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Edition 5.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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International Standard IEC 60336 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fifth edition cancels and replaces the fourth edition published in 2005. This edition constitutes a technical revision.

The significant changes of this fifth edition with respect to the previous edition are detailed in Clause E.6. These changes are:

a) introduction of digital detectors and discretization errors;
b) fewer normative requirements;
c) support for both SLIT CAMERA and PINHOLE CAMERA;
d) reintroduction of distorted (skewed) FOCAL SPOT;
e) keeping of STAR PATTERNS and BLOOMING VALUE as informative.

The text of this document is based on the following documents:

CDV	Report on voting
62B/1138/CDV	62B/1181/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman type;

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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- withdrawn,
- replaced by a revised edition, or
- amended.

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

1 Scope

This document applies to FOCAL SPOTS in medical diagnostic X-RAY TUBE ASSEMBLIES for medical use, operating at X-RAY TUBE VOLTAGES up to and including 150 kV.

This document describes the test methods employing digital detectors for determining:

a) FOCAL SPOT dimensions in terms of NOMINAL FOCAL SPOT VALUES, ranging from 0,1 to 3,0;

b) LINE SPREAD FUNCTIONS;

c) one-dimensional MODULATION TRANSFER FUNCTIONS;

d) FOCAL SPOT PINHOLE RADIOGRAMS,

and the means for indicating compliance.

In informative annexes, STAR PATTERN imaging and BLOOMING VALUE are described.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60417, *Graphical symbols for use on equipment* (available at http://www.graphical-symbols.info/equipment)

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

3 Terms and definitions

For the purposes of this document, terms and definitions given in IEC TR 60788:2004, IEC 60613:2010, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ACTUAL FOCAL SPOT
area on the surface of the TARGET that intercepts the beam of accelerated particles

Note 1 to entry: Regarding accelerated particles, only the intended primary beam is included.

3.2
BLOOMING VALUE
ratio of two resolution limits obtained under specific LOADING conditions

Note 1 to entry: The BLOOMING VALUE is a characteristic of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE.

3.3
DIGITAL FOCAL SPOT DETECTOR
pixel-array device applied to FOCAL SPOT analysis of X-RAY TUBE ASSEMBLIES, providing a digital output value per pixel which is linearly related to the input X-ray intensity

3.4
EFFECTIVE FOCAL SPOT
FOCAL SPOT
perpendicular PROJECTION of the ACTUAL FOCAL SPOT on the REFERENCE PLANE

3.5
FOCAL SPOT PINHOLE RADIOGRAM
RADIOGRAM obtained by means of a PINHOLE CAMERA, showing the shape and orientation of an EFFECTIVE FOCAL SPOT, and the spatial distribution of intensity of radiation across it

3.6
FOCAL SPOT SLIT RADIOGRAM
RADIOGRAM obtained by means of a SLIT CAMERA, showing the distribution, across an EFFECTIVE FOCAL SPOT, in the direction normal to the length of the slit, of the intensity of the radiation emitted

3.7
FOCAL SPOT STAR RADIOGRAM
RADIOGRAM obtained by means of a STAR PATTERN CAMERA for the determination of the STAR PATTERN RESOLUTION LIMIT in one or more directions across an EFFECTIVE FOCAL SPOT

3.8
NOMINAL FOCAL SPOT VALUE
dimensionless numerical value having a specific relation to the dimensions of the EFFECTIVE FOCAL SPOT of an X-RAY TUBE, measured under specific conditions

3.9
PINHOLE CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT PINHOLE RADIOGRAM

3.10
REFERENCE AXIS
<RADIATION SOURCE> line in the REFERENCE DIRECTION through the centre of the RADIATION SOURCE

3.11
REFERENCE DIRECTION
<RADIATION SOURCE> specified direction to which characteristics such as TARGET ANGLE, RADIATION FIELD and specifications with respect to the imaging quality of the RADIATION SOURCE are referenced

3.12
REFERENCE PLANE
<diagnostic X-RAY EQUIPMENT for an EFFECTIVE FOCAL SPOT> plane perpendicular to the REFERENCE DIRECTION containing the point at which the REFERENCE AXIS intersects with the ACTUAL FOCAL SPOT

Note 1 to entry: By convention, the point of intersection forms the centre of the EFFECTIVE FOCAL SPOT.

