SLOVENSKI STANDARD

SIST EN 60336:2006

januar 2006

Medicinska električna oprema – Rentgenske naprave za medicinsko diagnostiko – Značilnosti žariščnih točk (IEC 60336:2005)

(istoveten EN 60336:2005)

Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots (IEC 60336:2005)

ICS 11.040.50; 11.040.55

Referenčna številka
SIST EN 60336:2006(en)

EUROPEAN STANDARD **EN 60336**

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2005

ICS 11.040.50 Supersedes EN 60336:1995

English version

Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
(IEC 60336:2005)

Appareils électromédicaux – Gaines équipées pour diagnostic médical - Caractéristiques des foyers (CEI 60336:2005)

Medizinische elektrische Geräte - Röntgenstrahler für medizinische Diagnostik – Kennwerte von Brennflecken (IEC 60336:2005)

This European Standard was approved by CENELEC on 2005-06-01. 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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

Ref. No. EN 60336:2005 E

Foreword

The text of document 62B/554/FDIS, future edition 4 of IEC 60336, 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 60336 on 2005-06-01.

This European Standard supersedes EN 60336:1995.

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)	2006-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-06-01

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60336:2005 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-2-28 NOTE Harmonized as EN 60601-2-28:1993 (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 Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60417	database	Graphical symbols for use on equipment	-	-
IEC 60613	- [1)]	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis	EN 60613	1990 [2)]
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

1) Undated reference.

2) Valid edition at date of issue.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60336

Quatrième édition
Fourth edition
2005-04

Appareils électromédicaux – Gaines équipées pour diagnostic médical – Caractéristiques des foyers

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS – CHARACTERISTICS OF FOCAL SPOTS

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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International Standard IEC 60336 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fourth edition cancels and replaces the third edition published in 1993 and constitutes a technical revision. The significant changes of this fourth edition are detailed in Annex C (see Clause C.6).

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/554/FDIS	62B/569/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following conventions apply.

a) Terms printed in small capitals are used as defined in IEC 60788 and in Clause 3 of this standard. Where a defined term is used as a qualifier in another defined or undefined term, it is not printed in small capitals, unless the concept thus qualified is defined or recognized as a “derived term without definition”.

b) Certain terms that are not printed in small capitals have particular meanings, as follows

   – "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;

   – "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the equipment under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

NOTE Attention is drawn to the fact that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of May 2006 have been included in this copy.

MEDICAL ELECTRICAL EQUIPMENT – X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS – CHARACTERISTICS OF FOCAL SPOTS

1 Scope

This International Standard applies to FOCAL SPOTs in medical diagnostic X-RAY TUBE assemblies for medical use, operating at X-RAY TUBE VOLTAGEs up to and including 200 kV.

This International Standard describes the test methods for evaluating FOCAL SPOT characteristics and the means for indicating compliance.

2 Normative references

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.

IEC 60417-DB:2002: *Graphical symbols for use on equipment* [1)]

IEC 60613, *Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60788 together with the following apply.

3.1
STAR PATTERN RESOLUTION LIMIT
characteristic of the FOCAL SPOT of an X-RAY TUBE; highest spatial frequency that can be resolved under specific measuring conditions

4 Determinations for the evaluation of the FOCAL SPOT characteristics

4.1 Statement of the FOCAL SPOT characteristics

The FOCAL SPOT characteristics shall be stated for two normal directions of evaluation referred to as the length direction and width direction. An illustration for this clause can be found in Figure A.1.

4.2 Longitudinal axis of the X-RAY TUBE ASSEMBLY

Generally, the longitudinal axis can be identified unambiguously. If the X-RAY TUBE ASSEMBLY does not have an identifiable longitudinal axis or if it is specified otherwise by the MANUFACTURER, the longitudinal axis shall be specified together with the FOCAL SPOT characteristics.

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1) "DB" refers to the IEC on-line database.

4.3 REFERENCE AXIS of the X-RAY TUBE ASSEMBLY

If not specified otherwise, the REFERENCE AXIS is normal to the longitudinal axis and intersects both the centre of the ACTUAL FOCAL SPOT and the longitudinal axis of the X-RAY TUBE ASSEMBLY.

4.4 Direction of evaluation for the FOCAL SPOT length

The direction of evaluation for the FOCAL SPOT length is normal to the REFERENCE AXIS in the plane given by the REFERENCE AXIS and the longitudinal axis of the X-RAY TUBE ASSEMBLY.

4.5 Direction of evaluation for the FOCAL SPOT width

The direction of evaluation for the FOCAL SPOT width is normal to the longitudinal axis of the X-RAY TUBE ASSEMBLY and normal to the REFERENCE AXIS.

5 FOCAL SPOT camera set-up

5.1 Overview

This clause deals with the design requirements of a camera for the production of FOCAL SPOT SLIT RADIOGRAMS to be used for the determination of FOCAL SPOT dimensions in accordance with Clause 8, and the determination of the modulation transfer function in accordance with Clause 9.

This clause deals also with the design requirements of a camera for the production of FOCAL SPOT PINHOLE RADIOGRAMS.

5.2 Test equipment

5.2.1 SLIT CAMERA

The diaphragm of the SLIT CAMERA shall be made from materials with high ATTENUATION properties and shall have dimensions as given in Figure 1.

Suitable materials are for example:

– tungsten;
– tantalum;
– alloy of gold and 10 % platinum;
– alloy of tungsten and 10 % rhenium;
– alloy of platinum and 10 % iridium;