SLOVENSKI STANDARD
SIST EN 60601-2-8:1998/A1:1998

01-september-1998

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za terapevtsko rentgensko opremo, ki deluje v območju od 10 kV do 1 MV - Dopolnilo A1 (IEC 60601-2-8:1987/A1:1997)

Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV - Amendment A1 (IEC 60601-2-8:1987/A1:1997)

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von Therapie-Röntgeneinrichtungen im Betriebsbereich von 10 kV bis 1 MV (IEC 60601-2-8:1987/A1:1997)

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour les équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV (CEI 60601-2-8:1987/A1:1997)

Ta slovenski standard je istoveten z: **EN 60601-2-8:1997/A1:1997**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-8:1998/A1:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-8/A1

September 1997

ICS 11.040.50

Descriptors: Medical electrical equipment, X-ray equipment, therapeutic X-ray generators, 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 therapeutic X-ray equipment operating in the range 10 kV to 1 MV
(IEC 60601-2-8:1987/A1:1997)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour les équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV
(CEI 60601-2-8:1987/A1:1997)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Therapie-Röntgeneinrichtungen im Betriebsbereich von 10 kV bis 1 MV
(IEC 60601-2-8:1987/A1:1997)

This amendment A1 modifies the European Standard EN 60601-2-8:1997; it was approved by CENELEC on 1997-07-01. 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, 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 82C/186/FDIS, future amendment 1 to IEC 60601-2-8:1987, 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 60601-2-8:1987 on 1997-07-01.

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) 1998-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1998-06-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes BB and ZA are normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of amendment 1:1997 to the International Standard IEC 60601-2-8:1987 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 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	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: General requirements for safety 4. Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996

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

Annex ZB (informative)

Other references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
IEC 60601-1-1	1992	Medical electrical equipment Part 1: General requirements for safety 1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
A1	1995		A1	1996
IEC 60601-1-3	1994	Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-8

1987

AMENDEMENT 1
AMENDMENT 1

1997-08

Amendement 1

Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour les équipements à rayonnement X de thérapie fonctionnant dans la gamme de 10 kV à 1 MV

Amendment 1

Medical electrical equipment –

Part 2:
Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE S

Pour prix, voir catalogue en vigueur
For price, see current catalogue

FOREWORD

This amendment has been prepared by subcommittee 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/186/FDIS	62C/193/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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Page 3

CONTENTS

Add, after PREFACE, *the following title:*

INTRODUCTION

Add the titles of the following new subclauses:

1.3.103 *IEC 61217*

1.5 *Collateral Standards*

6.3 *Marking of controls and instruments*

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

SECTION TWO – ENVIRONMENTAL CONDITIONS

Replace the title of clause 18 by the following:

18 Protective earthing, functional earthing and potential equalization

Page 5

Add the titles of the following new subclauses:

29.103 *Indication of X-RADIATION output*

29.104 *Agreement between indicated values and effective values*

29.105 *General test conditions*

29.106 *Settings for measurements*

29.107 *Number of measurements*

29.108 *Measurements and evaluation*

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

Delete the title of clause 48 and replace it by "**Biocompatibility**".

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

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

Delete the titles of subclauses 50.1 to 50.104.

Page 7

Delete the title of clause 59.4.

Replace "APPENDIX AA" *by* "ANNEX AA".

Add, after ANNEX AA, *the following new ANNEX BB:*

ANNEX BB – List of standards mentioned in this Particular Standard

Page 9

FOREWORD

Replace the title by the following:

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

Page 9

Replace the foreword and the preface by the following new foreword:

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

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 60601-2-8 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Six Months' Rule	Report on voting
62B(CO)49	62B(CO)64

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

Subclauses, figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, etc., and additional items aa), bb), etc.

Annex AA is for information only.

Annex BB forms an integral part of this standard.

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

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

– explanations, advice, general statements and exceptions: in small roman type;

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN LISTED IN ANNEX AA AND DEFINED IN CLAUSE 2, OR IN THE GENERAL STANDARD 60601-1 AND ITS COLLATERAL STANDARDS OR IN IEC 60788: SMALL CAPITALS.

Replace, throughout the Standard, the term "X-RAY GENERATOR" *by* "X-RAY EQUIPMENT".

Add, after the foreword, the following new introduction:

INTRODUCTION

The use of X-RAY EQUIPMENT for RADIOTHERAPY purposes may expose the PATIENT to danger if the EQUIPMENT fails to deliver the required dose to the PATIENT, or if the EQUIPMENT design does not satisfy standards of electrical and mechanical safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the RADIATION adequately and/or if there are inadequacies in the design of the TREATMENT ROOM.

This Particular Standard establishes requirements to be complied with by the MANUFACTURERS in the design and construction of therapeutic X-RAY EQUIPMENT. Clause 29 contains limits beyond which INTERLOCKS prevent, INTERRUPT or TERMINATE IRRADIATION in order to avoid an unsafe condition.

Clause 29 does not attempt to define optimum performance requirements. Its purpose is to identify those features of design that are regarded, at the present time, as essential for the safe operation of such EQUIPMENT. It places limits on the degradation of EQUIPMENT performance beyond which it can be presumed that a fault condition exists, e.g. a component failure, and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.

It should be understood that, before installation, a MANUFACTURER can provide a Compliance Certificate relating only to TYPE TESTS: data available from SITE TESTS should be incorporated in the ACCOMPANYING DOCUMENTS, in the form of a SITE TEST report, by those who test the EQUIPMENT at installation.

Page 11

Replace the title by the following new title:

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV