BRITISH STANDARD

BS EN 60336:2005

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 British Standard

ICS 11.040.50

BSi

British Standards

National foreword

This British Standard is the official English language version of EN 60336:2005. It is identical with IEC 60336:2005. It supersedes BS EN 60336:1995 which will be withdrawn on 1 June 2008.

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:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60336

July 2005

English version

Medical electrical equipment –
X-ray tube assemblies for medical diagnosis –
Characteristics of focal spots
(IEC 60336:2005)

Appareils électromédicaux –
Gaines 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
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62B/554/FDIS, future edition 4 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 was approved by CENELEC as EN 60336 on 2005-06-01.

This European Standard supersedes EN 60336:1995.

The following dates were fixed:

–   latest date by which the EN has to be implemented
    at national level by publication of an identical
    national standard or by endorsement   (dop)   2006-03-01

–   latest date by which the national standards conflicting
    with the EN have to be withdrawn   (dow)   2008-06-01

Annex ZA has been added by CENELEC.

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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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CONTENTS

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

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[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
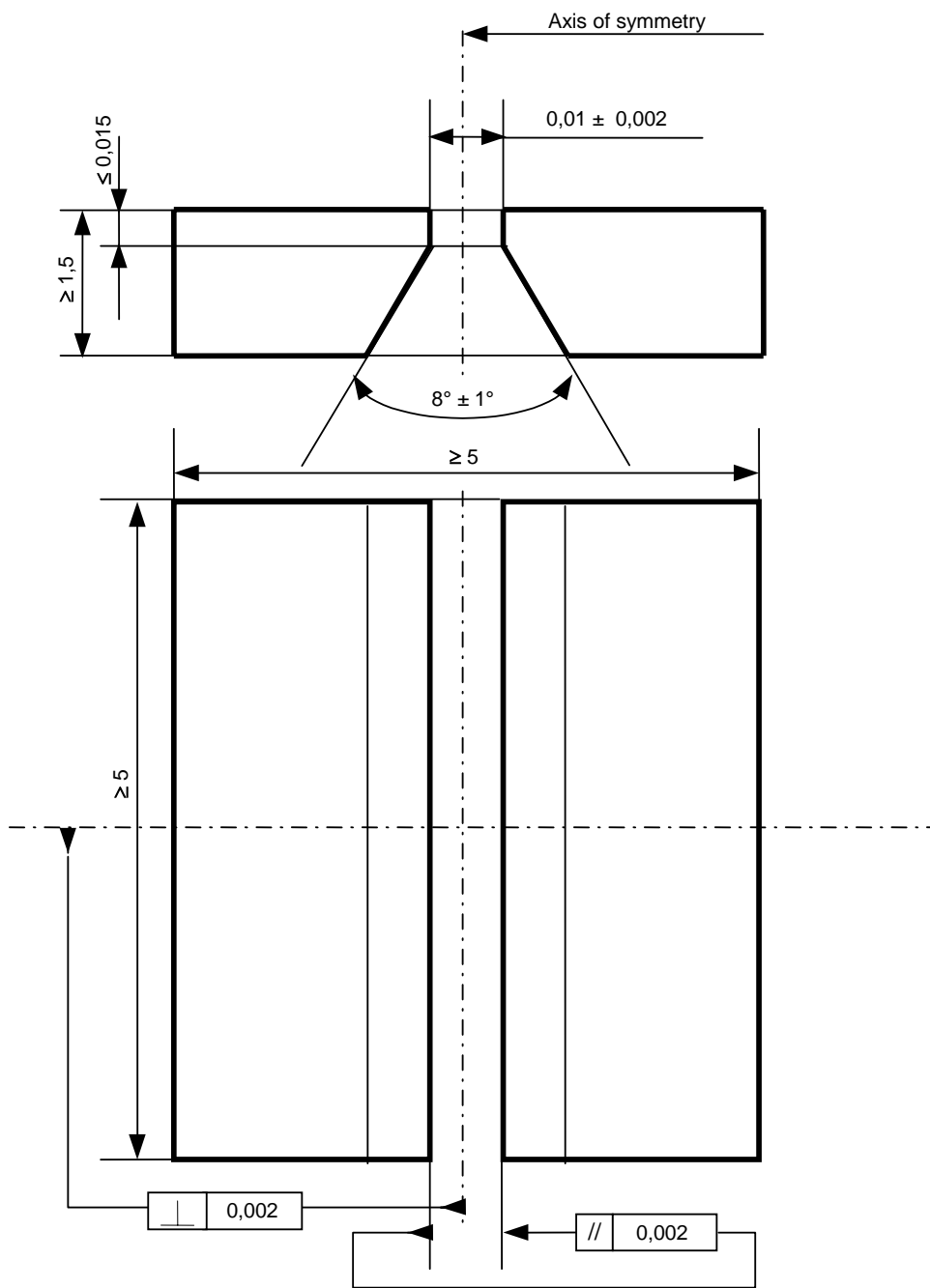
Figure 1 – Essential dimensions of the slit diaphragm

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

IEC   527/05
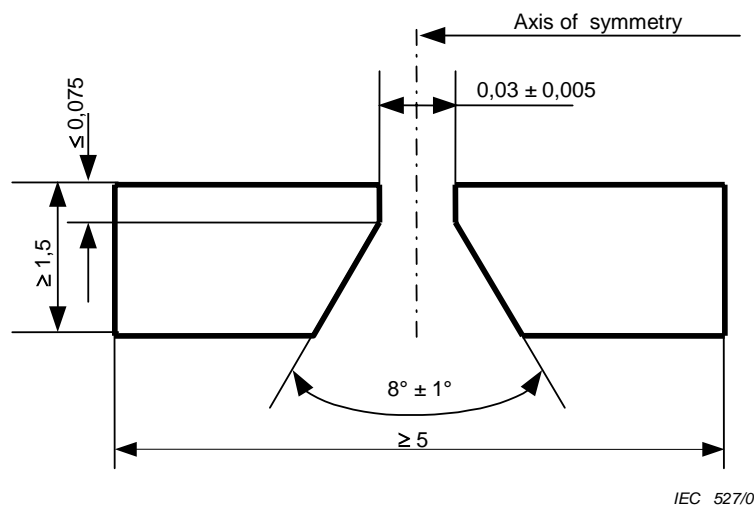
Figure 2 – Essential dimensions of the pinhole diaphragm

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).

EFFECTIVE FOCAL SPOT

REFERENCE PLANE

m
(100 mm min.)

