SIST

SLOVENSKI STANDARD
SIST EN 60601-2-17:1998/A1:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment - Amendment A1 (IEC 60601-2-17:1989/A1:1996)

Medical electrical equipment -- Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit ferngesteuerter, automatisch betriebener Afterloading-Geräte für Gamma-Strahlung

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des appareils projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma

Ta slovenski standard je istoveten z: **EN 60601-2-17:1996/A1:1996**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-17:1998/A1:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-17/A1

March 1996

UDC 615.849.114:539.122:614.8
ICS 11.040.60

Descriptors: Medical electrical equipment, gamma-ray therapy, sealed radioactive sources, remote-controlled automatically-driven afterloading equipment, 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 remote-controlled automatically-driven gamma-ray after-loading equipment
(IEC 601-2-17:1989/A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des appareils projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma
(CEI 601-2-17:1989/A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit ferngesteuerter, automatisch betriebener Afterloading-Geräte für Gamma-Strahlung
(IEC 601-2-17:1989/A1:1996)

This amendment A1 modifies the European Standard EN 60601-2-17:1996; it was approved by CENELEC on 1996-03-05. 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, 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 62C/142/FDIS, future amendment 1 to IEC 601-2-17:1989, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, 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 60601-2-17:1996 on 1996-03-05.

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) 1997-03-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1997-03-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annex ZA is normative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:1996 to the International Standard IEC 601-2-17:1989 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

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 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1	1993
A2	1995		A2[1)]	1995
			+ A12	1993
			+ A13	1996
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 788	1984	Medical radiology - Terminology	HD 501 S1	1988
ISO 361	1975	Basic ionizing radiation symbol	-	-

1) IEC 601-1:1988/A2:1995 includes the corrigendum June 1995.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-17

1989

AMENDEMENT 1
AMENDMENT 1

1996-02

Amendement 1

Appareils électromédicaux –
Partie 2:
Règles particulières de sécurité des appareils projecteurs de sources radioactives automatiques télécommandés utilisés en radiothérapie par rayonnement gamma

Amendment 1

Medical electrical equipment –
Part 2:
Particular requirements for the safety of remote-controlled automatically-driven gamma-ray afterloading equipment

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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For price, see current catalogue

FOREWORD

This amendment has been prepared by sub-committee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, 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
62C/142/FDIS	62C/155/RVD

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

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CONTENTS

Add the title of the following new subclause:

1.5 Collateral Standards

Replace the title of SECTION TWO *by the following:*

SECTION TWO – ENVIRONMENTAL CONDITIONS

Replace the title of clause 10 by the following:

10 Environmental conditions

Delete the titles of clauses 11 and 12.

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Replace the title of SECTION SIX *by the following:*

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

Replace the title of SECTION SEVEN *by the following:*

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Replace the title of SECTION EIGHT *by the following:*

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

Replace the title of clause 51 by the following:

51 Protection against hazardous output

Replace the title of SECTION NINE *by the following:*

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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FOREWORD

Delete item 4).

PREFACE

Replace the list of publications by the following:

Publication Nos. 601-1 (1988): Medical electrical equipment – Part 1: General requirements for safety.
Amendment 1 (1991).
Amendment 2 (1995).

601-1-2 (1993): Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests.

788 (1984): Medical radiology – Terminology.

Other publication quoted:

ISO 361 (1975): Basic ionizing radiation symbol.

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INTRODUCTION

Replace the text in brackets by the following:

IEC 601-1, second edition (1988) with amendments 1 (1991) and 2 (1995).

Delete the footnote.