SLOVENSKI STANDARD
SIST EN 60601-2-18:1998/A1:2002

01-februar-2002

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za endoskopsko opremo - Dopolnilo A1 (IEC 60601-2-18:1996/A1:2000)

Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996/A1:2000)

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von endoskopischen Geräten (IEC 60601-2-18:1996/A1:2000)

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour appareils d'endoscopie (CEI 60601-2-18:1996/A1:2000)

Ta slovenski standard je istoveten z: **EN 60601-2-18:1996/A1:2000**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-18:1998/A1:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-18/A1

December 2000

ICS 11.040.50

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of endoscopic equipment
(IEC 60601-2-18:1996/A1:2000)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour appareils d'endoscopie
(CEI 60601-2-18:1996/A1:2000)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von endoskopischen Geräten
(IEC 60601-2-18:1996/A1:2000)

This amendment A1 modifies the European Standard EN 60601-2-18:1996; it was approved by CENELEC on 2000-08-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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/360/FDIS, future amendment 1 to IEC 6061-2-18:1996, 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 amendment A1 to EN 60601-2-18:1996 on 2000-08-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2003-08-01

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.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:2000 to the International Standard IEC 60601-2-18:1996 was approved by CENELEC as an amendment to the European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
Add / update the references for the identified standards as follows:				
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	1993
IEC 60601-1-4	1996	Part 1-4: General requirements for safety Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60601-2-2	1998	Part 2-2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	2000
CISPR 11 (mod)	1997	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011	1998

INTERNATIONAL STANDARD

IEC 60601-2-18

1996

AMENDMENT 1
2000-07

Amendment 1

Medical electrical equipment –

Part 2-18:
Particular requirements for the safety of endoscopic equipment

Amendement 1

Appareils électromédicaux –

Partie 2-18:
Règles particulières de sécurité pour appareils d'endoscopie

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE K

For price, see current catalogue

FOREWORD

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

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

FDIS	Report on Voting
62D/360/FDIS	62D/365/RVD

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until 2002. At this date, the publication will be:

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

INTRODUCTION

The only significant amendment relates to the addition of an exclusion from subclause 56.3 c) of Amendment 2 of the General Standard, as this subclause was added to the General Standard amendment after the text of the 2nd edition of IEC 60601-2-18 had been finalized, and was therefore not taken into account during its preparation.

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CONTENTS

Add the following after the SECTION 10 heading:

Page 11

INTRODUCTION

Replace the text of the first paragraph as follows:

This Particular Standard concerns the safety of ENDOSCOPIC EQUIPMENT. The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in 1.3 and 1.5 respectively.

Page 13

1.3 Particular Standards

Replace the text of the instruction and the first three paragraphs of this subclause as follows:

Replacement:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2 and associated Collateral Standards (see subclause 1.5).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The term "this Standard" covers this Particular Standard, used together with the General Standard and relevant Collateral Standards.

Page 15

In the first line of the fourth paragraph on this page, replace "...clause of subclause...*" by "*...clause or subclause*..." (English version only).*

In the second line of the eighth paragraph on this page, replace "...irrelevant*..." by "*...relevant*..." (English version only).*

In the ninth paragraph on this page, replace the text as follows:

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the corresponding General Requirement(s).

Add, after 1.3 the following new subclause 1.5:

1.5 Collateral Standards

Addition:

The following Collateral Standards apply to ENDOSCOPIC EQUIPMENT:

IEC 60601-1-1: 1992, *Medical electrical equipment – Part 1: General requirements for safety – Section 1: Collateral Standard: Safety requirements for medical electrical systems*, amendment 1; IEC 60601-1-2: 1993, *Medical electrical equipment – Part 1: General requirements for safety*, 2. *Collateral Standard: Electromagnetic compatibility - Requirements and tests,* and IEC 60601-1-4: 1996, *Medical electrical equipment – Part 1: General requirements for safety*, 4. *Collateral Standard: Programmable electrical medical systems.*

2.1.4 APPLIED PART

Replace the subclause number by 2.1.5 so that it reads:

2.1.5 APPLIED PART

(English version only)

Amend the text at end of subclause 2.1.5, within the existing parentheses, as follows:

", see 17 *a)* and 17 *c)* of the General Standard"