REFERENCE AXIS

∅0,4 per
100 mm

Incident face of the slit
or pinhole diaphragm

Centre of diaphragm

n

IMAGE RECEPTION PLANE
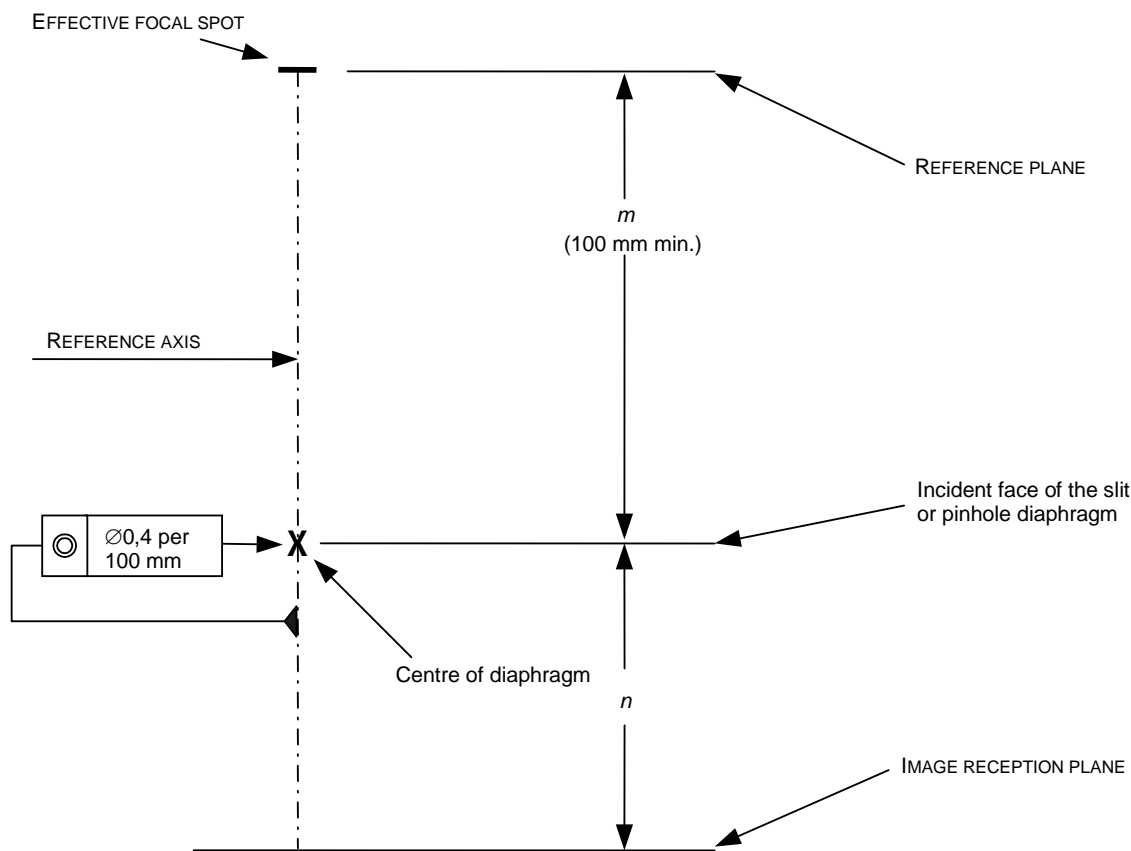
IEC   528/05

**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 ± 5 % along the REFERENCE AXIS (see Figure 4). This is met when

   $p < 5$ mm and $k < 5$ 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.
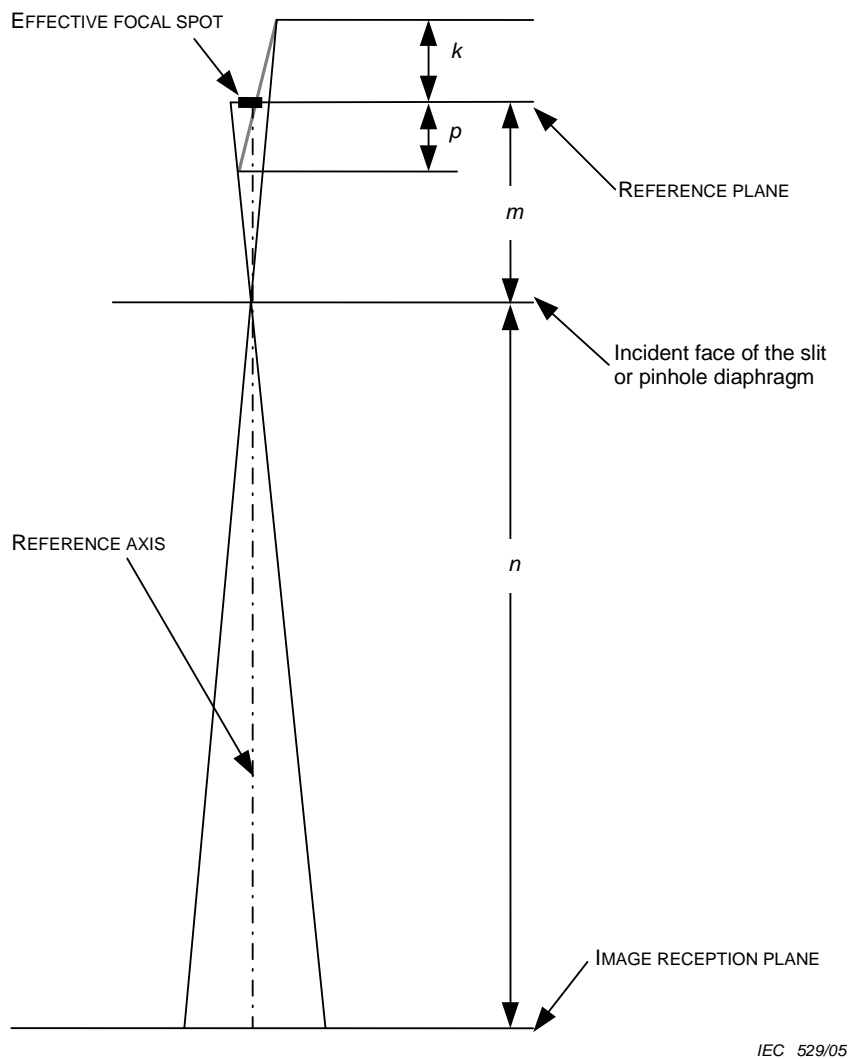
IEC 529/05

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 ±1°.

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 ±1° 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 ±3 %.

Table 1 – Enlargement for FOCAL SPOT RADIOGRAMS

NOMINAL FOCAL SPOT VALUE (*f*) [a]	Enlargement (*E = n / m*) [b]
f ≤ 0,4	*E* ≥ 3
0,4 < *f* < 1,1	*E* > 2
1,1 ≤ *f*	*E* ≥ 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.

For ROTATING ANODE X-RAY TUBES, the ANODE shall be rotated at the highest ANODE SPEED specified in the applicable RADIOGRAPHIC RATINGS.

Table 2 – LOADING FACTORS

	NOMINAL X-RAY TUBE VOLTAGE kV	Required X-RAY TUBE VOLTAGE	Exposure time	Required X-RAY TUBE power
RADIOGRAPHY other than COMPUTED TOMOGRAPHY	$U < 75$	NOMINAL X-RAY TUBE VOLTAGE	As required to meet the optical density requirement, see 6.3.3	50 % of the NOMINAL ANODE INPUT POWER as specified by IEC 60613
	$75 \leq U \leq 150$	75 kV		
	$150 < U \leq 200$	50 % of the NOMINAL X-RAY TUBE VOLTAGE		
COMPUTED TOMOGRAPHY		120 kV		

6.2.4 Special LOADING FACTORS

If the LOADING FACTORs according to Table 2 do not fall within the RADIOGRAPHIC RATINGS for the X-RAY TUBE concerned or if they otherwise do not cover the typical special applications of specified NORMAL USE of the X-RAY TUBE, LOADING FACTORs shall be chosen to correspond to those specific conditions. In this case, the LOADING FACTORs under which the FOCAL SPOT SLIT RADIOGRAMs or FOCAL SPOT PINHOLE RADIOGRAMs were obtained shall be stated together with the characteristics.

In particular cases, it may be appropriate to state the characteristics of a FOCAL SPOT under multiple LOADING conditions.

6.2.5 Special arrangements

If, for the purpose of production of suitable FOCAL SPOT RADIOGRAMs, special arrangements were made for the adjustment and alignment of either the SLIT CAMERA and X-RAY TUBE ASSEMBLY or if special electrical or LOADING conditions prevailed, details shall be stated together with the characteristics in the statement of compliance.

6.3 Production of FOCAL SPOT SLIT RADIOGRAMS or FOCAL SPOT PINHOLE RADIOGRAMS

6.3.1 Production of FOCAL SPOT SLIT RADIOGRAMS

A pair of FOCAL SPOT SLIT RADIOGRAMs shall be made with the operating conditions described in 6.2.

6.3.2 Production of FOCAL SPOT PINHOLE RADIOGRAMS

FOCAL SPOT PINHOLE RADIOGRAMs shall be made with the operating conditions described in 6.2.

6.3.3 RADIOGRAPHIC FILM exposure

The RADIOGRAPHIC FILM shall be exposed so that, after development, a local diffuse density between 1,0 and 1,4 is obtained in areas of greatest blackening. The blackening of the film due to fog and base shall not exceed a diffuse density of 0,25.

6.4 Statement of compliance

If compliance with this standard is to be stated for a pair of FOCAL SPOT SLIT RADIOGRAMS or for a FOCAL SPOT PINHOLE RADIOGRAM, it shall be stated as follows:

FOCAL SPOT SLIT RADIOGRAM with enlargement of....[2] according to IEC 60336 or FOCAL SPOT PINHOLE RADIOGRAM with enlargement of ...[3] according to IEC 60336

and as appropriate: Subclause

REFERENCE AXIS   4.3

LOADING FACTORS   6.2.3

Special arrangements   6.2.5

Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY   4.2

7 Determination of the LINE SPREAD FUNCTION

7.1 Overview

This clause deals with the determination of a pair of LINE SPREAD FUNCTIONS 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. These LINE SPREAD FUNCTIONS shall be deduced from FOCAL SPOT SLIT RADIOGRAMS.

A method of indicating compliance with this standard of a pair of LINE SPREAD FUNCTIONS is included.

7.2 Measuring equipment and measuring arrangement

The FOCAL SPOT SLIT RADIOGRAMS obtained in accordance with Clause 5 and Clause 6 shall be scanned by means of an optical densitometer. The aperture of the optical densitometer shall have a width b not exceeding the width of the slit diaphragm used for the production of the FOCAL SPOT SLIT RADIOGRAMS.

The length of the aperture of the optical densitometer shall be limited, so that it can be aligned with the direction of the diaphragm slit projected on the RADIOGRAM in such a way that the effective width b_{eff} of the optical densitometer aperture normal to the direction of the projected diaphragm slit will be smaller than twice the width b of the optical densitometer aperture, as shown in Figure 5.

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[2] Enlargement used and determined in accordance with Clause 5.

[3] Enlargement used and determined in accordance with Clause 5.
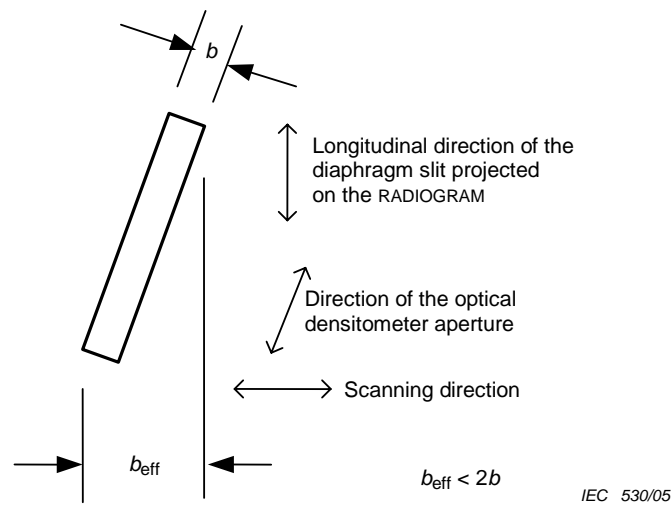
Figure 5 – Alignment of the optical densitometer slit

7.3   Measurement of the density distribution

The density distribution of each FOCAL SPOT SLIT RADIOGRAM shall be scanned normal to its longitudinal direction at the centre half of its length. The scanning direction shall be aligned normal to the direction of the diaphragm slit to within ±2°.

The total range scanned divided by the enlargement E used to acquire the FOCAL SPOT SLIT RADIOGRAM shall be at least four times the maximum allowed value relating to the claimed NOMINAL FOCAL SPOT VALUE.

The results of this measurement shall be presented as a curve showing density over the width of the RADIOGRAM.

7.4   Determination of the LINE SPREAD FUNCTION

The values of density above base and fog shall be transformed into a curve showing the linear distribution over the width of the RADIOGRAM of the radiant intensity, by means of a densitometric curve showing the relation between radiant intensity and density.

The densitometric curve shall be established using an identical RADIOGRAPHIC FILM processed under the same conditions as those used for the FOCAL SPOT SLIT RADIOGRAM.

The LINE SPREAD FUNCTION shall be deduced from the curve showing the linear distribution of the radiant intensity over the width of the RADIOGRAM, where the axis values in the scanning direction are divided by the enlargement E used to acquire the FOCAL SPOT SLIT RADIOGRAM.

7.5   Statement of compliance

If compliance with this standard for a LINE SPREAD FUNCTION is to be stated, this shall be done as follows:

LINE SPREAD FUNCTION according to IEC 60336

and as appropriate: Subclause

REFERENCE AXIS   4.3

LOADING FACTORS   6.2.3

Special arrangements   6.2.5

Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY   4.2

8   Determination of FOCAL SPOT dimensions

8.1   Overview

This clause deals with the determination of the FOCAL SPOT dimensions on the basis of a pair of LINE SPREAD FUNCTIONS. These functions shall be obtained from a pair of FOCAL SPOT SLIT RADIOGRAMS as described in Clause 6.

Criteria for compliance with this standard and the method of indicating NOMINAL FOCAL SPOT VALUES in compliance with this standard are included.

8.2   Measurement and determination

The actual dimension of the FOCAL SPOT shall be determined as the size of the related LINE SPREAD FUNCTION according to Clause 7 measured at 15 % of the peak value, as shown in Figure 6.
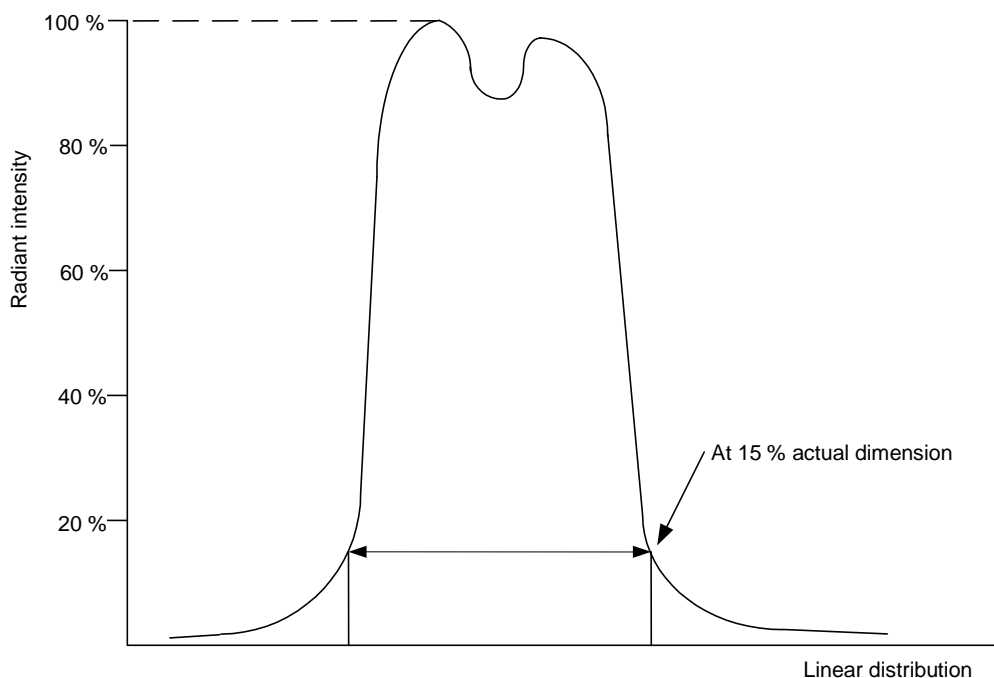
IEC   531/05

Figure 6 – LINE SPREAD FUNCTION

8.3   Specified NOMINAL FOCAL SPOT VALUES

8.3.1   Nominal values

The FOCAL SPOTs of each type of X-ray tube assembly, NOMINAL FOCAL SPOT VALUES shall be assigned, being the numbers

– from 0,1 to 0,25 in steps of 0,05,

– from 0,3 to 2,0 in steps of 0,1, and

– from 2,2 and upwards in steps of 0,2.

The FOCAL SPOTs of X-RAY TUBE assemblies specified for special applications (such as for CT) shall be stated in NOMINAL FOCAL SPOT VALUES consisting of a pair of numbers, for example 1,0 × 1,6, where the first number refers to the width of the EFFECTIVE FOCAL SPOT in the direction normal to the REFERENCE AXIS or the axis of the X-RAY TUBE ASSEMBLY, and the second to the length of the EFFECTIVE FOCAL SPOT in the direction parallel to that axis. This pair of values shall be stated in the same steps as given above.

8.3.2   Actual values

The NOMINAL FOCAL SPOT VALUE shall be related to the dimensions in the two directions of evaluation over the FOCAL SPOT so that the actual values for the width and the length of the FOCAL SPOT determined in accordance with 8.2 are smaller than the maximum permissible values for width and length given in Table 3.

Each number of a pair of FOCAL SPOT values for special applications such as for CT shall be related to the NOMINAL FOCAL SPOT VALUE in Table 3 using the column of maximum permissible values for width only.

For these determinations, no correction is required for measurement errors.

**Table 3 – Maximum permissible values of FOCAL SPOT dimensions
for NOMINAL FOCAL SPOT VALUES**

NOMINAL FOCAL SPOT VALUE	FOCAL SPOT dimensions, Maximum permissible values mm	
f	Width	Length
0,1	0,15	0,15
0,15	0,23	0,23
0,2	0,30	0,30
0,25	0,38	0,38
0,3	0,45	0,65
0,4	0,60	0,85
0,5	0,75	1,10
0,6	0,90	1,30
0,7	1,10	1,50
0,8	1,20	1,60
0,9	1,30	1,80
1,0	1,40	2,00
1,1	1,50	2,20
1,2	1,70	2,40
1,3	1,80	2,60
1,4	1,90	2,80
1,5	2,00	3,00
1,6	2,10	3,10
1,7	2,20	3,20
1,8	2,30	3,30
1,9	2,40	3,50
2,0	2,60	3,70
2,2	2,90	4,00
2.4	3,10	4,40
2,6	3,40	4,80
2,8	3,60	5,20
3,0	3,90	5,60

NOTE For NOMINAL FOCAL SPOT VALUES 0,3 to 3,0, the maximum permissible values for the length have been adjusted with the factor 0,7 (see Annex C).

8.4 Statement of compliance

If compliance with this standard for one or more NOMINAL FOCAL SPOT VALUES is to be stated, this shall be done:

– as plain numbers (no units to be quoted), for example:
NOMINAL FOCAL SPOT VALUE 0,6 in accordance with IEC 60336 Ed.4.

– or as a pair of plain numbers for special application X-RAY TUBE ASSEMBLIES (see 8.3.1), no units to be quoted, for example:
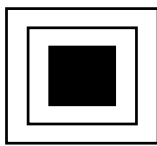NOMINAL FOCAL SPOT VALUES 1,0 x 0,6 in accordance with IEC 60336 Ed.4.

