SLOVENSKI STANDARD
SIST EN 60601-2-28:1995

01-maj-1995

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za vire rentgenskih žarkov in sklope rentgenskih cevi za medicinsko diagnostiko (IEC 60601-2-28:1993)

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

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von Röntgenstrahler einschließlich Blendensystem für medizinische Diagnostik

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

Ta slovenski standard je istoveten z: **EN 60601-2-28:1993**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-28:1995 **en**

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

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Appareils électromédicaux

Partie 2:
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Medical electrical equipment

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 601-2-28 has been prepared by IEC by sub-committee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This Standard integrates IEC 637. Consequently, this Standard cancels and replaces the first edition of IEC 637, published in 1979.

The text of this Particular Standard is based on the following documents:

DIS	Report on Voting
62B(CO)103	62B(CO)104

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annex AA is for information only.

In this Particular Standard, the following print types are used:

– Requirements, compliance with which can be tested, and definitions: in roman type.

– Explanations, advice, introductions, general statements, and exceptions: in smaller type.

– *Test specifications: in italic type.*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF IEC 601-1 AND IN IEC 788: SMALL CAPITALS.

NOTE - Attention is drawn to the existence in some countries of legislation concerning RADIATION safety which may not align with the provisions of this Particular Standard.