

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

The European Standard EN 60336:2005 has the status of a
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National foreword

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The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment, which has the responsibility to:

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
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**Medical electrical equipment –
X-ray tube assemblies for medical diagnosis –
Characteristics of focal spots
(IEC 60336:2005)**

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

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

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CENELEC

European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

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Foreword

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The following dates were fixed:

- | | | |
|--|-------|------------|
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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).

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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

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

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.

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

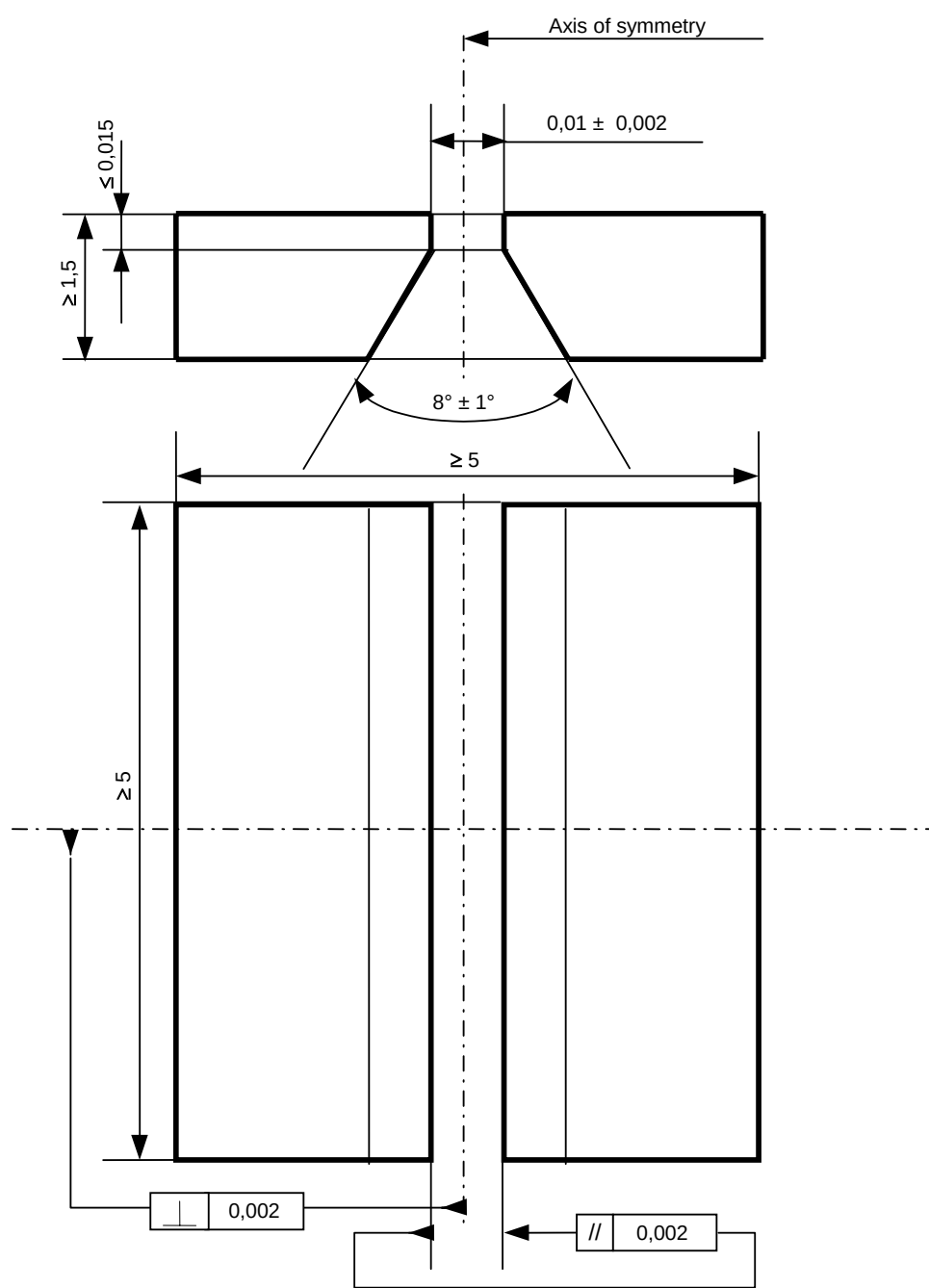
The diaphragm of the SLIT CAMERA shall be made from materials with high ATTENUATION properties and shall have dimensions as given in Figure 1.