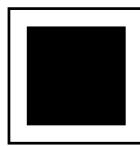| and as appropriate:	Subclause
REFERENCE AXIS	4.3
LOADING FACTORS	6.2.3
Special arrangements	6.2.5
Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY	4.2

8.5 Marking of compliance

If compliance with this standard for one or more specified NOMINAL FOCAL SPOT VALUES is to be marked on X-RAY TUBE assemblies, or otherwise to be stated in a shortened form, this shall be done as follows, using graphical symbols of IEC 60417, for example:

Symbol IEC 60417-5325 (DB:2002-10)	Symbol IEC 60417-5326 (DB:2002-10)	Symbol IEC 60417-5327 (DB:2002-10)
0,6 IEC 60336	1,0 x 1,6 IEC 60336	1,8 x 1,2 IEC 60336

9 Determination of the MODULATION TRANSFER FUNCTION

9.1 Overview

This clause deals with the determination of the one-dimensional MODULATION TRANSFER FUNCTIONS belonging to the FOCAL SPOT of an X-RAY TUBE ASSEMBLY on the basis of a pair of LINE SPREAD FUNCTIONS.

Criteria for compliance with this standard and a method of indicating modulation transfer functions in compliance with this standard are included.

9.2 Specified MODULATION TRANSFER FUNCTION

If the statement of the modulation transfer function is required, a pair of one-dimensional modulation transfer functions of the geometry of each FOCAL SPOT shall be specified for each type of X-RAY TUBE ASSEMBLY.

If compliance for an individual X-RAY TUBE ASSEMBLY is to be stated with this standard, it shall be evaluated in accordance with 9.4.

9.3   Calculation of the MODULATION TRANSFER FUNCTION

9.3.1   Calculation for the theoretical magnification approaching infinity

The one-dimensional MODULATION TRANSFER FUNCTION of the geometry of a FOCAL SPOT shall be calculated by means of the magnitude of the Fourier transform.

The input values for carrying out the Fourier transform shall be the DIGITISED LINE SPREAD FUNCTION obtained in Clause 7, which shall be scanned over a range of at least three times the FOCAL SPOT size. The distance between the measurement points along the abscissa shall be chosen so that the extent and the structures of the linear distribution of radiant intensity over the FOCAL SPOT will be taken into account, and a further reduction of the distance shall not result in a significant change in the stated values, i.e. the distance between measuring points is such that a further 50 % reduction of the distance does not change the reported MTF at any point by more than 5 %.

NOTE   In most cases, it is sufficient if the step between two measuring points divided by the enlargement (E) used to acquire the FOCAL SPOT SLIT RADIOGRAM is less than 10 % of the related NOMINAL FOCAL SPOT VALUE if this value is smaller than or equal to 0,15, and is less than 5 % of the related NOMINAL FOCAL SPOT VALUE if this value is greater than 0,15.

9.3.2   Calculation for the standard magnification

The values of spatial frequency obtained in accordance with 9.3.1 shall be transformed in accordance with the formula:

$$f_s = f_i \cdot M_s \, / \, (M_s\text{-}1)$$

where

M_s is the standard magnification given in Table 4;

f_s is the spatial frequency in the object plane determined by the standard magnification M_s;

f_i is the spatial frequency obtained in accordance with 9.3.1.

Table 4 – Standard magnifications for MODULATION TRANSFER FUNCTIONS

NOMINAL FOCAL SPOT VALUE f	Standard magnification M_s
$f < 0,6$	2
$0,6 \leq f$	1,3

NOTE   In general the magnification M for any object is given by $M = (n + m)/m$ (analogous to Figures 3 and 8).

9.3.3   Calculation for finite magnification

For the application of the MODULATION TRANSFER FUNCTION under practical radiological conditions, the values obtained in accordance with 9.3.2 or those given in accordance with 9.3.4 are transformed in accordance with the formula:

$$f_p = f_s \cdot \{ \, (M_s\text{-}1) \, / \, M_s \, \} \cdot \{ \, M_p \, / \, (M_p\text{-}1) \, \}$$

where

f_p is the spatial frequency in the image plane determined by the actual magnification;

M_p is the actual magnification.

9.3.4 Presentation of the MODULATION TRANSFER FUNCTION

The MODULATION TRANSFER FUNCTION shall be represented as a graph showing the magnitude of the Fourier transform at the standard magnification given in Table 4 as a function of spatial frequency. The graph shall use a linear scale for both axes of coordinates. The graph shall be normalized so that the magnitude of the Fourier transform is 100 % at the spatial frequency zero.

The modulation transfer function shall extend to the spatial frequencies for which the magnitude of Fourier transformation is greater than 10 %.

NOTE   Generally, the MODULATION TRANSFER FUNCTION below 10 % is of little importance for practical applications.

The pair of one-dimensional modulation transfer functions of the geometry of the width and the length of one FOCAL SPOT shall be presented in one graph, together with the NOMINAL FOCAL SPOT VALUE in accordance with Clause 8 and the standard magnification in accordance with Table 4.

9.4 Evaluation of compliance of the MTF

Each one-dimensional MODULATION TRANSFER FUNCTION of an individual FOCAL SPOT at any spatial frequency shall coincide with, or be higher than, the specified MODULATION TRANSFER FUNCTION of the X-RAY TUBE ASSEMBLY according to 9.2.

9.5 Statement of compliance

If compliance with this standard of a pair of MODULATION TRANSFER FUNCTIONS is to be stated, this shall be done in the following manner:

MODULATION TRANSFER FUNCTION for a NOMINAL FOCAL SPOT VALUE of 0,6 and magnification of 1,3 in accordance with IEC 60336

and where appropriate:	Subclause
REFERENCE AXIS	4.3
loading factors	6.2.3
Special arrangements	6.2.5
Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY	4.2

10 FOCAL SPOT STAR RADIOGRAMS

10.1 Overview

This clause deals with the production of FOCAL SPOT STAR RADIOGRAMS as used for the determination of the star pattern resolution limit and blooming value of focal spots in accordance with Clause 11 and 12 respectively.

A method of indicating compliance with this standard of a FOCAL SPOT STAR RADIOGRAM is included.

10.2 Test equipment

10.2.1 STAR PATTERN CAMERA

FOCAL SPOT STAR RADIOGRAMS shall be obtained by means of a STAR PATTERN CAMERA containing a test pattern, which consists of an array of alternating high and low absorbing wedges. The high absorbing wedges shall be made of lead or an equivalently absorbing material and shall have a thickness of 0,03 mm to 0,05 mm.

All wedges shall have a vertex angle Θ equal to or less than 0,035 rad (approximately 2 °).

The active area of the test pattern shall cover 2π rad and shall have a diameter of at least 45 mm.

The essential dimensions of the test pattern and its basic structure shall be in compliance with Figure 7.

2° max.

45 mm min.

IEC 532/05
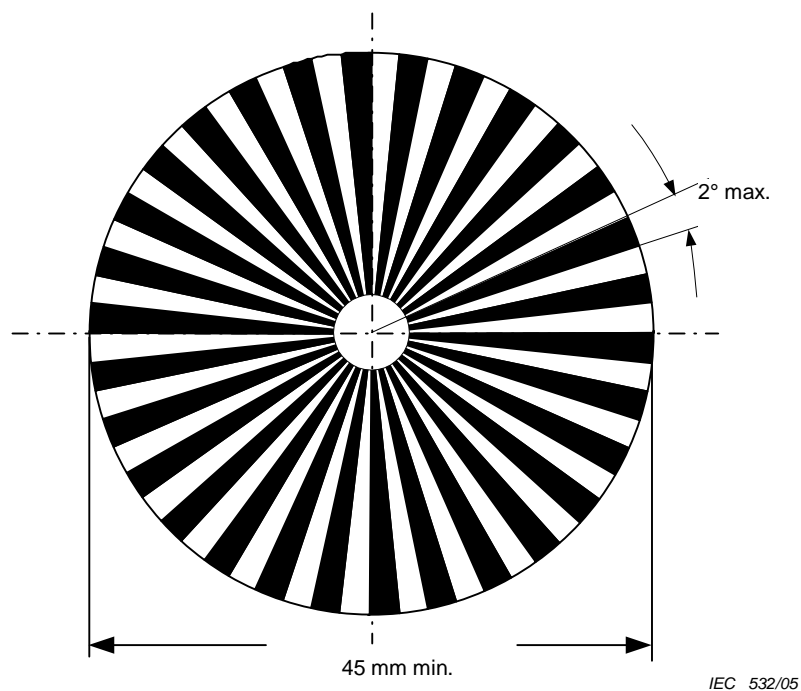
Figure 7 – Essential dimensions of the star test pattern

10.2.2 RADIOGRAPHIC FILM

FOCAL SPOT STAR RADIOGRAMS shall be made using fine-grain RADIOGRAPHIC FILM without INTENSIFYING SCREENS.

10.2.3 Position of the STAR PATTERN CAMERA normal to the REFERENCE AXIS

The STAR PATTERN CAMERA 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 8).

