SLOVENSKI STANDARD
SIST EN 60601-2-29:1998/A1:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of radiotherapy simulators - Amendment A1 (IEC 60601-2-29:1993/A1:1996)

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/A1:1996**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-29:1998/A1:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-29/A1

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Descriptors: Medical electrical equipment, radiotherapy simulators, 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/A1:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
des simulateurs de radiothérapie
(CEI 601-2-29:1993/A1:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen
für die Sicherheit von
Strahlentherapiesimulatoren
(IEC 601-2-29:1993/A1:1996)

This amendment A1 modifies the European Standard EN 60601-2-29:1995; it was approved by CENELEC on 1996-10-01. 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.

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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/159/FDIS, future amendment 1 to 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 IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-29:1995 on 1996-10-01.

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) 1997-07-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1998-06-13

Endorsement notice

The text of amendment 1:1996 to the International Standard IEC 601-2-29:1993 was approved by CENELEC as an amendment to the European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
601-2-29

1993

AMENDEMENT 1
AMENDMENT 1

1996-10

Amendement 1

Appareils électromédicaux –

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

Amendment 1

Medical electrical equipment –

Part 2:
Particular requirements for the safety of radiotherapy simulators

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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/159/FDIS	62C/177/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.

INTRODUCTION

Since the publication in 1993 of IEC 601-2-29: *Medical electrical equipment – Part 2: Particular requirements for the safety of radiotherapy simulators*, three Collateral Standards have been published. Two of these, IEC 601-1-3: *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*, and IEC 601-1-2: *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*, apply to IEC 601-2-29.

This amendment incorporates the revisions to, and facilitates the application of, these Collateral Standards, and the consequent revisions relevant to their use with IEC 601-2-29.

CONTENTS:

After clause 29, add:

36 ELECTROMAGNETIC COMPATIBILITY

After Appendix AA, add:

Annex BB Bibliography

Add the following subclauses:

1.5 *Collateral Standards*

Additional subclauses:

1.5.101 *IEC 601-1-1*

This Collateral Standard does not apply.

1.5.102 *IEC 601-1-2: (1993)*

All clauses and subclauses of this Collateral Standard, together with those given in clause 36, apply to RADIOTHERAPY SIMULATORS and any INFORMATION TECHNOLOGY EQUIPMENT that forms part of a RADIOTHERAPY SIMULATOR.

NOTE – IEC 601-1-2 applies to MEDICAL ELECTRICAL EQUIPMENT and INFORMATION TECHNOLOGY EQUIPMENT (ITE) used in medical electrical applications. RADIOTHERAPY SIMULATORS and any associated ITE are not excluded from compliance with IEC 601-1-2; it has not been possible at the date of publication of this amendment to determine fully whether further amendments to its requirements or tests will need to be made in addition to those given in clause 36 of this Particular Standard.

1.5.103 *IEC 601-1-3: (1994)*

All clauses and subclauses of this Collateral Standard apply, except as amended in clause 29.

29 RADIATION safety of RADIOTHERAPY SIMULATORS

Add the following:

29.202.3 *Confinement of EXTRA-FOCAL RADIATION*

This subclause does not apply.

29.202.7 *Indication by LIGHT FIELD-INDICATOR*

Modify as follows:

The requirement for an average illumination of not less than 100 lx is reduced to 50 lx.

29.203.3 *Interception of the X-RAY BEAM IN RADIOSCOPY*

This subclause does not apply.

29.203.4 *Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA*

This subclause does not apply.

29.205 *FOCAL SPOT TO SKIN DISTANCE*

This subclause (including 29.205.1, 29.205.2 and 29.205.3) does not apply.

29.206 *ATTENUATION of the X-RAY BEAM*

Add the following line to table 206:

PATIENT SUPPORT, RADIOTHERAPY SIMULATORS:	5,0 mm

29.207 *PRIMARY PROTECTIVE SHIELDING*

This subclause (including 29.207.1, 29.207.2 and 29.207.3) does not apply.

29.208 *Protection against STRAY RADIATION*

29.208.1 *Protection by distance*

This subclause does not apply.

29.208.2 *Control from a PROTECTED AREA*

Replace as follows:

Means shall be provided to allow the following control functions only by OPERATOR action at the TREATMENT CONTROL PANEL situated within a PROTECTED AREA:

- selection and control of modes of operation;
- selection of LOADING FACTORS;
- actuation of the IRRADIATION SWITCH;

The IRRADIATION SWITCH shall be protected from accidental operation and require continuous pressure by the OPERATOR.