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;

Dimensions in millimetres

Not drawn to scale



IEC 526/05

Figure 1 – Essential dimensions of the slit diaphragm

5.2.2 PINHOLE CAMERA

The diaphragm of the PINHOLE CAMERA shall be constructed from materials with high ATTENUATION and shall have dimensions as given in Figure 2.

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.

Dimensions in millimetres

Not drawn to scale

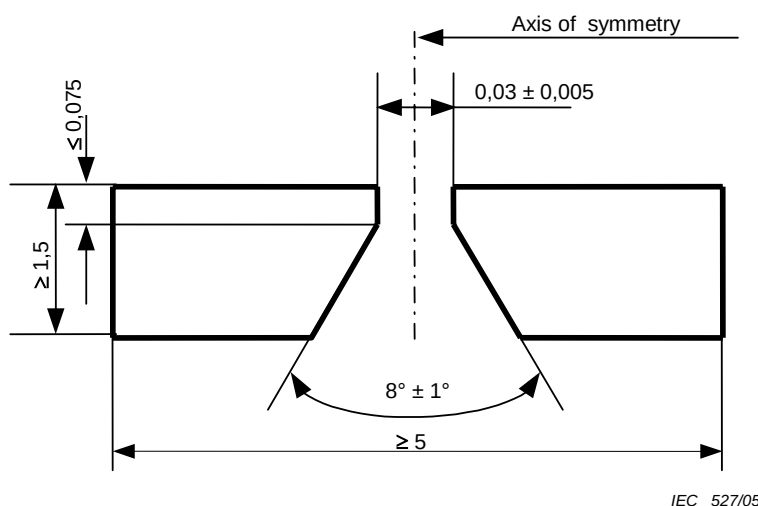


Figure 2 – Essential dimensions of the pinhole diaphragm

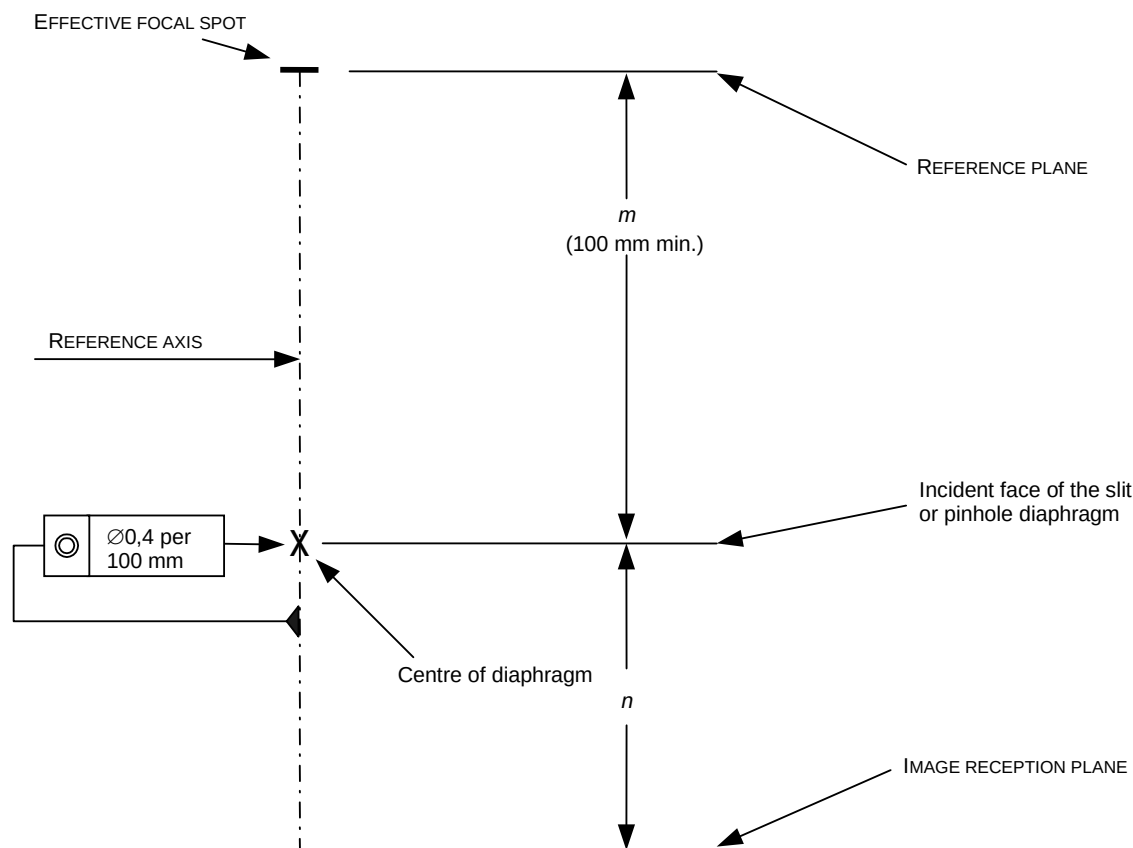
5.2.3 RADIOGRAPHIC FILM

FOCAL SPOT SLIT RADIOGRAMS OR FOCAL SPOT PINHOLE RADIOGRAMS shall be made using fine-grain radiographic film, for example dental radiographic film, without INTENSIFYING SCREENS.

5.3 Test arrangement

5.3.1 Position of the slit or pinhole diaphragm normal to the REFERENCE AXIS

