SLOVENSKI STANDARD
SIST EN 60601-2-16:1998

01-september-1998

Nadomešča:
SIST HD 395.2.16 S1:1998

Medicinska električna oprema - 2-16. del: Posebne varnostne zahteve za opremo za hemodializo, hemodiafiltracijo in hemofiltracijo (IEC 60601-2-16:1998)

Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:1998)

Medizinische elektrische Geräte - Teil 2-16: Besondere Festlegungen für die Sicherheit von Hämodialyse-, Hämodiafiltrations- und Hämofiltrationsgeräte (IEC 60601-2-16:1998)

Appareils électromédicaux - Partie 2-16: Règles particulières de sécurité pour les appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration (CEI 60601-2-16:1998)

Ta slovenski standard je istoveten z: **EN 60601-2-16:1998**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN 60601-2-16:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-16

April 1998

ICS 11.040; 11.040.20

Supersedes HD 395.2.16 S1:1989 and EN 50072:1992

Descriptors: Medical electrical equipment, hémodialysis equipment, haemidiafiltration equipment, haemofiltration equipment, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment
(IEC 60601-2-16:1998)

Appareils électromédicaux
Partie 2-16: Règles particulières de sécurité pour les appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration
(CEI 60601-2-16:1998)

Medizinische elektrische Geräte
Teil 2-16: Besondere Festlegungen für die Sicherheit von Hämodialyse-, Hämodiafiltrations- und Hämofiltrationsgeräte
(IEC 60601-2-16:1998)

This European Standard was approved by CENELEC on 1998-04-01. 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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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

Foreword

The text of document 62D/254/FDIS, future edition 2 of IEC 60601-2-16, 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 60601-2-16 on 1998-04-01.

This European Standard supersedes HD 395.2.16 S1:1989 and EN 50072:1992.

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) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

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 annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-16:1998 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 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
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[1)] A13	1995 1996
IEC 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. December	1993 1997
IEC 60651 A1	1979 1993	Sound level meters	EN 60651 A1	1994 1994
IEC 60804 + A1 A2	1985 1989 1993	Integrating-averaging sound level meters	EN 60804 A2	1994 1994
ISO 594-2	1991	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings	-	-
ISO 3744	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane	EN ISO 3744	1995

1) A2 includes corrigendum June 1995 to IEC 60601-1:1988/A2.

Annex ZB (informative)

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

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60513	1994	Fundamental aspects of safety standards for medical electrical equipment	-	-
IEC 60801-3	1984	Electromagnetic compatibility for industrial-process measurement and control equipment Part 3: Radiated electromagnetic field requirements	HD 481.3 S1[1)]	1987

1) HD 481.3 S1 is superseded by EN 61000-4-3:1996, which is based on IEC 61000-4-3:1995, mod.

INTERNATIONAL STANDARD

IEC 60601-2-16

Second edition
1998-02

Medical electrical equipment –

Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

Appareils électromédicaux –

Partie 2-16:
Règles particulières de sécurité pour les appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

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 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 60601-2-16 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/254/FDIS	62D/271/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.

Annex AA is for information only.

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 type;
– *test specifications: italic type*;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 60601-1: SMALL CAPITALS.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

This particular standard does not take into consideration the specific safety aspects of systems using regeneration of DIALYSING FLUID.

This particular standard amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

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 (*).

It is considered that a 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 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

SECTION 1: 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 the minimum safety requirements for single PATIENT HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT (as defined in 2.101). These devices are intended for use either by medical staff or under the supervision of medical expertise, including HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT operated by the PATIENT. These particular requirements do not apply to

– EXTRACORPOREAL CIRCUITS,
– DIALYSERS,
– DIALYSING FLUID CONCENTRATES,
– water purification EQUIPMENT,
– EQUIPMENT used to perform peritoneal dialysis (see IEC 60601-2-39).

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 IEC 60601-1 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 to 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 clause or subclause 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.

1.5 Collateral standards

IEC 60601-1-2 applies (see clause 36).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The EXTRACORPOREAL CIRCUIT and the DIALYSING FLUID circuit and/or all parts permanently and conductively connected to it.

2.2.15 MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT)

Addition:

Under the scope of this particular standard EQUIPMENT means HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT.

Additional definitions:

2.101 HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT

A system or combination of units used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION (also refer to 2.2.15).

2.102 HAEMODIALYSIS (HD)

Process whereby solute imbalances in a PATIENT's blood are corrected mainly by diffusion across a semi-permeable membrane.

NOTE – This process normally includes fluid removal.

2.103 HAEMOFILTRATION (HF)

A process whereby solute imbalances of a PATIENT's blood are corrected mainly by filtration across a semi-permeable membrane.

NOTE – This process includes fluid exchange and normally fluid removal.