Magnification = $(n + m)/m$

IEC 533/05
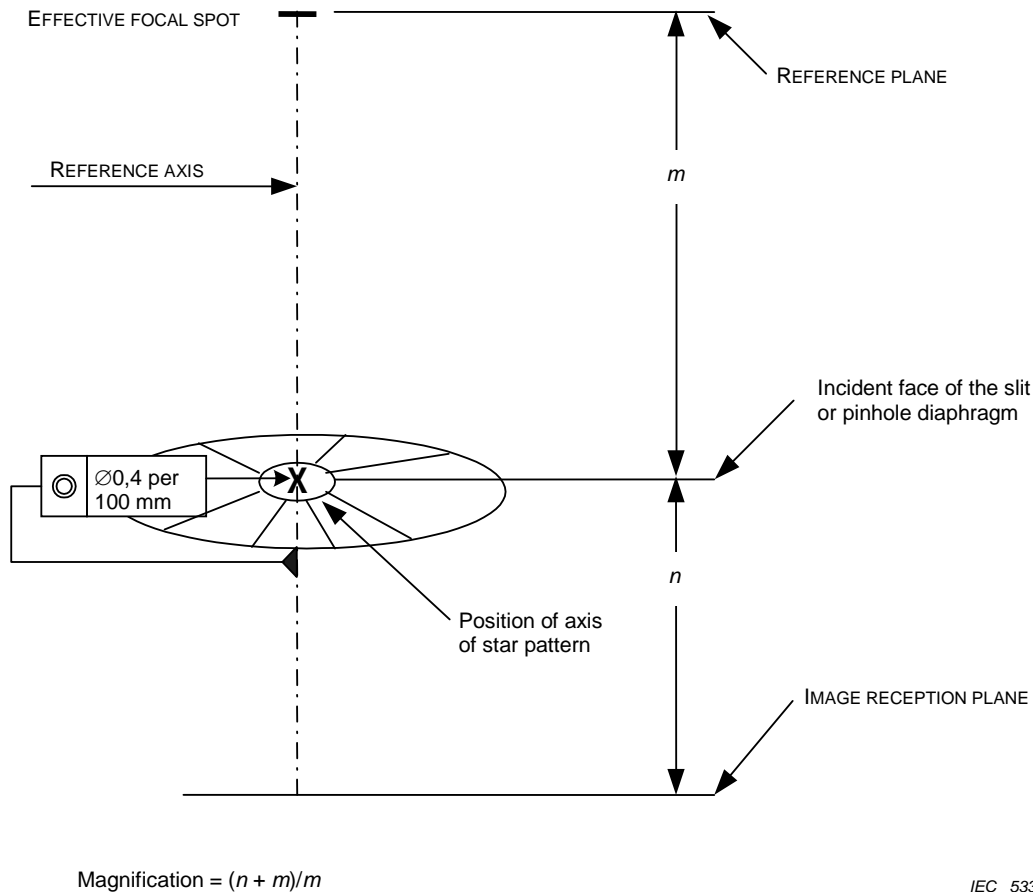
Figure 8 – Essential dimensions of the star test pattern

10.2.4 Position of the STAR PATTERN CAMERA in REFERENCE DIRECTION

The incident face of the test pattern shall be placed at a distance from the FOCAL SPOT allowing a magnification M' that the dimensions Z_W and Z_L (see Figure 9) measured in accordance with 11.3 will be more than or, where not practicable, as near as possible to one-third of the diameter of the image of the test pattern, but not less than 25 mm (see also 10.2.6).

10.2.5 Alignment of the STAR PATTERN CAMERA

The incident face of the test pattern shall be placed normal within ± 2 ° to the REFERENCE DIRECTION.

10.2.6 Position of the RADIOGRAPHIC FILM

The RADIOGRAPHIC FILM shall be placed normal to the REFERENCE DIRECTION within ± 2 ° at a distance from the incident face of the test pattern, which results in a magnification M' as determined from the expected STAR PATTERN RESOLUTION LIMIT R in accordance with the formula:

$$M' = R \cdot Z \cdot \theta$$

where

M' is the magnification to be used;

R is the expected STAR PATTERN RESOLUTION LIMIT in line pairs per millimetre;

Z is the dimension in millimetres on the RADIOGRAPHIC FILM of the outermost zone of minimal modulation in the direction Z_W or Z_L as appropriate;

θ is the vertex angle of the absorbing wedges in radians.

10.2.7   Operating conditions

The FOCAL SPOT STAR RADIOGRAM shall be obtained under the operating conditions described in 6.2.

10.2.8   Production of the FOCAL SPOT STAR RADIOGRAM

The RADIOGRAPHIC FILM of the STAR PATTERN CAMERA shall be exposed as described in 6.2.

10.2.9   Statement of compliance

If compliance with this standard for a FOCAL SPOT STAR RADIOGRAM is to be stated, this shall be done together with the magnification determined in accordance with 11.4.1 as follows:

FOCAL SPOT STAR RADIOGRAM with magnification of ...[4] in accordance with IEC 60336 [5]

and as appropriate:	Subclause
REFERENCE AXIS	4.3
LOADING FACTORS	6.2.3
Special arrangements	6.2.5
Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY	4.2

11   STAR PATTERN RESOLUTION LIMIT

11.1   Overview

This Clause deals with the determination of the STAR PATTERN RESOLUTION LIMIT.

The results of this method are useful to detect changes in the characteristics of a particular FOCAL SPOT over varying conditions of the X-RAY TUBE LOAD, or after extended use of the X-RAY TUBE.

NOTE   The method described in Clause 10 gives unprecise results if the MODULATION TRANSFER FUNCTION does not contain a clearly defined minimum, as for example in cases where the radiant intensity has an approximately Gaussian distribution over the FOCAL SPOT.

11.2   Specified STAR PATTERN RESOLUTION LIMIT

If a type-related STAR PATTERN RESOLUTION LIMIT for the standard magnification given in Table 5 is established for a FOCAL SPOT of an X-RAY TUBE ASSEMBLY, compliance with this standard of the STAR PATTERN RESOLUTION LIMIT for an individual X-RAY TUBE ASSEMBLY shall be evaluated in accordance with 11.5.

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[4] Magnification used.

[5] A reference to the second or third edition of IEC 60336 is technically equivalent to and in compliance with this fourth edition.

11.3 Measurement

In FOCAL SPOT STAR RADIOGRAMS obtained in accordance with Clause 10, the dimensions Z_W and Z_L of the outermost zones of minimal modulation shall be measured in the two directions of evaluation (see Clause 4 and Figure 9).
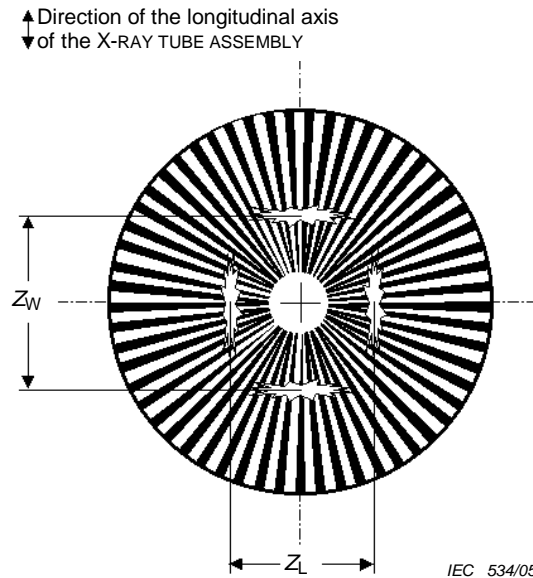

Direction of the longitudinal axis
of the X-RAY TUBE ASSEMBLY

Z_W

Z_L

IEC 534/05

Figure 9 – Illustration of the zones of minimum modulation

11.4 Determination of the STAR PATTERN RESOLUTION LIMIT

11.4.1 Determination of magnification

The magnification M' used for the production of the FOCAL SPOT STAR RADIOGRAMS shall be determined with an accuracy within ± 3 %.

11.4.2 STAR PATTERN RESOLUTION LIMIT for standard magnification

The STAR PATTERN RESOLUTION LIMITS, R_{WS} and R_{LS}, for the standard magnification given in Table 5 shall be determined from the formulae:

$$R_{WS} = \{(M' - 1) / (Z_W \cdot \theta)\} \cdot \{M_S / (M_S - 1)\}$$
$$R_{LS} = \{(M' - 1) / (Z_L \cdot \theta)\} \cdot \{M_S / (M_S - 1)\}$$

where

R_{WS} and R_{LS} are the values for the two directions of evaluation in line pairs per millimetre;

M' is the magnification in accordance with 10.2.6;

M_S is the standard magnification according to Table 5;

Z_W is the mean diameter of the outermost zone of minimal modulation measured in the direction parallel to the longitudinal axis of the X-RAY TUBE ASSEMBLY in millimetres;

Z_L is the mean diameter of the outermost zone of minimal modulation measured in the direction normal to the longitudinal axis of the X-RAY TUBE ASSEMBLY in millimetres;

θ is the vertex angle of the absorbing wedges in radians.

Table 5 – Standard magnifications for STAR PATTERN RESOLUTION LIMIT

NOMINAL FOCAL SPOT VALUE (*f*)	Standard magnification (M_S)
f < 0,6	2
0,6 ≤ *f*	1,3

11.4.3 STAR PATTERN RESOLUTION LIMIT **for finite magnification**

For the application of the STAR PATTERN RESOLUTION LIMIT at an actual magnification, the values R_{WS} and R_{LS} obtained in accordance with 11.4.2, or those specified in accordance with 11.2, can be transformed in accordance with the formulae:

$$R_{WP} = R_{WS} \cdot \{(M_S - 1) / M_S\} \cdot \{M_P / (M_P - 1)\}$$
$$R_{LP} = R_{LS} \cdot \{(M_S - 1) / M_S\} \cdot \{M_P / (M_P - 1)\}$$

where

R_{WP} and R_{LP} are the values for the actual magnification;

R_{WS} and R_{LS} are the values obtained according to 11.4.2 or specified in accordance with 11.2;

M_S is the standard magnification;

M_P is the actual magnification.

11.4.4 **Presentation of** STAR PATTERN RESOLUTION LIMIT

The STAR PATTERN RESOLUTION LIMIT shall be given for the standard magnification in Table 5.

11.5 **Evaluation and statement of compliance**

11.5.1 **Evaluation of compliance**

If, for a FOCAL SPOT of an X-RAY TUBE ASSEMBLY, the STAR PATTERN RESOLUTION LIMIT is to be stated, each value determined in accordance with 11.4.2 shall be equal to or greater than the specified value.

11.5.2 **Statement of compliance**

If compliance with this standard for a specified STAR PATTERN RESOLUTION LIMIT is to be stated, this shall be indicated as follows:

STAR PATTERN RESOLUTION LIMIT ... [6] lp/mm at standard magnification of ... [7] in accordance with IEC 60336

and as appropriate: Subclause

REFERENCE AXIS   4.3

LOADING FACTORS   6.2.3

Special arrangements   6.2.5

Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY   4.2

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[6] Numerical value

[7] Value of standard magnification in accordance with Table 4.

12 BLOOMING VALUE

12.1 Overview

This clause deals with the determination of the BLOOMING VALUE of a FOCAL SPOT showing the dependence of the STAR PATTERN RESOLUTION LIMIT upon X-RAY TUBE LOAD.

If a type-related BLOOMING VALUE is established for a FOCAL SPOT of a type of X-RAY TUBE ASSEMBLY, compliance with this standard of the BLOOMING VALUE for an individual X-RAY TUBE ASSEMBLY shall be evaluated in accordance with 12.3.1 based upon values established in accordance with 12.3.

12.2 Determination of the BLOOMING VALUE

The BLOOMING VALUE shall be determined using pairs of STAR PATTERN RESOLUTION LIMITS established in accordance with Clause 11, however based upon FOCAL SPOT STAR RADIOGRAMS obtained with constant LOADING FACTORS in accordance with Table 2 and Table 6 under otherwise the same operating conditions.

Table 6 – LOADING FACTORS for the determination of the BLOOMING VALUE

	NOMINAL X-RAY TUBE VOLTAGE kV	Required X-RAY TUBE VOLTAGE	Exposure time	Required X-RAY TUBE CURRENT
RADIOGRAPHY other than COMPUTED TOMOGRAPHY	$U < 75$	NOMINAL X-RAY TUBE VOLTAGE	As required to meet the optical density requirement, see 6.3.3	100 % of the NOMINAL ANODE INPUT POWER as specified by IEC 60613
	$75 \leq U \leq 150$	75 kV		
	$150 < U \leq 200$	50 % of the NOMINAL X-RAY TUBE VOLTAGE		
COMPUTED TOMOGRAPHY		120 kV		

The BLOOMING VALUE, B, results from the following formula:

$$B = R_{50} / R_{100}$$

where

R_{50} is the STAR PATTERN RESOLUTION LIMIT under operating conditions in accordance with Table 2;

R_{100} is the STAR PATTERN RESOLUTION LIMIT under operating conditions in accordance with Table 6.

12.3 Evaluation and statement of compliance

12.3.1 Evaluation of compliance

If, for a FOCAL SPOT of an X-RAY TUBE ASSEMBLY, the BLOOMING VALUE is specified, each value determined in accordance with 12.3.2 shall be smaller than or equal to the specified value.

12.3.2 Statement of compliance

If compliance with this standard for a specified BLOOMING VALUE is to be stated, this shall be indicated as follows:

BLOOMING VALUE ... [8] in accordance with IEC 60336 [9]

and as appropriate:	Subclause
REFERENCE AXIS	4.3
LOADING FACTORS	12.2
Special arrangements	6.2.5
Description of the longitudinal axis of the X-RAY TUBE ASSEMBLY	4.2

13 Alternate measurement methods

It is understood that MANUFACTURERS of X-RAY TUBE assemblies claiming compliance with this standard may employ measurement techniques other than those specified in this standard. This is permissible so long as these measurement techniques are correlated by the MANUFACTURER to the standard measurement techniques and can be demonstrated to be equivalent.

The use of these measurement techniques shall yield the same results as those produced by the standard measurement techniques specified in this standard in order to claim compliance with this standard.
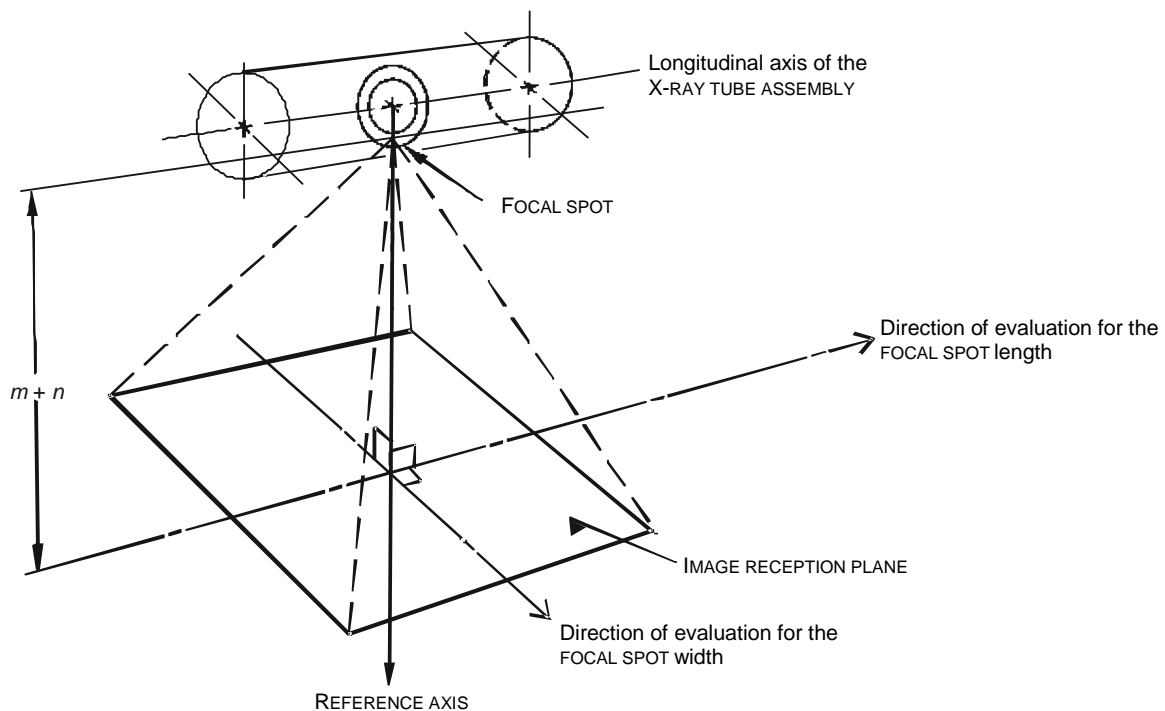
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[8] Numerical value

[9] A reference to the second or third edition of IEC 60336 is technically equivalent to and in compliance with this fourth edition.

Annex A
(informative)

Alignment to the REFERENCE AXIS

Figure A.1 gives an overview of the different axes and directions for a FOCAL SPOT measurement.

Figure A.1 – The REFERENCE AXIS and directions of evaluation

The values of the characteristics of a FOCAL SPOT, obtained by measurement and determination in accordance with the present standard, are dependent upon a number of factors which are difficult to avoid or to compensate for without expensive test instrumentation and test procedures which can be expected in purpose-equipped test laboratories only. One of these factors is the geometric alignment of the imaging diaphragm to the centre of the EFFECTIVE FOCAL SPOT (see Note).

Without proper alignment of the FOCAL SPOT camera to the REFERENCE AXIS in accordance with 5.3, any result obtained for the characteristics of a FOCAL SPOT shall be considered qualitative only. The exact position of the REFERENCE AXIS is not a characteristic of the type but of the individual x-ray-tube assembly, also the position of the REFERENCE AXIS changes due to thermal effects normally more than the tolerance stated in 5.3.1.

IEC 536/05
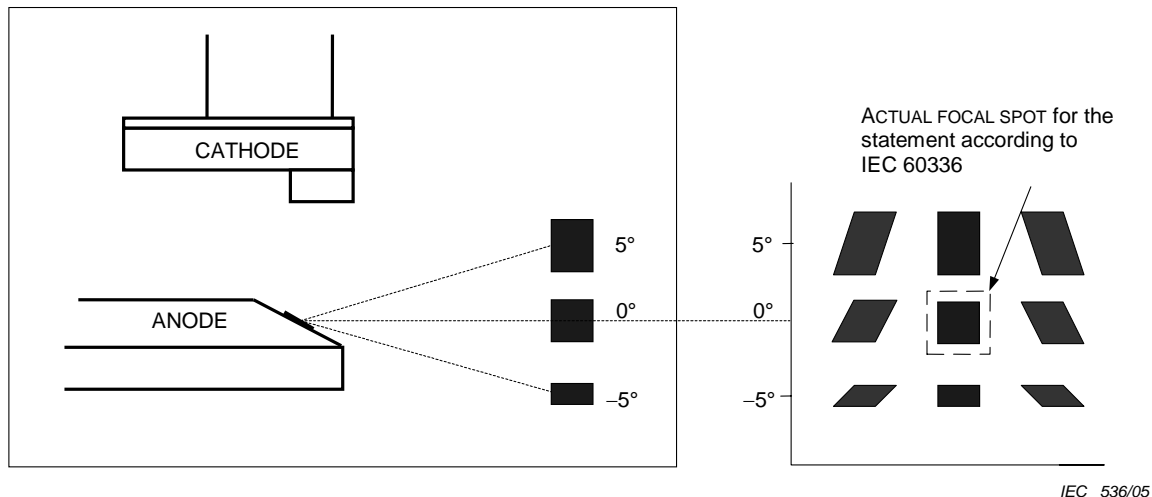
Figure A.2 – Projection of the ACTUAL FOCAL SPOT on the IMAGE RECEPTION PLANE

NOTE   Shape and dimensions of the FOCAL SPOT over the radiation field depend strongly on the direction of the projection of the FOCAL SPOT; see Figure A.2. Statements in accordance with this standard refer only to the projection in REFERENCE DIRECTION (marked FOCAL SPOT in Figure A.2). A graphical representation is shown in Figure A.2.

Annex B
(informative)

Application of digital X-ray image detectors
for determination of the FOCAL SPOT characteristics

The standard method for determination of FOCAL SPOT characteristics uses RADIOGRAPHIC FILM. However, the use of digital X-ray imaging detectors is providing MANUFACTURERS with many production measurement advantages for the determination of the FOCAL SPOT size, provided these measurement results can be shown to be equivalent to the standard measurement results using RADIOGRAPHIC FILM. While RADIOGRAPHIC FILM remains the standard method of imaging, this annex serves to provide guidance and a degree of uniformity to digital imaging methods used for FOCAL SPOT measurements.

The availability of large-area digital X-ray imaging detectors enables direct measurement of the FOCAL SPOT characteristics. Such detectors have many inherent advantages over film including: greater X-ray sensitivity; linear response to X-ray exposure; no inaccuracies due to film scanning; no chemical process sensitivity; and no production of chemical or hazardous waste.

Any digital imaging system shall return values consistent with the standard film-based method under equivalent exposure conditions. "Consistent" is defined here as a linear regression between digital and film-based measurements where the slope differs from 1 % by less than 5 % and any offset is less than the gage repeatability and reproducibility of the film-based measurement system.

Additionally, the digital imaging system should:

– employ all techniques and methods of this standard with the exception of the use of RADIOGRAPHIC FILM;

– have a signal-to-noise ratio of 20 or greater;

– have sufficient dynamic range such that the imaging system is not saturated during the exposure.

Annex C
(informative)

Historical background

C.1 Introduction

The purpose of this annex is to describe the history behind the standard as it is today and, hopefully, to clarify the reasons behind some difficult parts.

C.2 The first edition (1970)

The first edition was called *Measurement of the dimensions of FOCAL SPOTs of diagnostic X-RAY TUBES using a pinhole camera*, and was based on earlier ICRU recommendations [3], [4] [10] and on national standards [5]. This first edition only described the pinhole measurements for determining the dimensions of FOCAL SPOTs. A magnifying glass with a magnification of 10 was to be used for direct film reading, as well as a 0,7 multiplying factor for the length.

C.3 The second edition (1982)

It was renamed *Characteristics of FOCAL SPOTs in diagnostic X-RAY TUBE assemblies for medical use*. It added the slit method, basically because the determination of the dimensions of a FOCAL SPOT based on FOCAL SPOT PINHOLE RADIOGRAMS becomes difficult for NOMINAL FOCAL SPOT VALUES smaller than 0,3, as the results are affected by factors, such as transmission through the shielding of the diaphragm and the need for repeated Irradiation of the RADIOGRAPHIC FILM due to tube-LOADING considerations. The new method was applied over the entire range of usual NOMINAL FOCAL SPOT VALUES. The method avoided former uncertainties in determining the dimensions of FOCAL SPOTs and gave valuable results even in cases of distorted FOCAL SPOTs. Furthermore, determination of the imaging properties of the FOCAL SPOT in the form of a pair of one-dimensional modulation transfer functions was also introduced.

Thus, the pinhole method was only used for showing the distribution and orientation of the FOCAL SPOT characteristics, and the slit method was to be used for determining the NOMINAL FOCAL SPOT VALUES and the MTF.

In addition, a third method was described for use in the field (FOCAL SPOT STAR RADIOGRAMS). The production of FOCAL SPOT STAR RADIOGRAMS had been standardized because of their usefulness in making a simple assessment of the imaging properties of a system under field conditions by establishing the STAR PATTERN RESOLUTION LIMIT under those conditions (assuming the FOCAL SPOT has such a characteristic).

The added nominal values (0,1; 0,15 and 0,2) did not use the factor of 0,7; see C.5.

C.4 The third edition (1993)

It was again renamed, to *X-RAY TUBE assemblies for medical diagnosis – Characteristics of FOCAL SPOTs*. No other changes, except that the support for CT (called special application) and the nominal value 0,25 were added. The added special application FOCAL SPOTs did not incorporate the 0,7 factor.

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[10] Numbers in square brackets refer to the Bibliography.

C.5   The factor 0,7 and the asymmetrical ranges

Two issues in the standard have caused a lot of misunderstanding and discussion:

– the multiplying factor of 0,7 for the length;

– the concept of the nominal value with non-symmetrical ranges (e.g. the NOMINAL FOCAL SPOT VALUE 0,8 allows sizes from 0,8 mm to 1,2 mm).

Both of them have been hard to understand. The only way to explain them is to show the LINE SPREAD FUNCTIONS for some typical FOCAL SPOTS.
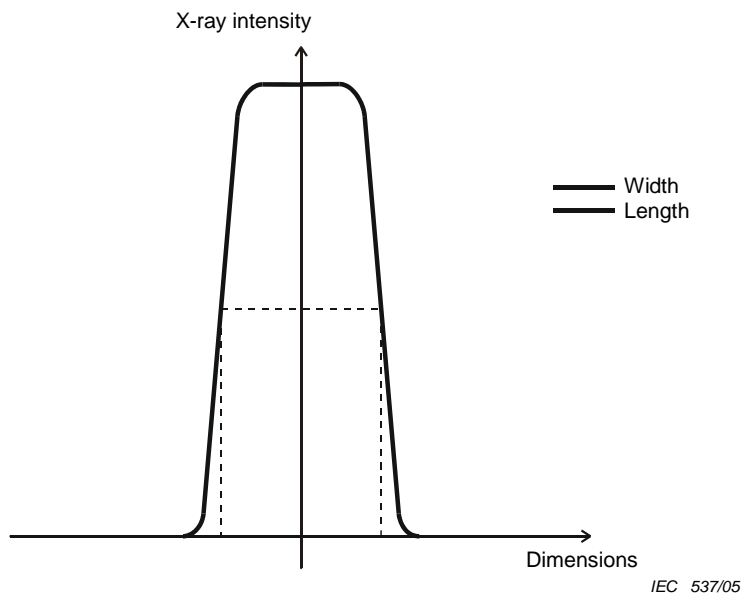
NOTE   Length and width have the same shape.

