

© Copyright SEK Svensk Elstandard. Reproduction in any form without permission is prohibited.

## 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.

### *Standarder underlättar utvecklingen och höjer elsäkerheten*

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

### *SEK är Sveriges röst i standardiseringsarbetet inom elområdet*

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

### *Stora delar av arbetet sker internationellt*

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

### *Var med och påverka!*

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

### **SEK Svensk Elstandard**

Box 1284  
164 29 Kista  
Tel 08-444 14 00  
[www.elstandard.se](http://www.elstandard.se)

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.

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.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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 (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

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](http://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                                                                                                                           | -                  | -           |

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



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

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



## THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

#### IEC publications search - [webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

#### IEC Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [sales@iec.ch](mailto:sales@iec.ch).

#### Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

#### IEC Glossary - [std.iec.ch/glossary](http://std.iec.ch/glossary)

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

---

### A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

### A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

#### Recherche de publications IEC -

[webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

#### Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [sales@iec.ch](mailto:sales@iec.ch).

**Electropedia** - [www.electropedia.org](http://www.electropedia.org)

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

#### Glossaire IEC - [std.iec.ch/glossary](http://std.iec.ch/glossary)

67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

# 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**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

---

ICS 11.040.50

ISBN 978-2-8322-9162-7

|                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Warning! Make sure that you obtained this publication from an authorized distributor.</b></p> <p><b>Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.</b></p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



## CONTENTS

|                                                                                                                           |    |
|---------------------------------------------------------------------------------------------------------------------------|----|
| FOREWORD.....                                                                                                             | 5  |
| 1 Scope.....                                                                                                              | 7  |
| 2 Normative references .....                                                                                              | 7  |
| 3 Terms and definitions .....                                                                                             | 7  |
| 4 Determinations for the evaluation of the FOCAL SPOT characteristics.....                                                | 9  |
| 4.1 Statement of the FOCAL SPOT characteristics.....                                                                      | 9  |
| 4.2 Longitudinal axis of the X-RAY TUBE ASSEMBLY .....                                                                    | 9  |
| 4.3 REFERENCE AXIS of the X-RAY TUBE ASSEMBLY .....                                                                       | 9  |
| 4.4 Direction of evaluation for the FOCAL SPOT length .....                                                               | 9  |
| 4.5 Direction of evaluation for the FOCAL SPOT width.....                                                                 | 10 |
| 4.6 Directions of evaluation for distorted FOCAL SPOTS.....                                                               | 10 |
| 5 FOCAL SPOT camera set-up.....                                                                                           | 10 |
| 5.1 Overview.....                                                                                                         | 10 |
| 5.2 Diaphragm of the SLIT CAMERA .....                                                                                    | 10 |
| 5.3 Diaphragm of the PINHOLE CAMERA.....                                                                                  | 11 |
| 5.4 Receptor .....                                                                                                        | 12 |
| 5.5 Test arrangement.....                                                                                                 | 12 |
| 5.5.1 Position of the slit or pinhole diaphragm normal to the REFERENCE AXIS.....                                         | 12 |
| 5.5.2 Position of the slit or pinhole diaphragm along the REFERENCE AXIS.....                                             | 13 |
| 5.5.3 Orientation of the slit or pinhole diaphragm.....                                                                   | 14 |
| 5.5.4 Position and orientation of the receptor of the DIGITAL FOCAL SPOT<br>DETECTOR.....                                 | 14 |
| 5.6 Total uncertainty of the camera set-up .....                                                                          | 15 |
| 6 Production of RADIOGRAMS .....                                                                                          | 16 |
| 6.1 Overview.....                                                                                                         | 16 |
| 6.2 Operating conditions .....                                                                                            | 16 |
| 6.2.1 X-RAY TUBE ASSEMBLY .....                                                                                           | 16 |
| 6.2.2 LOADING FACTORS .....                                                                                               | 16 |
| 6.2.3 Special LOADING FACTORS .....                                                                                       | 17 |
| 6.2.4 Special arrangements .....                                                                                          | 17 |
| 6.3 Production of FOCAL SPOT SLIT RADIOGRAMS, FOCAL SPOT PINHOLE RADIOGRAMS<br>and FOCAL SPOT LINE SPREAD FUNCTIONS ..... | 17 |
| 6.3.1 DIGITAL FOCAL SPOT DETECTOR requirements for FOCAL SPOT SLIT<br>RADIOGRAMS.....                                     | 17 |
| 6.3.2 DIGITAL FOCAL SPOT DETECTOR requirements for FOCAL SPOT PINHOLE<br>RADIOGRAMS .....                                 | 17 |
| 6.3.3 Determination of the RADIOGRAMS and of the LINE SPREAD FUNCTIONS .....                                              | 18 |
| 6.4 Statement of compliance of the FOCAL SPOT PINHOLE RADIOGRAM.....                                                      | 18 |
| 6.5 Statement of compliance of LINE SPREAD FUNCTIONS .....                                                                | 18 |
| 7 Determination of FOCAL SPOT dimensions and NOMINAL FOCAL SPOT VALUES .....                                              | 19 |
| 7.1 Overview.....                                                                                                         | 19 |
| 7.2 Measurement and determination of FOCAL SPOT dimensions .....                                                          | 19 |
| 7.3 Specified NOMINAL FOCAL SPOT VALUES .....                                                                             | 19 |
| 7.3.1 Nominal values .....                                                                                                | 19 |
| 7.3.2 Actual dimensions .....                                                                                             | 20 |
| 7.4 Statement of compliance.....                                                                                          | 21 |
| 7.5 Marking of compliance .....                                                                                           | 21 |

