SVENSK STANDARD SS-EN 60601-2-29

Fastställd	Utgåva	Sida	Ansvarig kommitté
2009-05-25	3	1 (1+26)	SEK TK 62BC

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

Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

Som svensk standard gäller europastandarden EN 60601-2-29:2008. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-29:2008.

Nationellt förord

Europastandarden EN 60601-2-29:2008

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-29, Third edition, 2008 - Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

Till SS-EN 60601-1 utges en serie tilläggstandarder 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 särskild behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

Tidigare fastställd svensk standard SS-EN 60601-2-29, utg 2, 1999, gäller ej fr o m 2011-11-01

ICS 11.040.60

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
Postadress: SEK, Box 1284, 164 29 KISTA
Telefon: 08 - 444 14 00. *Telefax*: 08 - 444 14 30
E-post: sek@elstandard.se. *Internet*: www.elstandard.se

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

SEK Svensk Elstandard
Box 1284
164 29 Kista
Tel 08-444 14 00
www.elstandard.se

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-29

November 2008

ICS 11.040.60

Supersedes EN 60601-2-29:1999

English version

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

(IEC 60601-2-29:2008)

Appareils électromédicaux - Partie 2-29: Exigences particulières pour la sécurité de base et les performances essentielles des simulateurs de radiothérapie (CEI 60601-2-29:2008)

Medizinische elektrische Geräte - Teil 2-29: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Strahlentherapiesimulatoren (IEC 60601-2-29:2008)

This European Standard was approved by CENELEC on 2008-11-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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 60601-2-29:2008 E

SEK Svensk Elstandard

Foreword

The text of document 62C/423/CDV, future edition 3 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 Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-29 on 2008-11-01.

This European Standard supersedes EN 60601-2-29:1999.

EN 60601-2-29:2008 constitutes a technical revision, which brings EN 60601-2-29 in line with EN 60601-1:2006 and its collateral standards.

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)	2009-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-11-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

———————

Endorsement notice

The text of the International Standard IEC 60601-2-29:2008 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-3	NOTE	Harmonized as EN 60601-1-3:2008 (not modified).
IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8:2007 (not modified).
IEC 60601-2-1	NOTE	Harmonized as EN 60601-2-1:1998 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

Addition *to Annex ZA of EN 60601-1:2006:*

Publication	Year	Title	EN/HD	Year
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61217	-[1)]	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	1996[2)]

[1)] Undated reference.

[2)] Valid edition at date of issue.

CONTENTS

INTRODUCTION

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 ME EQUIPMENT. It places limits on the degradation of ME 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 ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of RADIOTHERAPY SIMULATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for RADIOTHERAPY SIMULATORS [as defined in 201.3.204].

201.1.3 *Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

The following collateral standard does not apply:

– IEC 60601-1-10.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*