SIS - Standardiseringskommissionen i Sverige

SVENSKA ELEKTROTEKNISKA NORMER, SEN

SVENSK STANDARD SS-EN 60 601-2-28

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Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på kombinationer av röntgenrör, rörkåpa och bländare för medicinsk diagnostik

Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

Som svensk standard gäller europastandarden EN 60 601-2-28: 1993. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60 601-2-28: 1993.

Nationellt förord

Europastandarden EN 60 601-2-28-: 1993

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

- **IEC 601-2-28, First edition, 1993 - Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis**

  utarbetad inom International Electrotechnical Commission, IEC

Standarden skall användas tillsammans med SS-EN 60 601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, vilken återger 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

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EUROPEAN STANDARD EN 60601-2-28

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

ENGLISH VERSION

Medical electrical equipment
Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
(IEC 601-2-28:1993)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour les ensembles radiogènes à rayonnement X et les gaines équipées pour diagnostic médical

(CEI 601-2-28:1993)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Röntgenstrahler einschließlich Blendensystem für medizinische Diagnostik
(IEC 601-2-28:1993)

This European Standard was approved by CENELEC on 1993-03-09.
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)103, 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 July 1992.

The reference document was approved by CENELEC as EN 60601-2-28 on 9 March 1993.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1994-03-01
- latest date of withdrawal of conflicting national standards	(dow)	1994-03-01

For products which have complied with the relevant national standard before 1994-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1999-03-01.

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

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-28:1993 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

Annex ZA of EN 60601:1990/A11:1993 applies with the following additions:

IEC Publication	Date	Title	EN/HD	Date
336	1982	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use	HD 509 S1	1988
522	1976	Inherent filtration of an X-ray tube assembly	-	-
526 (mod)	1978	High-voltage cable plug and socket connections for medical X-ray equipment	HD 364 S2	1983
601-1-3	-	Medical electrical equipment Part 1: General requirements for safety 3. Collateral Standard: General requirements for protection against ionizing radiation (under consideration)	-	-
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
601-2-15	1988	Part 2: Particular requirements for the safety of capacitor discharge X-ray generators	HD 395.2.15 S1	1989
613	1989	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis	EN 60613	1990
788	1984	Medical radiology - Terminology	HD 501 S1	1988
806	1984	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis	HD 513 S1	1989

CONTENTS

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS: ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis

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*

Replacement:

This Standard applies to X-RAY SOURCE ASSEMBLIES and X-RAY TUBE ASSEMBLIES for medical diagnosis, and to components thereof, specified for use in medical X-RAY EQUIPMENT including equipment for COMPUTED TOMOGRAPHY, that incorporates a specified HIGH-VOLTAGE GENERATOR complying with IEC 601-2-7 or IEC 601-2-15.

1.2 *Object*

Replacement:

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

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, and to IEC 601-1-3: *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for protection against ionizing radiation* (under consideration).

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 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 appendices are lettered AA, etc., and additional items aa), bb), etc.

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

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).

Where there is no corresponding clause or subclause in this Particular Standard, the 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 X-RAY SOURCE ASSEMBLIES, a statement to that effect is given in this Particular Standard.