|     |                                                                                                                                         |    |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------|----|
| 8   | Determination of the MODULATION TRANSFER FUNCTION .....                                                                                 | 22 |
| 8.1 | Overview.....                                                                                                                           | 22 |
| 8.2 | Calculation and presentation of the MODULATION TRANSFER FUNCTION.....                                                                   | 22 |
| 8.3 | Statement of compliance.....                                                                                                            | 22 |
| 9   | Alternative measurement methods for determining NOMINAL FOCAL SPOT VALUES.....                                                          | 23 |
|     | Annex A (informative) Alignment to the REFERENCE AXIS .....                                                                             | 24 |
|     | Annex B (informative) FOCAL SPOT STAR RADIOGRAM .....                                                                                   | 26 |
|     | B.1 Overview.....                                                                                                                       | 26 |
|     | B.2 Test EQUIPMENT .....                                                                                                                | 26 |
|     | B.2.1 STAR PATTERN CAMERA.....                                                                                                          | 26 |
|     | B.2.2 RADIOGRAPHIC FILM.....                                                                                                            | 27 |
|     | B.2.3 Position of the STAR PATTERN CAMERA normal to the REFERENCE AXIS .....                                                            | 27 |
|     | B.2.4 Position of the STAR PATTERN CAMERA in REFERENCE DIRECTION .....                                                                  | 27 |
|     | B.2.5 Alignment of the STAR PATTERN CAMERA.....                                                                                         | 27 |
|     | B.2.6 Position of the RADIOGRAPHIC FILM .....                                                                                           | 28 |
|     | B.2.7 Operating conditions.....                                                                                                         | 28 |
|     | B.2.8 Production of the FOCAL SPOT STAR RADIOGRAM.....                                                                                  | 28 |
|     | Annex C (informative) STAR PATTERN RESOLUTION LIMIT .....                                                                               | 29 |
|     | C.1 Overview.....                                                                                                                       | 29 |
|     | C.2 Measurement.....                                                                                                                    | 29 |
|     | C.3 Determination of the STAR PATTERN RESOLUTION LIMIT.....                                                                             | 30 |
|     | C.3.1 Determination of the magnification.....                                                                                           | 30 |
|     | C.3.2 STAR PATTERN RESOLUTION LIMIT for standard magnification .....                                                                    | 30 |
|     | C.3.3 STAR PATTERN RESOLUTION LIMIT for finite magnification .....                                                                      | 30 |
|     | C.3.4 Presentation of STAR PATTERN RESOLUTION LIMIT .....                                                                               | 31 |
|     | Annex D (informative) BLOOMING VALUE .....                                                                                              | 32 |
|     | D.1 Overview.....                                                                                                                       | 32 |
|     | D.2 Determination of the BLOOMING VALUE.....                                                                                            | 32 |
|     | Annex E (informative) Historical background.....                                                                                        | 33 |
|     | E.1 Overview.....                                                                                                                       | 33 |
|     | E.2 First edition (1970).....                                                                                                           | 33 |
|     | E.3 Second edition (1982) .....                                                                                                         | 33 |
|     | E.4 Third edition (1993).....                                                                                                           | 33 |
|     | E.5 Fourth edition (2005) .....                                                                                                         | 36 |
|     | E.6 Fifth edition (2020).....                                                                                                           | 37 |
|     | E.6.1 Overview .....                                                                                                                    | 37 |
|     | E.6.2 Fifth edition technical details .....                                                                                             | 37 |
|     | Bibliography.....                                                                                                                       | 42 |
|     | Index of defined terms .....                                                                                                            | 43 |
|     | Figure 1 – Directions of evaluation over distorted FOCAL SPOTS .....                                                                    | 10 |
|     | Figure 2 – Essential dimensions of the slit diaphragm .....                                                                             | 11 |
|     | Figure 3 – Essential dimensions of the pinhole diaphragm .....                                                                          | 12 |
|     | Figure 4 – Position of the centre of the slit or pinhole diaphragm (marked as x in the figure) with respect to the REFERENCE AXIS ..... | 13 |
|     | Figure 5 – Reference dimensions and planes.....                                                                                         | 14 |