Means, compliant with the requirements of 22.4.102 and 22.4.103, shall be provided at the TREATMENT CONTROL PANEL for the remote control of powered movements for:

- GANTRY;
- RADIATION HEAD;
- DELINEATED RADIATION FIELD size;
- X-RAY IMAGE RECEPTOR;
- PATIENT SUPPORT.

The ACCOMPANYING DOCUMENTS shall contain:

- a warning against allowing persons, other than the PATIENT, to remain inside the RADIOTHERAPY SIMULATOR room during the LOADING STATE;
- a statement drawing the attention of the USER to the need for providing the OPERATOR with means for verbal communication with, and an unobstructed view of, the PATIENT.

Compliance is checked by inspection of the EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

29.208.3 *Designated SIGNIFICANT ZONES OF OCCUPANCY*

This subclause does not apply.

29.208.4 *SIGNIFICANT ZONES OF OCCUPANCY with limited STRAY RADIATION*

This subclause does not apply.

29.208.5 *Handgrips and control devices*

This subclause does not apply.

29.208.6 *Test for STRAY RADIATION*

This subclause does not apply.

29.3 *Adventitious IONIZING RADIATION*

NOTE – Clause 29 of the General Standard has been replaced; its subclause 29.2 is reinstated here in a relevant form.

For EQUIPMENT or EQUIPMENT parts not intended to produce IONIZING RADIATION and which form part of a RADIOTHERAPY SIMULATOR, IONIZING RADIATION emitted by thermionic valves excited by voltages exceeding 5 kV shall not produce an ambient dose equivalent, $H^*(d)$[1)], exceeding 5 μSv in one hour at a distance of 5 cm from any accessible surface.

Compliance is checked by performing measurements of ambient DOSE EQUIVALENT, averaged over an area not exceeding 10 cm^2. In order to assess the dose due to small angle beams, use a RADIATION DETECTOR suitable for the emitted RADIATION ENERGY. Record the method, positions and results of measurements. Controls and adjustments are set at the position resulting in the maximum emission of X-RADIATION. Single failures of components causing the least favourable situation are provoked in turn.

1) See ICRU, Report 39: section 3.1.1 etc.; or ICRU, Report 51: section 1.4.3/1.4.3.1.1, and ICRP 60: A.14, A.14.1 (A27) etc.

Add the following:

36 ELECTROMAGNETIC COMPATIBILITY

Replacement:

The requirements and tests of IEC 601-1-2, with the additions to 36.201, 36.202 and 36.202.1 given below, shall apply to RADIOTHERAPY SIMULATORS and any associated INFORMATION TECHNOLOGY EQUIPMENT that forms part of a RADIOTHERAPY SIMULATOR.

The site(s) used for measurements shall be typical of those generally used for the installation of RADIOTHERAPY SIMULATORS; they may be those of USERS or of the MANUFACTURER. Any allowances made shall be justified and included in the ACCOMPANYING DOCUMENTS.

36.201 *EMISSIONS*

36.201.1 *Radiofrequency (RF) EMISSIONS*

Addition:

aa) The requirements for compliance shall be those applying to CISPR 11 designated Group 1, Class A, PERMANENTLY INSTALLED EQUIPMENT.

bb) For radiofrequency EMISSIONS, the attenuation of ELECTROMAGNETIC DISTURBANCES by structures within the bounds of the exterior walls from which measurements are made at a distance, shall be regarded as though this was due to the inherent attenuation of the EQUIPMENT.

Compliance is checked by measurements, made in accordance with IEC 601-1-2, at 30 m from the exterior walls of the building containing the location in which the EQUIPMENT has been installed.

36.202 *IMMUNITY*

Addition:

aa) The requirements for compliance shall be those applying to PERMANENTLY INSTALLED EQUIPMENT.

36.202.2 *Radiated radiofrequency electromagnetic fields*

aa) For IMMUNITY to radiofrequency electromagnetic fields, the attenuation provided by the structural protection against IONIZING RADIATION shall be regarded as though this was due to the inherent attenuation of the EQUIPMENT.

Compliance is checked by tests made in accordance with IEC 601-1-2. For 36.202.2: radiated radiofrequency electromagnetic fields, the test antenna shall be placed at 3 m from the outside of the structural protection against IONIZING RADIATION.