31:1995 + A1:1998

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

Ref. No. EN 60601-2-31:2008 E

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:*

Publication	Year	Title	EN/HD	Year
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:*

Publication	Year	Title	EN/HD	Year
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.

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IEC 60601-2-31

Edition 2.0 2008-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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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 60601-2-31 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994 and its Amendment 1 (1998). This edition constitutes a technical revision.

This second edition of IEC 60601-2-31 is aligned with IEC 60601-1:2005, and contains minimal technical revisions from the first edition.

The text of this particular standard is based on the following documents:

Enquiry draft	Report on voting
62D/603/CDV	62D/667/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

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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 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.