SLOVENSKI STANDARD
SIST EN 60601-2-8:1998

01-oktober-1998

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

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)

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)

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)

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

ICS:

11.040.50 Radiografska oprema Radiographic equipment

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EUROPEAN STANDARD

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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)

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)

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)

This European Standard 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 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

Ref. No. EN 60601-2-8:1997 E

Foreword

The text of the International Standard IEC 60601-2-8:1987, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.8 S1:1988 on 1988-06-28.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-8 on 1997-07-01.

The following date was 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) 1998-06-01

Subclauses, tables and figures which are additional to those in part 1 are numbered starting from 101.
Annexes which are additional to those in part 1 are lettered AA, BB, etc. and additional items aa), bb), etc.

Endorsement notice

The text of the International Standard IEC 60601-2-8:1987 was approved by CENELEC as a European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

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Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité pour groupes radiogènes de radiothérapie

Medical electrical equipment

Part 2:
Particular requirements for the safety of therapeutic X-ray generators

Bureau central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève Suisse

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CONTENTS

SECTION TEN — CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of therapeutic X-ray generators

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.
2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.
3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.
4) The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its recommendations.

PREFACE

This Particular Standard has been prepared by Sub-Committee 62B: X-ray Equipment Operating up to 400 kV and Accessories, of IEC Technical Committee No. 62: Electrical Equipment in Medical Practice.

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

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

Further information can be found in the Report on Voting indicated in the table above.

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977): Safety of Medical Electrical Equipment. Part 1: General Requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard will be changed in the next editions to read: Medical Electrical Equipment, Part 1: General Requirements for Safety. This change is anticipated in the title of this Particular Standard.

The numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard.

Sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc. and additional items *aa)*, *bb)*, etc.

In this standard, the following print types are used:

— requirements, compliance with which can be tested and definitions: in roman type;
— explanations, advice, introductions, general statements, exceptions and references: in smaller type;
— *test specifications: in italic type;*
— TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC PUBLICATION 788 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of therapeutic X-ray generators

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SECTION ONE — GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular Standard applies to therapeutic X-RAY GENERATORS that operate with NOMINAL X-RAY TUBE VOLTAGES from 10 kV to 400 kV inclusive when connected to alternating current SUPPLY MAINS.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish the particular requirements for safety including the requirements for accuracy and reproducibility of performance to the extent that these are related to RADIATION QUALITY and the quantity of IONIZING RADIATION produced and thus must be considered as aspects of safety.

An object of this Particular Standard is to present the general functional requirements of the demand for safety, rather than any particular technological means of implementation.

1.3 *Particular Standards*

Additional sub-clauses:

1.3.101 *Relation to the General Standard*

This Particular Standard refers to, and is to be read in conjunction with IEC Publication 601-1 (1977): Safety of Medical Electrical Equipment, Part 1: General Requirements and its Amendment No. 1 (1984).

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

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

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

Where there is no corresponding clause or sub-clause in this Particular Standard, the clause or sub-clause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied to therapeutic X-RAY GENERATORS, a statement to that effect is given in this Particular Standard.

1.3.102 *Superseded IEC Standard*

This Standard deals with some aspects of therapeutic X-RAY EQUIPMENT, particularly of therapeutic X-RAY GENERATORS and sub-assemblies thereof, that were covered by IEC Publication 407 (1973): Radiation Protection in Medical X-ray Equipment 10 kV to 400 kV.

Within its scope, this Particular Standard supersedes the corresponding requirements of IEC Publication 407.

1.4 *Environmental conditions*

a) Transport and storage

Item 2) *a)*
Replacement:

a) an ambient temperature between −20 °C and +70 °C (see Item *v)* of Sub-clause 6.1 of the General Standard regarding marking of the packing).

b) Operation

2) *Power supply*

Item a) A SUPPLY MAINS having:

Replacement of the sixth dash:

— a frequency which does not deviate more than 1% from the nominal value for all frequencies.

Replacement of the second paragraph in small print:

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ±2% of the peak value of the ideal waveform.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

In this Particular Standard, terms in capital letters are used as defined in:

— the General Standard
— IEC Publication 788 (1984): Medical Radiology–Terminology

An index of these terms, referring to the standards mentioned is given in Appendix AA.

3. General requirements

This clause of the General Standard applies except as follows:

Additional sub-clause:

3.101 *Conventional meaning of electrical quantities*

In this Particular Standard unless otherwise indicated, values of X-RAY TUBE VOLTAGE refer to peak values.

4. General requirements for tests

This clause of the General Standard applies except as follows:

4.1 *Type tests and routine tests*

a) Type tests

Addition:

The tests described in this Particular Standard are type tests, which are to be carried out under controlled conditions, usually prevailing only in test laboratories.

4.7 *Supply and test voltages, type of current, nature of supply, frequency*

Additional item:

aa) For all tests for the measurement of AIR KERMA and AIR KERMA RATE in air for compliance with requirements on LEAKAGE RADIATION and STRAY RADIATION it is assumed that the SUPPLY MAINS used for the test is delivering its ouput at its NOMINAL VALUES.

4.10 *Moisture pre-conditioning treatment*

Addition (see Sub-clause 1.3.101)*:*

This test shall be applied only to those parts of therapeutic X-RAY GENERATORS likely to be influenced by the climatic conditions that are simulated by the test.

Where it is not practicable to treat a therapeutic X-RAY GENERATOR as a whole, the treatment may be given sequentially to separate parts.

Also, where testing cannot be carried out without dismantling or reassembling, a period longer than that required in the General Standard may elapse between treatment and testing.

5. Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

Therapeutic X-RAY GENERATORS shall be classified as CLASS I EQUIPMENT.

5.2 *Replacement:*

Therapeutic X-RAY GENERATORS shall be classified as TYPE B EQUIPMENT.

5.3 *Replacement:*

Unless otherwise specified, therapeutic X-RAY GENERATORS are ordinary MEDICAL ELECTRICAL EQUIPMENT (enclosed equipment without protection against ingress of liquids).

5.6 *Replacement:*

Unless otherwise specified, therapeutic X-RAY GENERATORS shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see Item *m)* of Sub-clause 6.1 and Sub-clause 6.8.5.

6. Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside of equipment and equipment parts*

Addition at the beginning of the sub-clause:

Therapeutic X-RAY GENERATORS and their constituent sub-assemblies and components shall be appropriately marked if their correlation to one another influences safety; see also Sub-clause 6.8.1.

g) Connection to the supply

Addition at the end of the item:

For therapeutic X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *g)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) Supply frequency (in hertz)

Addition at the end of the item:

For therapeutic X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *h)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) Power input

Addition at the end of the item:

For therapeutic X-RAY GENERATORS that are specified to be permanently installed, the information required in Item *j)* of Sub-clause 6.1 of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

m) Mode of operation

Replacement:

The mode of operation — where appropriate, together with maximum permissible ratings — shall be stated in the ACCOMPANYING DOCUMENTS; see Sub-clauses 5.6 and 6.8.5.