Figure C.1 – The LSFs for a typical X-RAY TUBE with small FOCAL SPOT (< 0,3 mm)
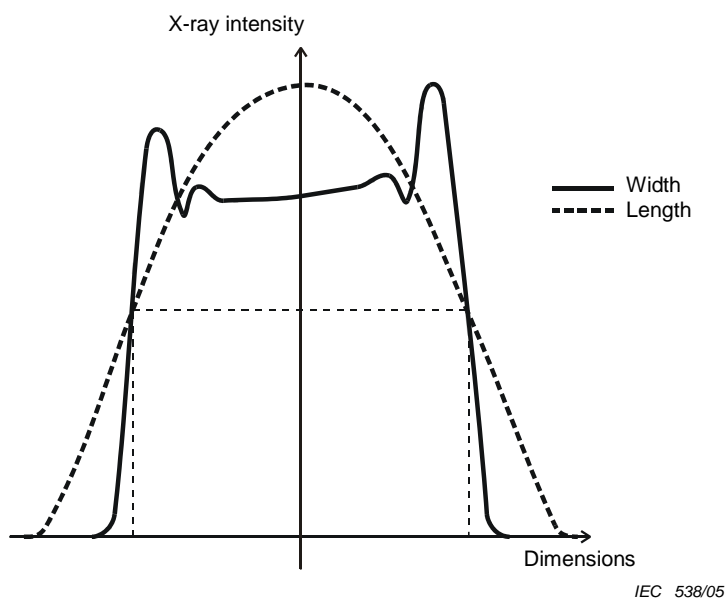
Figure C.2 – The LSFs for a typical X-RAY TUBE with large FOCAL SPOT (≥0,3 mm)

As seen, the slope of the edges of the LSFs varies. The natural reading of the size is obviously at full width half maximum (FWHM), which is at 50 % of the peak level. But since the technology of the 1950s and 1960s only allowed for film reading with a magnifying glass, the reading obtained was corresponding to something like 10 % to 20 % on the LSF. Since the measured value then, as seen in Figures C.1 and C.2, will be larger, this basically explains the reason for the ranges not being symmetrical.
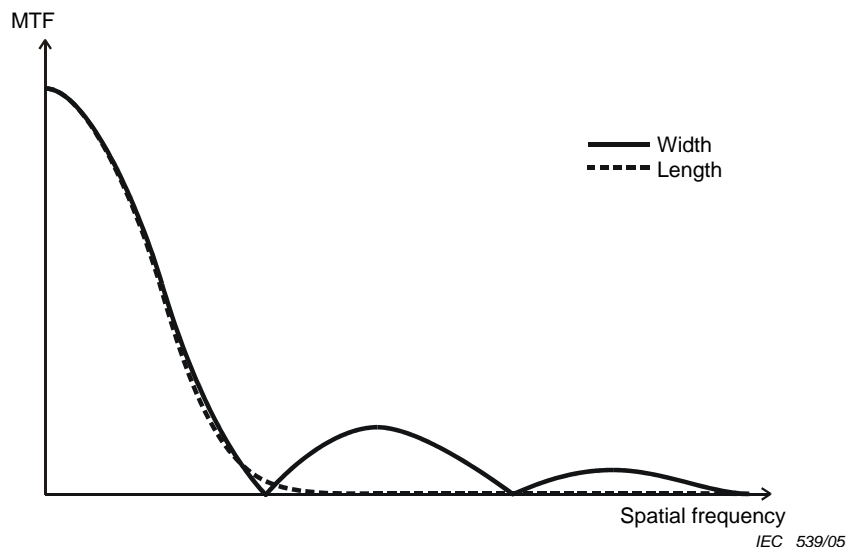

Figure C.3 – The corresponding MTFs for the LSFs in Figure C.2

The typical LSF for the length of a large FOCAL SPOT shows even more shallow edges, as shown in Figure C.2. This can also be seen as the length reading (at 10 % to 20 %) being typically 40 % larger than the width reading for a tube where the MTFs are approximately equal.

Thus, to get a nominal value corresponding to the image quality obtained, the 0,7 factor was introduced. As seen in Figure C.3, the LSFs in Figure C.2 gives almost identical MTFs up to the first minimum, i.e. in practice they give the same image quality.

NOTE   In the more refined RMS method, the width of the square shaped LSF, which gives the same image characteristics as any shaped LSF, is calculated. The RMS method may be used in future editions of this standard.

C.6   The fourth edition

The main changes in the fourth edition of this standard are:

a)   practical specifications for tolerances, mainly for camera design and camera alignment;

b)   the LINE SPREAD FUNCTION is now used solely as basis for FOCAL SPOT size determination; the density distribution used for determination of length and width is now determined using densitometric evaluation, replacing the visual evaluation;

c)   distorted (skewed) FOCAL SPOTS are no longer taken into account;

d)   the range of permissible values corresponding to the NOMINAL FOCAL SPOT VALUE is replaced with a maximum permissible value only;

e) allowing other methods of measurement, provided equivalence to this standard is verified;

Concerning a): In the 3rd edition of this Standard, some tolerances, particularly in the test arrangement for the FOCAL SPOT camera, were unnecessarily narrow, for example the angle between the REFERENCE AXIS and the axis of symmetry of the diaphragm was required to be within 0,001 rad, while no tolerance was specified for others such as the position of the diaphragm with respect to the REFERENCE AXIS. This is now avoided by means of an overall tolerance.

Concerning b): In the past, most MANUFACTURERS performed a densitometric analysis of the FOCAL SPOT RADIOGRAMS when determining the FOCAL SPOT sizes. This was the same procedure, the evaluation of the LINE SPREAD FUNCTION, which had to be performed to determine the MTF. To this extent, it was reasonable to standardise this procedure and to withdraw the method relying on visual evaluation. Hence, determination of both MTF and FOCAL SPOT dimensions are now based on measurements from the LINE SPREAD FUNCTION based on the same FOCAL SPOT SLIT RADIOGRAM.

Concerning c): With better fabrication and development methods of X-RAY TUBEs, the occurrence of distorted FOCAL SPOTs has been greatly reduced. Additionally, FOCAL SPOT dimension measurements from FOCAL SPOT SLIT RADIOGRAMS are not as sensitive to FOCAL SPOT distortion as FOCAL SPOT PINHOLE RADIOGRAMS. Therefore the clause concerning this was eliminated.

Concerning e): There is a large number of measuring equipment in the market, that use for example a CCD camera instead of RADIOGRAPHIC FILM in order to determine FOCAL SPOT characteristics. These methods are increasingly used by MANUFACTURERS for routine testing and Annex B gives recommendations for those cases. Obviously MANUFACTURERS also intend to use this measuring equipment to determine the FOCAL SPOT. Provided the test results can be verified to be identical to the standardised method using RADIOGRAPHIC FILM this standard allows those methods. The same applies to visually evaluated measurements using a magnifying glass in the previous editions of this standard.

This standard does not require the statement of all characteristics as listed in Table C.1. The information to be provided with an X-RAY TUBE ASSEMBLY is the subject of IEC 60601-2-28.

In the third edition of this standard, the method of characterising the FOCAL SPOT by means of the RMS value was given in a note. This method has not been widely accepted. However, following the omission of the mandatory specification of the one dimensional modulation transfer function in IEC 60601-2-28 and because of the advancement of digital radiographic acquisition systems, the RMS approach could gain in importance.

Table C.1 – Methods for evaluation of specific aspects characterising the FOCAL SPOT

Information obtained by means of	According to Clause	About	According to Clause	Used for evaluating compliance with requirements on
Pair of FOCAL SPOT SLIT RADIOGRAMS	6	Dimensions	8	Specified NOMINAL FOCAL SPOT VALUE
		Imaging properties	9	Specified pair of one-dimensional MODULATION TRANSFER FUNCTIONS
FOCAL SPOT PINHOLE RADIOGRAM	6	Orientation		
		Radiation intensity distribution		
		Symmetry		
FOCAL SPOT STAR RADIOGRAM [a]	10	STAR PATTERN RESOLUTION LIMIT	11	STAR PATTERN RESOLUTION LIMIT
		BLOOMING VALUE	12	BLOOMING VALUE
		Modification of FOCAL SPOT properties over the life time		
[a] The distribution of radiant intensity over a FOCAL SPOT does not always provide a point where the MODULATION TRANSFER FUNCTION will reach the spatial frequency axis. In this case, the method by means of a FOCAL SPOT STAR RADIOGRAM is not applicable.				

Annex ZA
(normative)

Normative references to international publications
with their corresponding European publications

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.

NOTE   Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60417	database	Graphical symbols for use on equipment	-	-
IEC 60613	- [1]	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis	EN 60613	1990 [2]
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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[1] Undated reference.

[2] Valid edition at date of issue.

Bibliography

[1] DOI, K. and ROSSMANN, K. Evaluation of FOCAL SPOT distribution by RMS value and its effect on blood vessel imaging in angiography. *Proceedings of the Symposium on Application of Optical Instrumentation in Medicine III,* Vol. 47. Palos Verdes Estates, CA: Society of Photo-Optical Engineers, 1975: 207-213

[2] DOI, K. et al. X-RAY TUBE FOCAL SPOT Sizes: Comprehensive Studies of Their Measurement and Effect of Measured Size in Angiography. *Radiation Physics*, July 1982, Volume 144, Number 2, p 383-393.

[3] National Bureau of Standards Handbook 78, Report of the International Commission on Radiological Units and Measurements, (ICRU) 19S9, U. S. Government Printing Office, Washington D. C., 1961

[4] National Bureau of Standards Handbook 89, Methods of Evaluating Radiological Equipment and Materials: Recommendations of the ICRU, U.S. Government Printing Office, Washington, DC, 1962

[5] DIN 6823, Roentgenroehren, Ermittlung der Brennfleckgroesse, Beuth-Verlag, Berlin, 1968

[6] IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

Index of defined terms

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BSI — British Standards Institution

BSI is the independent national body responsible for preparing
British Standards. It presents the UK view on standards in Europe and at the
international level. It is incorporated by Royal Charter.

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