SLOVENSKI STANDARD
SIST EN 60601-2-26:2004

01-marec-2004

Nadomešča:
SIST EN 60601-2-26:1995

Medicinska električna oprema - 2-26. del: Posebne varnostne zahteve za elektroencefalografe (IEC 60601-2-26:2002)

Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002)

Medizinische elektrische Geräte - Teil 2-26: Besondere Festlegungen für die Sicherheit von Elektroenzephalographen (IEC 60601-2-26:2002)

Appareils électromédicaux - Partie 2-26: Règles particulières de sécurité pour les électroencéphalographes (CEI 60601-2-26:2002)

Ta slovenski standard je istoveten z: **EN 60601-2-26:2003**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-26:2004 **en**

EUROPEAN STANDARD **EN 60601-2-26**

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2003

ICS 11.040.55; 11.040.99 Supersedes EN 60601-2-26:1994

English version

Medical electrical equipment
Part 2-26: Particular requirements for the safety of electroencephalographs
(IEC 60601-2-26:2002)

Appareils électromédicaux
Partie 2-26: Règles particulières
de sécurité pour
les électroencéphalographes
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Medizinische elektrische Geräte
Teil 2-26: Besondere Festlegungen
für die Sicherheit von
Elektroenzephalographen
(IEC 60601-2-26:2002)

This European Standard was approved by CENELEC on 2003-03-01. 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, Lithuania, 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 60601-2-26:2003 E

Foreword

The text of document 62D/463/FDIS, future edition 2 of IEC 60601-2-26, 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 60601-2-26 on 2003-03-01.

This European Standard supersedes EN 60601-2-26:1994.

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)	2004-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2006-03-01

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 annex AA is informative.
Annex ZA has been added by CENELEC.

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 roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-26:2002 was approved by CENELEC as a European Standard without any modification.

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
Addition to annex ZA of EN 60601-1:1990/A2:1995				
IEC 60050-891	1998	International Electrotechnical Vocabulry Part 891: Electrobiology	-	-
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 + A13	1995 1996
Replacement in annex ZA of EN 60601-1:1990/A2:1995				
IEC 60601-1-2	2001	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	1999		A1	1999

INTERNATIONAL STANDARD

IEC 60601-2-26

Second edition
2002-11

Medical electrical equipment –

Part 2-26: Particular requirements for the safety of electroencephalographs

Appareils électromédicaux –

Partie 2-26: Règles particulières de sécurité pour les électroencéphalographes

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE K

For price, see current catalogue

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SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-26: Particular requirements for the safety of electroencephalographs

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-26 has been prepared by sub-committee 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 constitutes a technical revision.

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

FDIS	Report on Voting
62D/463/FDIS	62D/466/RVD

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

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

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller roman type;
– *test specifications: 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 2006. At this date, the publication will be

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