SLOVENSKI STANDARD
SIST EN IEC 60336:2021

01-april-2021

Nadomešča:
SIST EN 60336:2006

Medicinska električna oprema - Rentgenske naprave za medicinsko diagnostiko - Mere žariščnih točk in s tem povezane značilnosti (IEC 60336:2020)

Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics (IEC 60336:2020)

Medizinische elektrische Geräte - Röntgenstrahler für medizinische Diagnostik - Kennwerte von Brennflecken (IEC 60336:2020)

Appareils électromédicaux - Gaines équipées pour diagnostic médical - Dimensions des foyers et caractéristiques connexes (IEC 60336:2020)

Ta slovenski standard je istoveten z: **EN IEC 60336:2021**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 60336:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60336

February 2021

ICS 11.040.50

Supersedes EN 60336:2005 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics (IEC 60336:2020)

Appareils électromédicaux - Gaines équipées pour diagnostic médical - Dimensions des foyers et caractéristiques connexes (IEC 60336:2020)

Medizinische elektrische Geräte - Röntgenstrahler für medizinische Diagnostik - Kennwerte von Brennflecken (IEC 60336:2020)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62B/1138/CDV, future edition 5 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 approved by CENELEC as EN IEC 60336:2021.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2021-10-21
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-01-21

This document supersedes EN 60336:2005 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60336:2020 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:

IEC 60601-2-28:2017	NOTE	Harmonized as EN IEC 60601-2-28:2019 (not modified)
IEC 60336:2005	NOTE	Harmonized as EN 60336:2005 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60417	-	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	-	-
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
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
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
IEC 60613	2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis	EN 60613	2010
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

IEC 60336

Edition 5.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics

Appareils électromédicaux – Gaines équipées pour diagnostic médical – Dimensions des foyers et caractéristiques connexes

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS – FOCAL SPOT DIMENSIONS AND RELATED CHARACTERISTICS

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 fifth edition cancels and replaces the fourth edition published in 2005. This edition constitutes a technical revision.

The significant changes of this fifth edition with respect to the previous edition are detailed in Clause E.6. These changes are:

a) introduction of digital detectors and discretization errors;
b) fewer normative requirements;
c) support for both SLIT CAMERA and PINHOLE CAMERA;
d) reintroduction of distorted (skewed) FOCAL SPOT;
e) keeping of STAR PATTERNS and BLOOMING VALUE as informative.

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

CDV	Report on voting
62B/1138/CDV	62B/1181/RVC

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

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

In this document, the following print types are used:

– requirements and definitions: roman 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 THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

MEDICAL ELECTRICAL EQUIPMENT – X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS – FOCAL SPOT DIMENSIONS AND RELATED CHARACTERISTICS

1 Scope

This document applies to FOCAL SPOTS in medical diagnostic X-RAY TUBE ASSEMBLIES for medical use, operating at X-RAY TUBE VOLTAGES up to and including 150 kV.

This document describes the test methods employing digital detectors for determining:

a) FOCAL SPOT dimensions in terms of NOMINAL FOCAL SPOT VALUES, ranging from 0,1 to 3,0;

b) LINE SPREAD FUNCTIONS;

c) one-dimensional MODULATION TRANSFER FUNCTIONS;

d) FOCAL SPOT PINHOLE RADIOGRAMS,

and the means for indicating compliance.

In informative annexes, STAR PATTERN imaging and BLOOMING VALUE are described.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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, *Graphical symbols for use on equipment* (available at http://www.graphical-symbols.info/equipment)

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

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*
IEC 60601-1-3:2008/AMD1:2013

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

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

3 Terms and definitions

For the purposes of this document, terms and definitions given in IEC TR 60788:2004, IEC 60613:2010, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ACTUAL FOCAL SPOT
area on the surface of the TARGET that intercepts the beam of accelerated particles

Note 1 to entry: Regarding accelerated particles, only the intended primary beam is included.

3.2
BLOOMING VALUE
ratio of two resolution limits obtained under specific LOADING conditions

Note 1 to entry: The BLOOMING VALUE is a characteristic of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE.

3.3
DIGITAL FOCAL SPOT DETECTOR
pixel-array device applied to FOCAL SPOT analysis of X-RAY TUBE ASSEMBLIES, providing a digital output value per pixel which is linearly related to the input X-ray intensity

3.4
EFFECTIVE FOCAL SPOT
FOCAL SPOT
perpendicular PROJECTION of the ACTUAL FOCAL SPOT on the REFERENCE PLANE

3.5
FOCAL SPOT PINHOLE RADIOGRAM
RADIOGRAM obtained by means of a PINHOLE CAMERA, showing the shape and orientation of an EFFECTIVE FOCAL SPOT, and the spatial distribution of intensity of radiation across it

3.6
FOCAL SPOT SLIT RADIOGRAM
RADIOGRAM obtained by means of a SLIT CAMERA, showing the distribution, across an EFFECTIVE FOCAL SPOT, in the direction normal to the length of the slit, of the intensity of the radiation emitted

3.7
FOCAL SPOT STAR RADIOGRAM
RADIOGRAM obtained by means of a STAR PATTERN CAMERA for the determination of the STAR PATTERN RESOLUTION LIMIT in one or more directions across an EFFECTIVE FOCAL SPOT

3.8
NOMINAL FOCAL SPOT VALUE
dimensionless numerical value having a specific relation to the dimensions of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE, measured under specific conditions

3.9
PINHOLE CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT PINHOLE RADIOGRAM

3.10
REFERENCE AXIS
<RADIATION SOURCE> line in the REFERENCE DIRECTION through the centre of the RADIATION SOURCE

3.11
REFERENCE DIRECTION
<RADIATION SOURCE> specified direction to which characteristics such as TARGET ANGLE, RADIATION FIELD and specifications with respect to the imaging quality of the RADIATION SOURCE are referenced

3.12
REFERENCE PLANE
<diagnostic X-RAY EQUIPMENT for an EFFECTIVE FOCAL SPOT> plane perpendicular to the REFERENCE DIRECTION containing the point at which the REFERENCE AXIS intersects with the ACTUAL FOCAL SPOT

Note 1 to entry: By convention, the point of intersection forms the centre of the EFFECTIVE FOCAL SPOT.

3.13
SLIT CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT SLIT RADIOGRAM

3.14
STAR PATTERN CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT STAR RADIOGRAM

3.15
STAR PATTERN RESOLUTION LIMIT
characteristic of the FOCAL SPOT of an X-RAY TUBE, which represents the highest spatial frequency that can be resolved under specific measuring conditions

3.16
TARGET
part of an X-RAY TUBE or a PARTICLE ACCELERATOR onto which is directed a beam of accelerated particles to produce IONIZING RADIATION or other particles

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 Clause 4 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.

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.

NOTE The direction of evaluation for the FOCAL SPOT length is normally parallel to the longitudinal axis of the X-RAY TUBE ASSEMBLY. See Figure A.1.