SVENSK STANDARD SS-EN IEC 60336

Fastställd	Utgåva	Sida	Ansvarig kommitté
2021-10-20	3	1 (1+46)	SEK TK 62BC

Elektrisk utrustning för medicinskt bruk – Röntgenrör för diagnostik – Fokusstorlek och tillhörande karakteristika

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

Som svensk standard gäller europastandarden EN IEC 60336:2021. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 60336:2021.

Nationellt förord

Europastandarden EN IEC 60336:2021

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60336, Fifth edition, 2020 - Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics**

utarbetad inom International Electrotechnical Commission, IEC.

Tidigare fastställd svensk standard SS-EN 60336, utgåva 2, 2005, gäller ej fr o m 2024-01-21.

ICS 11.040.50

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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)

This European Standard was approved by CENELEC on 2021-01-21. 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.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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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

Ref. No. EN IEC 60336:2021 E

SEK Svensk Elstandard SS-EN IEC 60336, utg 3:2021

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

SEK Svensk Elstandard

SS-EN IEC 60336, utg 3:2021

IEC 60336:2020-12(en-fr)

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IEC 60336

Edition 5.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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INTERNATIONAL
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CONTENTS

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.

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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*