SLOVENSKI STANDARD
SIST EN 60601-2-4:2003

01-april-2003

Nadomešča:
SIST HD 395.2.4 S1:1998

Medicinska električna oprema - 2-4. del: Posebne varnostne zahteve za srčne defibrilatorje (IEC 60601-2-4:2002)

Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002)

Medizinische elektrische Geräte - Teil 2-4: Besondere Festlegungen für die Sicherheit von Defibrillatoren (IEC 60601-2-4:2002)

Appareils électromédicaux - Partie 2-4: Règles particulières de sécurité pour les défibrillateurs cardiaques (CEI 60601-2-4:2002)

Ta slovenski standard je istoveten z: **EN 60601-2-4:2003**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 60601-2-4:2003 **en**

EUROPEAN STANDARD **EN 60601-2-4**

NORME EUROPÉENNE

EUROPÄISCHE NORM January 2003

ICS 11.040.10 Supersedes HD 395.2.4 S1:1988

English version

Medical electrical equipment
Part 2-4: Particular requirements for the safety of cardiac defibrillators
(IEC 60601-2-4:2002)

Appareils électromédicaux
Partie 2-4: Règles particulières de sécurité pour les défibrillateurs cardiaques
(CEI 60601-2-4:2002)

Medizinische elektrische Geräte
Teil 2-4: Besondere Festlegungen für die Sicherheit von Defibrillatoren
(IEC 60601-2-4:2002)

This European Standard was approved by CENELEC on 2002-10-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and 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 60601-2-4:2003 E

Foreword

The text of document 62D/455/FDIS, future edition 2 of IEC 60601-2-4, prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-4 on 2002-10-01.

This European Standard supersedes HD 395.2.4 S1:1988.

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)	2003-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2005-10-01

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA, BB and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-4:2002 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60300-3-9	- [1)]	Dependability management Part 3: Application guide – Section 9: Risk analysis of technological systems	-	-
IEC 60651	- [1)]	Sound level meters	EN 60651	1994 [2)]
IEC 61000-4-2	- [1)]	Electromagnetic compatibility (EMC) Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	1995 [2)]
IEC 61000-4-3	- [1)]	Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	2002 [2)]
IEC 61000-4-4	- [1)]	Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	EN 61000-4-4	1995 [2)]
IEC 61000-4-5	- [1)]	Part 4-5: Testing and measurement techniques - Surge immunity test	EN 61000-4-5	1995 [2)]
IEC 61000-4-6	- [1)]	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996 [2)]
IEC 61000-4-8	- [1)]	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993 [2)]

1) Undated reference.

2) Valid edition at date of issue.

Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the European publications

Publication	Year	Title	EN/HD	Year
IEC 60601-2-27	- [1)]	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment	EN 60601-2-27	1994 [2)]

1) Undated reference.

2) Valid edition at date of issue.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-4

Deuxième édition
Second edition
2002-08

Appareils électromédicaux –

Partie 2-4:
Règles particulières de sécurité pour les défibrillateurs cardiaques

Medical electrical equipment –

Part 2-4:

Particular requirements for the safety of cardiac defibrillators

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International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE XA

Pour prix, voir catalogue en vigueur
For price, see current catalogue

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AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

SECTION 101 – ADDITIONAL REQUIREMENTS RELATING TO SAFETY

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the safety of cardiac defibrillators

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 60601-2-4 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-4 cancels and replaces the first edition published in 1983 of which it constitutes a technical revision.

This bilingual version (2005-09) replaces the English version.

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

FDIS	Report on voting
62D/455/FDIS	62D/460/RVD

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

The French version of this standard has not been voted upon.

The contents of the corrigendum 1 of April 2004 have been included in this copy.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;
– *test specifications, headings of subclauses and headings of items: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

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

This Particular Standard concerns the safety of CARDIAC DEFIBRILLATORS. It amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, including its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard.

A first edition of this Particular Standard, based on the first edition (1977) of IEC 60601-1 was published in 1983. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above through minor changes to the technical content.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a 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 this annex does not form part of the requirements of this standard.

Clauses and subclauses for which a corresponding rationale statement is given in Annex AA are marked with an asterisk * before their number in the text.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the safety of cardiac defibrillators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand alone CARDIAC MONITORS (which are standardized by IEC 60601-2-27). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which address considerations in waveform selection.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of CARDIAC DEFIBRILLATORS as defined in 2.1.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. 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 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.

“Amendment” means that the clause or subclause of the General 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 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard.

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.1.101
CARDIAC DEFIBRILLATOR
MEDICAL ELECTRICAL EQUIPMENT intended to defibrillate the heart by an electrical pulse via electrodes applied either to the PATIENT's skin (external electrodes) or to the exposed heart (internal electrodes). May be referred to as DEFIBRILLATOR or EQUIPMENT

NOTE Such EQUIPMENT may also include other monitoring or therapeutic functions.

2.1.102
MONITOR
part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this Particular Standard to distinguish such a MONITOR from one which forms a separate EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

2.1.103
CHARGING CIRCUIT
circuit within the DEFIBRILLATOR intended for charging the ENERGY STORAGE DEVICE. This circuit includes all parts conductively connected to the ENERGY STORAGE DEVICE during the charging period

2.1.104
DEFIBRILLATOR ELECTRODES
electrodes intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation

NOTE DEFIBRILLATOR ELECTRODES may also provide other monitoring (e.g. ECG acquisition) or therapeutic (e.g. transcutaneous pacing) functions and may be disposable or reusable.

2.1.105
DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which connects the ENERGY STORAGE DEVICE to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

2.1.106
DISCHARGE CONTROL CIRCUIT
circuit including the manually operated discharge controls and all parts conductively connected to them

2.1.107
INTERNAL DISCHARGE CIRCUIT
circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

2.1.108
SYNCHRONIZER
device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle