SLOVENSKI STANDARD
SIST EN 60601-2-29:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of radiotherapy simulators (IEC 60601-2-29:1993)

Medical electrical equipment -- Part 2: Particular requirements for the safety of radiotherapy simulators

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Strahlentherapiesimulatoren

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité des simulateurs de radiothérapie

Ta slovenski standard je istoveten z: **EN 60601-2-29:1995**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-29:1998 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-29

November 1995

ICS 11.040.60

Descriptors: Medical electrical equipment, radiotherapy simulatores, diagnostic X-ray equipment, therapeutic radiation beam, 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 radiotherapy simulators
(IEC 601-2-29:1993)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour les simulateurs de radiothérapie
(CEI 601-2-29:1993)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Strahlentherapiesimulatoren
(IEC 601-2-29:1993)

This European Standard was approved by CENELEC on 1995-05-15. 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 60601-2-29:1995 E

Foreword

The text of the International Standard IEC 601-2-29:1993, 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 formal vote and was approved by CENELEC as EN 60601-2-29 on 1995-05-15 without any modification.

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) 1996-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-07-01

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 appendix AA and annex ZAA are informative.
Annexes ZA and ZAA have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-2-29:1993 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 601-1-3	1994	Medical electrical equipment Part 1: General requirements for safety 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994
IEC 601-2-1	1981	Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV Section 1: General Section 2: Radiation safety for equipment	-	-
IEC 601-2-7	1987	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	HD 395.2.7 S1	1989
IEC 788	1984	Medical radiology Terminology	HD 501 S1	1988

Annex ZAA (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard falls under Directive 93/42/EEC.

NOTE (from CEN/CENELEC IR Part 2, 3.1.9): Where standards fall under EC Directives, it is the view of the Commission of the European Communities (OJ No C 59; 1982-03-09) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovich (European Court Reports 1980, p. 3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA-country are **valid instead** of the relevant provisions of the European Standard in that country until they have been removed.

Deviation

Switzerland (SR 734.261 of 1990-12-14)

Equipment with hazardous radiation, such as X-ray equipment, is subject to compulsory approval.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
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601-2-29

Première édition
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Appareils électromédicaux

Partie 2:
Règles particulières de sécurité
pour les simulateurs de radiothérapie

Medical electrical equipment

Part 2:
Particular requirements for the safety
of radiotherapy simulators

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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 cooperation 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, 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.

3) They have the form of recommendations for international use 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.

International Standard IEC 601-2-29 has been prepared by sub-committee 62C: High-energy radiation equipment and equipment for nuclear medicine, of IEC technical committee 62: Electrical equipment in medical practice.

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

DIS	Report on Voting	Amendment to DIS	Report on Voting
62C(CO)59	62C(CO)66	62C(CO)69	62C(CO)71

Full information on the voting for the approval of this Particular Standard can be found in the reports on voting indicated in the above table.

Appendix 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 exceptions: in smaller type.

– *Test specifications and procedures: in italic type.*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THIS PARTICULAR STANDARD, IN IEC 788, IN IEC 601-1 AND IN IEC 601-2-1: SMALL CAPITALS.

NOTE – Attention is drawn to the existence in some countries of legislation concerning RADIATION safety which may not align with the provisions of this Particular Standard.

INTRODUCTION

The use of RADIOTHERAPY SIMULATORS may expose PATIENTS to danger if the EQUIPMENT does not satisfy standards of electrical and mechanical safety. The RADIOTHERAPY SIMULATOR is used in conjunction with RADIOTHERAPY EQUIPMENT and common standards of safety, performance and terminology should be employed for both types of EQUIPMENT to reduce the risks of OPERATOR errors.

RADIOTHERAPY SIMULATORS in use at the present time use an X-RADIATION SOURCE to simulate a RADIOTHERAPY beam. The safety standards required for the HIGH VOLTAGE GENERATOR are currently defined in IEC 601-2-7. IEC 601-2-7 and other Particular Standards in preparation which apply to RADIOTHERAPY SIMULATORS are considered as part of this Particular Standard, except where noted in this Standard. RADIOTHERAPY SIMULATORS have unique application in a RADIOTHERAPY department. This Standard is restricted to the use of the EQUIPMENT in this application.

Section One: General; Section Two: Environmental conditions; Section Three: Protection against electric shock hazards; Section Four: Protection against mechanical hazards; and Section Five: Protection against unwanted or excessive RADIATION, describe requirements to be met by MANUFACTURERS in the design and construction of RADIOTHERAPY SIMULATORS.

Section Five contains specific requirements and exclusions for the X-RAY EQUIPMENT used on RADIOTHERAPY SIMULATORS and Sections Six to Ten some other amendments to IEC 601-1, General Standard, for RADIOTHERAPY SIMULATORS.

This Particular Standard introduces a number of new requirements in the construction and design of RADIOTHERAPY SIMULATORS. Enforcing authorities are advised that some time will be required by MANUFACTURERS before EQUIPMENT which conforms to this Particular Standard is available.

Unless otherwise stated, all other sections or clauses mentioned in IEC 601-1 apply. The numbering of sections and clauses of this Particular Standard conforms to the numbering of IEC 601-1, unless otherwise mentioned. As in the General Standard, the requirements are followed by compliance tests. The requirements of this Particular Standard take priority over those of the General Standard entitled "*Medical electrical equipment, Part 1: General requirements for safety*".

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of radiotherapy simulators

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 *Scope*

Addition:

This Standard applies to RADIOTHERAPY SIMULATORS which use diagnostic X-RAY EQUIPMENT to simulate physically a therapeutic RADIATION BEAM, so that the TREATMENT VOLUME to be irradiated during RADIOTHERAPY can be localized, and the position and size of the therapeutic RADIATION FIELD can be confirmed.

This Standard applies to RADIOTHERAPY SIMULATORS using HIGH-VOLTAGE GENERATORS complying with IEC 601-2-7.

This Standard applies to RADIOTHERAPY SIMULATORS intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY, and not for any other purpose such as general diagnostic examinations.

This Standard applies to RADIOTHERAPY SIMULATORS comprising the following parts:

a) A system for producing a RADIATION BEAM not exceeding 400 kV which simulates the geometry of the RADIOTHERAPY RADIATION BEAM.

b) A system for producing images of the transmitted X-RAY BEAM, for example either by RADIOGRAPHY or by RADIOSCOPY.

c) An assembly to control the size of the RADIATION BEAM and to DELINEATE the intended treatment area.

d) A mechanical structure which physically simulates the geometry and motions of the RADIOTHERAPY EQUIPMENT and supports the imaging system.

e) A PATIENT SUPPORT system.