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**SVENSK STANDARD SS-EN 60601-2-29**

| Handläggande organ | Fastställd | Utgåva | Sida | Ingår i |
|---|---|---|---|---|
| **Svenska Elektriska Kommissionen, SEK** | 1999-06-18 | 2 | 1 (1+31) | SEK Översikt 62 |

**Reg 486 03 49**



# Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-29: Särskilda fordringar på simulatorer för strålterapi

*Medical electrical equipment 0*
*Part 2-29: Particular requirements for the safety of radiotherapy simulators*

Som svensk standard gäller europastandarden EN 60601-2-29:1999. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-29:1999.

**Nationellt förord**

Europastandarden EN 60601-2-29:1999

består av:

– **europastandardens ikraftsättningsdokument, utarbetat inom CENELEC**
– **IEC 60601-2-29, Second edition, 1999 - Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

Utgåva 2 är föranledd av ny utgåva av EN 60601-2-29.

SS-EN 60601-2-29, utgåva 1, 1996, gäller ej fr o m 2000-01-01.

ICS 11.040.60

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EUROPEAN STANDARD **EN 60601-2-29**

NORME EUROPÉENNE

EUROPÄISCHE NORM April 1999

ICS 11.040.60

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)



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.

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## Endorsement notice

The text of the International Standard IEC 60601-2-29:1999 was approved by CENELEC as a European Standard without any modification.

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## **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<br>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<br>Part 1: General requirements for safety<br>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<br>Part 1: General requirements for safety | EN 60601-1<br>+ corr. July | 1990<br>1994 |
| A1 | 1991 | | A1<br>+ corr. July | 1993<br>1994 |
| A2<br>+ corr. June | 1995 | | A2<br>A13 | 1995<br>1996 |

# CONTENTS

# MEDICAL ELECTRICAL EQUIPMENT

## Part 2-29: 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

#### 1.1 Scope

*Addition:*

This Particular Standard applies to RADIOTHERAPY SIMULATORS:

– that use diagnostic X-RAY EQUIPMENT to simulate physically a RADIOTHERAPY RADIATION BEAM, so that the TREATMENT VOLUME to be subjected to IRRADIATION during RADIOTHERAPY can be localized, and the position and size of the RADIOTHERAPY RADIATION FIELD can be confirmed;

– intended exclusively for RADIOTHERAPY simulation as a prelude to intended RADIOTHERAPY, and not for any other purpose such as general diagnostic examinations;

– used within the environmental and electrical supply conditions SPECIFIED in the technical description;

– comprising the following parts:

  • a system for producing an X-RAY BEAM, which simulates the geometry of the RADIOTHERAPY RADIATION BEAM;

  • a system for producing images of the transmitted X-RAY BEAM, for example, either by RADIOGRAPHY or RADIOSCOPY;

  • an assembly to control the size and position of the RADIATION BEAM and to delineate the intended treatment area;

  • a mechanical structure that physically simulates the geometry and movements of the RADIOTHERAPY EQUIPMENT and supports the imaging system;

  • a PATIENT SUPPORT system.

#### 1.2 Object

*Addition:*

This Particular Standard establishes requirements to ensure the IONIZING RADIATION safety and enhanced mechanical and electrical safety of RADIOTHERAPY SIMULATORS; it identifies geometrical parameters that are critical for the accurate simulation of a RADIOTHERAPY treatment.

### 1.3 Particular Standards

*Additional subclauses:*

#### 1.3.101 Relationship to the General Standard.

NOTE – See appendix L for normative references.

The requirements of this Particular Standard take priority over those of all other standards; it is to be read in conjunction with IEC 60601-1 (1988), *Medical electrical equipment Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and corrigendum (1995) – hereinafter referred to as the General Standard – which it amends and supplements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard. Unless otherwise stated, all clauses of the General Standard apply.

As in the General Standard, the requirements are followed by compliance tests. The term “this standard” is used throughout to refer to the General Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard (but see 29.1 b)). The changes to the text of the General Standard, or its Collateral Standards, are SPECIFIED by the use of the following words:

“Replacement” means that the clause or subclause of the General/Collateral Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General/Collateral Standard.

“Amendment” means that the clause or subclause of the General/Collateral Standard is amended as indicated by the text of this Particular Standard.

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

#### 1.3.102 Relationship to other standards and documents

**a) IEC 60601-2-7**

This standard applies to HIGH-VOLTAGE GENERATORS of diagnostic X-RAY GENERATORS used with RADIOTHERAPY SIMULATORS (see 29.1 a)).

**b) IEC 61217**

This standard gives guidance on the designation of EQUIPMENT movements, the marking of scales, their zero positions, and the direction of movement with increasing value (see 6.3.101 a)).