3.13
SLIT CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT SLIT RADIOGRAM

3.14
STAR PATTERN CAMERA
assembly of EQUIPMENT used to obtain a FOCAL SPOT STAR RADIOGRAM

3.15
STAR PATTERN RESOLUTION LIMIT
characteristic of the FOCAL SPOT of an X-RAY TUBE, which represents the highest spatial frequency that can be resolved under specific measuring conditions

3.16
TARGET
part of an X-RAY TUBE or a PARTICLE ACCELERATOR onto which is directed a beam of accelerated particles to produce IONIZING RADIATION or other particles

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 Clause 4 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 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.

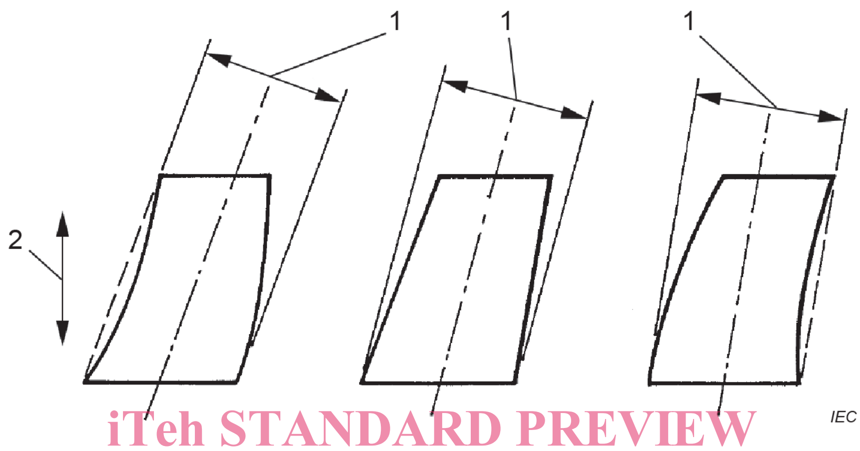
NOTE The direction of evaluation for the FOCAL SPOT length is normally parallel to the longitudinal axis of the X-RAY TUBE ASSEMBLY. See Figure A.1.

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.

4.6 Directions of evaluation for distorted FOCAL SPOTS

If the PROJECTION of the EFFECTIVE FOCAL SPOT in the REFERENCE DIRECTION is distorted, the direction of evaluation over the width may be chosen normal to the pronounced orientation of the regions of highest radiation intensity, which is usually the direction over the FOCAL SPOT showing the smallest width (see Figure 1).



Key

1 direction over the width

2 direction over the length

Figure 1 – Directions of evaluation over distorted FOCAL SPOTS

The direction of evaluation over the width of distorted FOCAL SPOTS shall not exceed ±20° from the standard evaluation direction as specified in 4.5. If a direction of evaluation other than the standard direction is used to determine the FOCAL SPOT width, then the value of this direction shall be stated as part of the statement of compliance with this document. The angle of such direction of evaluation is counted positive if the direction of evaluation has been rotated clockwise, as seen from the FOCAL SPOT.

5 FOCAL SPOT camera set-up

5.1 Overview

Clause 5 deals with the design requirements of the camera: the diaphragm, the receptor and the position and orientation of the diaphragm and the receptor.

