



NSAI
Standards

Irish Standard
I.S. EN IEC 60336:2021

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

I.S. EN IEC 60336:2021

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN IEC 60336:2021 is the adopted Irish version of the European Document EN IEC 60336:2021, Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics

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EUROPEAN STANDARD

EN IEC 60336

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

EN IEC 60336:2021 (E)

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- latest date by which the national standards conflicting with the (dow) 2024-01-21 document have to be withdrawn

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	-	-

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IEC 60336

Edition 5.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**





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IEC 60336

Edition 5.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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.

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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*

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.

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