SLOVENSKI STANDARD
SIST EN 60601-2-18:1998

01-september-1998

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za endoskopsko opremo (IEC 60601-2-18:1996)

Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996)

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von endoskopischen Geräten (IEC 60601-2-18:1996)

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour appareils d'endoscopie (CEI 60601-2-18:1996)

Ta slovenski standard je istoveten z: **EN 60601-2-18:1996**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-18:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-18

September 1996

ICS 11.040.50

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

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of endoscopic equipment
(IEC 601-2-18:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour appareils d'endoscopie
(CEI 601-2-18:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von endoskopischen Geräten
(IEC 601-2-18:1996)

This European Standard was approved by CENELEC on 1996-07-02. 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, 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/191/FDIS, future edition 2 of IEC 601-2-18, 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 60601-2-18 on 1996-07-02.

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) 1997-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-05-01

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.

Endorsement notice

The text of the International Standard IEC 601-2-18:1996 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 417	1973	Graphical symbols for use on equipment Index, survey and compilation of the single sheets	HD 243 S12[1)]	1995
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
			+ corr. July	1994
A1	1991		A1	1993
			+ corr. July	1994
A2	1995		A2	1995
			A13	1996
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
A1	1995		A1	1996
IEC 601-2-2	1991	Part 2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	1993
IEC 601-2-37	199X[2)]	Part 2: Particular requirements for safety of ultrasonic diagnostic and monitoring equipment	-	-
IEC 664-1 (mod)	1992	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	HD 625.1 S1	1996
CISPR 11 (mod)	1990	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	EN 55011	1991

1) HD 243 S12 includes supplements A:1974 to M:1994 to IEC 417.

2) At present at the stage of Committee Draft ref 62B/290/CD.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
601-2-18

Deuxième édition
Second edition
1996-08

Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour appareils d'endoscopie

Medical electrical equipment –

Part 2:
Particular requirements for the safety of endoscopic equipment

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of endoscopic 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. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 601-2-18 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 601-2-18 cancels and replaces the first edition published in 1990. This second edition constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/191/FDIS	62D/208/RVD

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.

Annex AA is for information only.

In this Particular Standard, the following print types are used:

– Requirements, compliance with which can be tested, and definitions: in roman type;

– Explanations, advice, introductions, general statements and references: in smaller type;

– *Test specifications: in italic types;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

INTRODUCTION

This Particular Standard concerns the safety of ENDOSCOPIC EQUIPMENT. The relationship of this Particular Standard with IEC 601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

The revisions for this second edition include the following:

1) A new definition of ENDOSCOPE;

2) The inclusion of requirements for INTERCONNECTION CONDITIONS with ENDOSCOPICALLY-USED ACCESSORIES.