SLOVENSKI STANDARD

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Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-29

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Supersedes EN 60601-2-29:1995 + A1:1996

English version

Medical electrical equipment
Part 2-29: Particular requirements for the safety of radiotherapy simulators
(IEC 60601-2-29:1999)

Appareils électromédicaux
Partie 2-29: Règles particulières de sécurité pour les simulateurs de radiothérapie
(CEI 60601-2-29:1999)

Medizinische elektrische Geräte
Teil 2-29: Besondere Festlegungen für die Sicherheit von Strahlentherapiesimulatoren
(IEC 60601-2-29:1999)

This European Standard was approved by CENELEC on 1999-04-01. 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, 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

Ref. No. EN 60601-2-29:1999 E

Foreword

The text of document 62C/250/FDIS, future edition 2 of IEC 60601-2-29, 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 EN 60601-2-29 on 1999-04-01.

This European Standard supersedes EN 60601-2-29:1995 and its amendment A1:1996.

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) 2000-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2002-04-01

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

Endorsement notice

The text of the International Standard IEC 60601-2-29:1999 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.

Addition:

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-2-7	1998	Medical electrical equipment Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	EN 60601-2-7	1998
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
IEC 61217	1996	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996
Replace the reference to IEC 60601-1-4 by:				
IEC 60601-1-4	1996	Medical electrical equipment Part 1: General requirements for safety 4. Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
A1	[1]		-	-

1) To be published.

Annex ZB (informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Addition:

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
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 + corr. June	1995		A2 A13	1995 1996

NORME INTERNATIONALE

INTERNATIONAL STANDARD

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Deuxième édition
Second edition
1999-01

Appareils électromédicaux –

Partie 2-29:
Règles particulières de sécurité pour les simulateurs de radiothérapie

Medical electrical equipment –

Part 2-29:
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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-29: Particular requirements for the safety of radiotherapy simulators

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 60601-2-29 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1993, and its amendment 1 (1997). Consideration has been given to the new IEC standards, amendments to existing IEC standards, to developments in technology and clinical usage, and to various hazards encountered and envisaged since the preparation of the first edition.

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

FDIS	Report on voting
62C/250/FDIS	62C/257/RVD

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

Appendix L and annex AA form an integral part of this standard.

Annex BB is for information only.

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

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN LISTED IN ANNEX AA, AND DEFINED IN CLAUSE 2 OR IN THE GENERAL STANDARD IEC 60601-1, ITS COLLATERAL OR PART 2 STANDARDS, OR IN IEC 60788: SMALL CAPITALS.

Certain defined terms have been abbreviated as follows:

Defined term	Abbreviation
BEAM LIMITING DEVICE	BLD
BEAM LIMITING SYSTEM	BLS
COMPUTED TOMOGRAPHY	CT
INFORMATION TECHNOLOGY EQUIPMENT	ITE
NORMAL CONDITION	NC
SINGLE FAULT CONDITION	SFC
TREATMENT CONTROL PANEL	TCP

Certain other terms have been given their commonly used abbreviations as follows:

Term	Abbreviation
International Commission on Radiological Protection	ICRP
International Commission on Radiation Units and Measurements	ICRU
Light emitting diode	LED

NOTE 1 – Although the actual titles of the persons fulfilling the following roles may vary from country to country, in this Particular Standard the term 'OPERATOR' is used to denote the person controlling the treatment simulation, and the term 'USER' to denote the organization or individual responsible for the use and maintenance of the RADIOTHERAPY SIMULATOR. The terms 'radiotherapist' and 'radiation oncologist', although not used in this Particular Standard, are used in many countries to denote the person exercising medical supervision and responsibility for determining and prescribing PATIENT treatment.

NOTE 2 – Attention is drawn to the existence, in some countries, of legislation containing requirements for:

- IONIZING RADIATION safety which may not align with the provisions of this Particular Standard, and
- maintenance, quality assurance and other related subjects, which are not covered by this standard.

INTRODUCTION

The use of RADIOTHERAPY SIMULATORS may expose PATIENTS to danger if the EQUIPMENT design does not satisfy standards of electrical, mechanical and IONIZING RADIATION safety. The EQUIPMENT may also cause danger to persons in the vicinity if the EQUIPMENT itself fails to contain the IONIZING RADIATION adequately and/or if there are inadequacies in the design of the SIMULATOR room.

This Particular Standard establishes requirements to be complied with by MANUFACTURERS in the design and construction of RADIOTHERAPY SIMULATORS; it does not attempt to define their 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, for example a component failure, and where an INTERLOCK then operates to prevent continued operation of the EQUIPMENT.