STANDARDISERINGEN I SVERIGE
SWEDISH STANDARDS INSTITUTION

SVENSK STANDARD SS-EN 60 601-2-32

SVENSKA ELEKTROTEKNISKA NORMER, SEN

Handläggande organ
Svenska Elektriska Kommissionen, SEK

Fastställd	Utgåva	Sida	Ingår i
1995-01-13	1	1 (1+4+17)	SEK Översikt 62

Registrering
Reg 486 03 52

Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på den mekaniska säkerheten hos bärande och rörliga delar av röntgenutrustningar

Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment

Som svensk standard gäller europastandarden EN 60 601-2-32: 1994. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60 601-2-32: 1994.

Nationellt förord

Europastandarden EN 60 601-2-32: 1994

består av

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

- **IEC 601-2-32, First edition, 1994 - Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment**

  utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60 601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, vilken innehåller den officiella engelska språkversionen av EN 60 601-1.

UDK 615.849:616-073.75:621.3:614.8

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
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Prisgrupp Q

Tryckt i februari 1995

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPÄISCHE NORM

EN 60601-2-32

July 1994

UDC 615.849:616-073.75:621.3:614.8

Descriptors: Electromedical equipment, X-ray equipment, safety requirements, equipment specifications, equipment protection, test

ENGLISH VERSION

Medical electrical equipment
Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
(IEC 601-2-32:1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour les équipements associés aux equipements à rayonnement X
(CEI 601-2-32:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Röntgenanwendungsgeräten
(IEC 601-2-32:1994)

This European Standard was approved by CENELEC on 1994-03-08. 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, 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

FOREWORD

The text of document 62B(CO)108A, as prepared by Sub-Committee 62B: Diagnostic imaging equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in May 1993.

The reference document was approved by CENELEC as EN 60601-2-32 on 8 March 1994.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1995-03-01
- latest date of withdrawal of conflicting national standards	(dow)	1995-03-01

For products which have complied with the relevant national standard before 1995-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-03-01.

Annexes designated "normative" are part of the body of the standard. Annexes designated "informative" are given only for information. In this standard, annexes AA and ZB are informative and annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-32:1994 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT 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.

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

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZA of EN 60601-1:1990/A11:1993:				
601-1	1988	Medical electrical equipment - Part 1:	EN 60601-1	1990
A1	1991	General requirements for safety	A1 + A11 + A12	1993
A2 (under consideration)			-	-
601-1-3	-	3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment (currently DIS 628(CO)111)	-	-
601-2-7	1987	Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	HD 395.2.7 S1	1989
601-2-8	1987	Part 2: Particular requirements for the safety of therapeutic X-ray generators	HD 395.2.8 S1	1988
601-2-15	1988	Part 2: Particular requirements for the safety of capacitor discharge X-ray generators	HD 395.2.15 S1	1989

Other publication:

ISO 6892:1984 - Metallic materials - Tensile testing

ANNEX ZB (informative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZB of EN 60601-1:1990/A11:1993:				
788	1984	Medical radiology - Terminology	HD 501 S1	1988

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SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

Tables

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of associated equipment of X-ray equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular Standard applies to equipment and devices associated with X-RAY EQUIPMENT as used for supporting and relatively positioning the functional components including the PATIENT SUPPORT used for the application of the X-RADIATION.

This Particular Standard applies to all ASSOCIATED EQUIPMENT not covered by other Particular Standards.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish particular requirements for the design and manufacture to ensure safety and to specify methods for demonstrating compliance with these requirements.

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety* with its amendments 1 and 2*, and to 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.*

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* Amendment 2 of IEC 601-1 is under consideration by SC 62A at the time of publication of this Particular Standard. Nevertheless SC 62B has checked this Particular Standard with the draft 62A(Secretariat)131 of that amendment 2. Reference to it has been considered as satisfactory. Any alignment, if necessary, will be initiated after final publication of amendment 2.

For brevity, IEC 601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s), and IEC 601-1-3 as the Collateral Standard.

The term "this Standard" is used to make reference to the General Standard, the Collateral Standard and this Particular Standard taken together.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. 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 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

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

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or the Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or the Collateral Standard, although possibly relevant, is not to be applied to ASSOCIATED EQUIPMENT, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or the Collateral Standard takes precedence over the corresponding General Requirement(s).