The slit or pinhole diaphragm shall be positioned in such a way that the distance from its centre to the REFERENCE AXIS is within 0,2 mm per 100 mm of m (as indicated in Figure 3).



IEC 528/05

Figure 3 – Position of the centre of the slit or pinhole diaphragm (marked as x in the figure) with respect to the REFERENCE AXIS

5.3.2 Position of the slit or pinhole diaphragm along the REFERENCE AXIS

The incident face of the slit or pinhole diaphragm shall be placed at a distance from the REFERENCE PLANE sufficient to ensure that the variation of the enlargement over the extension of the ACTUAL FOCAL SPOT does not exceed $\pm 5\%$ along the REFERENCE AXIS (see Figure 4). This is met when

$$p < 5 \text{ mm and } k < 5 \text{ mm per 100 mm of distance } m;$$

where

k is the distance from the REFERENCE PLANE to the edge of the ACTUAL FOCAL SPOT farthest away from the slit or pinhole diaphragm;

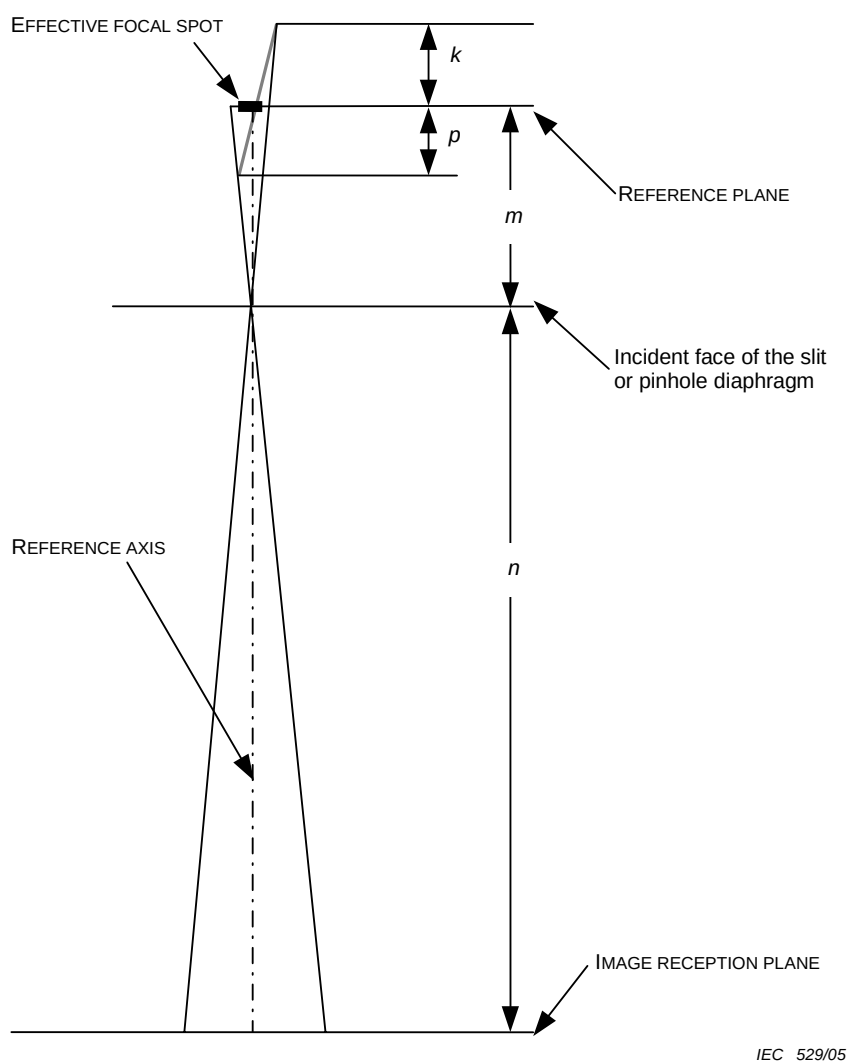
p is the distance from the REFERENCE PLANE to the edge of the ACTUAL FOCAL SPOT closest to the slit or pinhole diaphragm;