|                                                                                                                     |    |
|---------------------------------------------------------------------------------------------------------------------|----|
| Figure 6 – Alignment of the receptor of the DIGITAL FOCAL SPOT DETECTOR with respect to the slit diaphragm .....    | 15 |
| Figure 7 – LINE SPREAD FUNCTION .....                                                                               | 19 |
| Figure 8 – Graphical symbols – FOCAL SPOTS.....                                                                     | 21 |
| Figure A.1 – REFERENCE AXIS and directions of evaluation .....                                                      | 24 |
| Figure A.2 – PROJECTION of the ACTUAL FOCAL SPOT on the IMAGE RECEPTION PLANE .....                                 | 25 |
| Figure B.1 – Essential dimensions of the star test pattern.....                                                     | 26 |
| Figure B.2 – Alignment of the STAR PATTERN CAMERA .....                                                             | 27 |
| Figure C.1 – Illustration of the zones of minimum modulation.....                                                   | 29 |
| Figure E.1 – LSFs for a typical X-RAY TUBE with small FOCAL SPOT ( $< 0,3$ mm).....                                 | 34 |
| Figure E.2 – LSFs for a typical X-RAY TUBE with large FOCAL SPOT ( $\geq 0,3$ mm) .....                             | 35 |
| Figure E.3 – Corresponding MTFs for the LSFs in Figure E.2.....                                                     | 35 |
| Figure E.4 – Percentage error of 15 % width.....                                                                    | 38 |
| Figure E.5 – Percentage error of LINE SPREAD FUNCTION width at 15 % .....                                           | 39 |
| Figure E.6 – Influence of the direction of evaluation on MTF-quality and on LINE SPREAD FUNCTION width at 15 %..... | 40 |
| Table 1 – Recommended enlargement for RADIOGRAMS.....                                                               | 15 |
| Table 2 – LOADING FACTORS.....                                                                                      | 16 |
| Table 3 – Maximum permissible values of FOCAL SPOT dimensions for NOMINAL FOCAL SPOT VALUES.....                    | 20 |
| Table C.1 – Standard magnifications for STAR PATTERN RESOLUTION LIMIT .....                                         | 30 |
| Table D.1 – LOADING FACTORS for the determination of the BLOOMING VALUE .....                                       | 32 |
| Table E.1 – Methods for evaluation of specific aspects characterising the FOCAL SPOT .....                          | 37 |

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

**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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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*