SVENSK STANDARD SS-EN 60601-2-54

Fastställd	Utgåva	Sida	Ansvarig kommitté
2010-05-24	1	1 (1+70)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-54: Särskilda fordringar på röntgenutrustning för bildtagning och genomlysning

Medical electrical equipment –
Part 2-54: Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy

Som svensk standard gäller europastandarden EN 60601-2-54:2009. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-54:2009.

Nationellt förord

Europastandarden EN 60601-2-54:2009

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-54, First edition, 2009**[*)] **- Medical electrical equipment - Part 2-54: Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy**

utarbetad inom International Electrotechnical Commission, IEC.

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

Tidigare fastställd svensk standard SS-EN 60601-2-7, utgåva 1, 1998 och SS-EN 60601-2-32, utgåva 1, 1995, gäller ej fr o m 2012-08-01. Standarden ersätter också delvis SS-EN 60601-2-28, utgåva 1, 1993 som ej gäller fr o m 2013-04-01.

[*)] Corrigendum, March 2010, till IEC 60601-2-54, är inarbetat i texten.

ICS 11.040.50

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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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

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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).

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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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-54

September 2009

ICS 11.040.50

Supersedes EN 60601-2-7:1998, EN 60601-2-28:1993 (partially) and EN 60601-2-32:1994

English version

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

(IEC 60601-2-54:2009)

Appareils électromédicaux -
Partie 2-54: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils à rayonnement X utilisés
pour la radiographie et la radioscopie
(CEI 60601-2-54:2009)

Medizinische elektrische Geräte -
Teil 2-54: Besondere Festlegungen
für die Sicherheit und die wesentlichen
Leistungsmerkmale
von Röntgeneinrichtungen
für Radiographie und Radioskopie
(IEC 60601-2-54:2009)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-54:2009 E

SEK Svensk Elstandard

Foreword

The text of document 62B/735/FDIS, future edition 1 of IEC 60601-2-54, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-54 on 2009-08-01.

EN 60601-2-54 was developed for use with EN 60601-1:2006.

This European Standard supersedes EN 60601-2-7:1998, EN 60601-2-32:1994 and EN 60601-2-28:1993 (partially).

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)	2010-05-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-08-01

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 MDD (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 60601-2-54:2009 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:

[1] IEC 60627	NOTE	Harmonized as EN 60627:2001 (not modified).
[2] IEC 61267	NOTE	Harmonized as EN 61267:2006 (not modified).
[3] ISO 4090	NOTE	Harmonized as EN ISO 4090:2004 (not modified).
[10] IEC 60601-2-7	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
[11] IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
[12] IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
[13] IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8:2007 (not modified).
[14] IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10:2008 (not modified).
[15] IEC 60601-2-43	NOTE	Harmonized as EN 60601-2-43:2000 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
***Replace** the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
***Replace** the reference to IEC 60601-1-3 by:*				
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
Addition:				
IEC 60336	-[1)]	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005[2)]
IEC 60580	2000	Medical electrical equipment - Dose area product meters	EN 60580	2000
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	–	–
IEC 60806	-[1)]	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis	EN 60806	2004[2)]
IEC 62220-1	2003	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency	EN 62220-1	2004

[1)] Undated reference.
[2)] Valid edition at date of issue.

CONTENTS

INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this particular standard.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental applications are excluded from the scope of this International Standard. The scope of this International Standard also excludes radiotherapy simulators.

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.

NOTE Taking into account economic and social factors, the scope of this particular standard includes ME EQUIPMENT intended to be used for DIRECT RADIOSCOPY. In some countries examinations performed with DIRECT RADIOSCOPY are prohibited.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

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 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

NOTE OPERATORS of X-RAY EQUIPMENT are used to audible signals as required in this particular standard rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

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 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable 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 standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 64.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60580:2000, *Medical electrical equipment – Dose area product meters*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60806, *Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis*

IEC 62220-1:2003, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency*

Amendment:

IEC 60601-1-2:2007 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:2008 *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*