m is the distance from the REFERENCE PLANE to the incident face of the diaphragm;

n is the distance from the incident face of the diaphragm to the IMAGE RECEPTION PLANE;

E is the enlargement given by n/m .

The distance from the FOCAL SPOT to the slit or pinhole diaphragm shall not be less than 100 mm.



IEC 529/05

Figure 4 – Reference dimensions and planes

5.3.3 Orientation of the slit or pinhole diaphragm

The axis of symmetry (see Figures 1 and 2) shall be aligned with the REFERENCE AXIS forming an angle that is smaller than 1° .

For the production of a pair of FOCAL SPOT SLIT RADIOGRAMS, the slit diaphragm shall be orientated such that the length of the slit is normal to the direction of evaluation within $\pm 1^\circ$.

5.3.4 Position of the RADIOGRAPHIC FILM

The RADIOGRAPHIC FILM should be placed in the IMAGE RECEPTION PLANE normal to the REFERENCE AXIS within $\pm 1^\circ$ and at a distance from the incident face of the slit or pinhole diaphragm determined from the appropriate enlargement according to Table 1. The enlargement E shall be determined with an accuracy to within $\pm 3\%$.

Table 1 – Enlargement for FOCAL SPOT RADIOGRAMS

NOMINAL FOCAL SPOT VALUE (f) ^a	Enlargement ($E = n / m$) ^b
$f \leq 0,4$	$E \geq 3$
$0,4 < f < 1,1$	$E > 2$
$1,1 \leq f$	$E \geq 1$
^a See 8.3. ^b See Figure 4.	

5.4 Total uncertainty of the camera set-up

The uncertainty in the FOCAL SPOT measurement contributed by the set-up of the FOCAL SPOT camera shall not exceed ± 5 %.

6 Production of RADIOGRAMS

6.1 Overview

This clause deals with production of FOCAL SPOT SLIT RADIOGRAMS and FOCAL SPOT PINHOLE RADIOGRAMS.

A method of indicating compliance with this standard of FOCAL SPOT SLIT RADIOGRAMS and FOCAL SPOT PINHOLE RADIOGRAMS is included.

6.2 Operating conditions

6.2.1 FOCAL SPOT SLIT RADIOGRAMS and FOCAL SPOT PINHOLE RADIOGRAMS

FOCAL SPOT SLIT RADIOGRAMS and FOCAL SPOT PINHOLE RADIOGRAMS shall be produced using a FOCAL SPOT camera according to Clause 5. Requirements for determining FOCAL SPOT dimensions from FOCAL SPOT SLIT RADIOGRAMS are described in Clause 8; requirements for determining the MODULATION TRANSFER FUNCTION are described in Clause 9.

FOCAL SPOT PINHOLE RADIOGRAMS are used only for showing the orientation, the symmetry and the distribution of radiant intensity over the FOCAL SPOT.

6.2.2 X-RAY TUBE ASSEMBLY

The X-RAY TUBE shall be installed in an X-RAY TUBE HOUSING of the type for which it is specified for NORMAL USE or it shall be placed under equivalent mounting and operating conditions as far as these can influence the results of the test.

No ADDITIONAL FILTRATION shall be used to decrease the X-ray output flux unless it is verified that the ADDITIONAL FILTRATION has no significant effect on the LINE SPREAD FUNCTION. However, all the materials belonging to the X-RAY TUBE ASSEMBLY in NORMAL USE shall be installed.

6.2.3 LOADING FACTORS

FOCAL SPOT SLIT RADIOGRAMS or FOCAL SPOT PINHOLE RADIOGRAMS for X-ray tube assemblies used in projection radiography or in COMPUTED TOMOGRAPHY shall be obtained with constant LOADING FACTORS in accordance with Table 2.