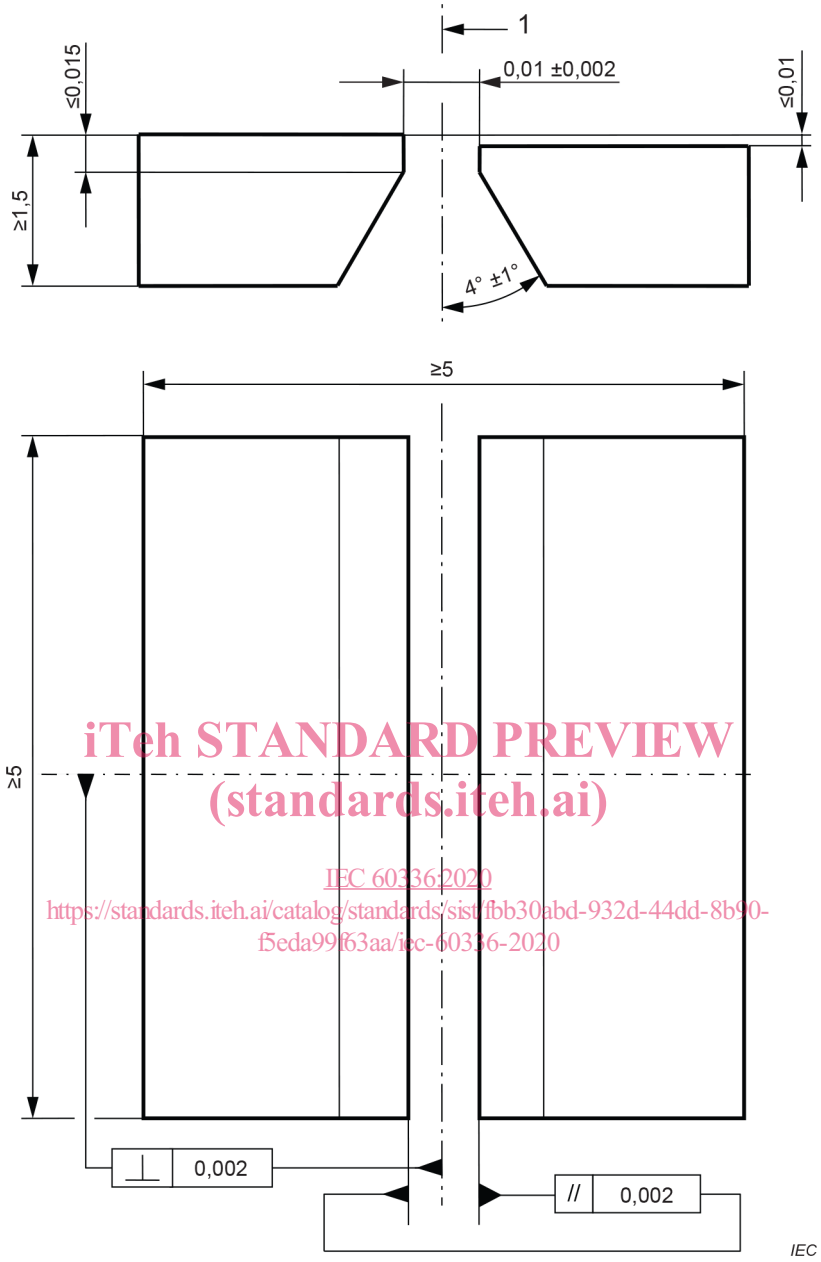
5.2 Diaphragm of the SLIT CAMERA

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



Key

1 axis of symmetry

Not drawn to scale.

Figure 2 – Essential dimensions of the slit diaphragm

5.3 Diaphragm of the PINHOLE CAMERA

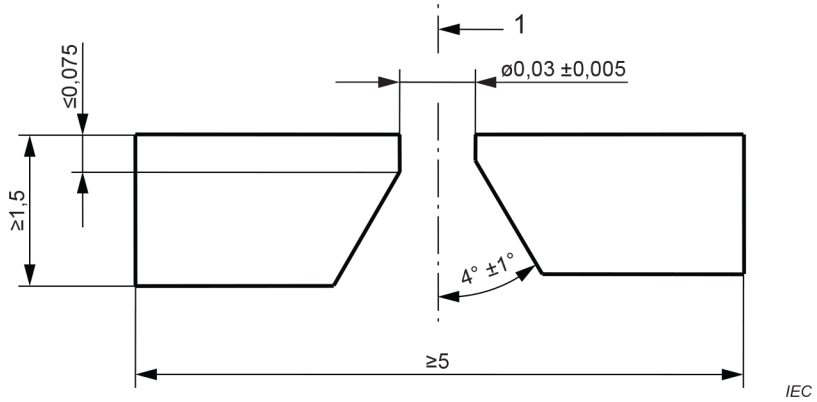
The diaphragm of the PINHOLE CAMERA shall be constructed from materials with high ATTENUATION and shall have dimensions as given in Figure 3.

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



Key

1 axis of symmetry

Not drawn to scale.

Figure 3 – Essential dimensions of the pinhole diaphragm

5.4 Receptor

The receptor is the X-RAY sensitive part of the DIGITAL FOCAL SPOT DETECTOR. The DIGITAL FOCAL SPOT DETECTOR is a pixel-array device providing a digital output value per pixel which is linearly related to the input X-ray intensity. Two types are specified for use in this document (see also Figure 6):

– 1D-detector; the receptor consists of one pixel-array. This detector shall be applied to obtain the FOCAL SPOT SLIT RADIOGRAMS (see 6.3.1).

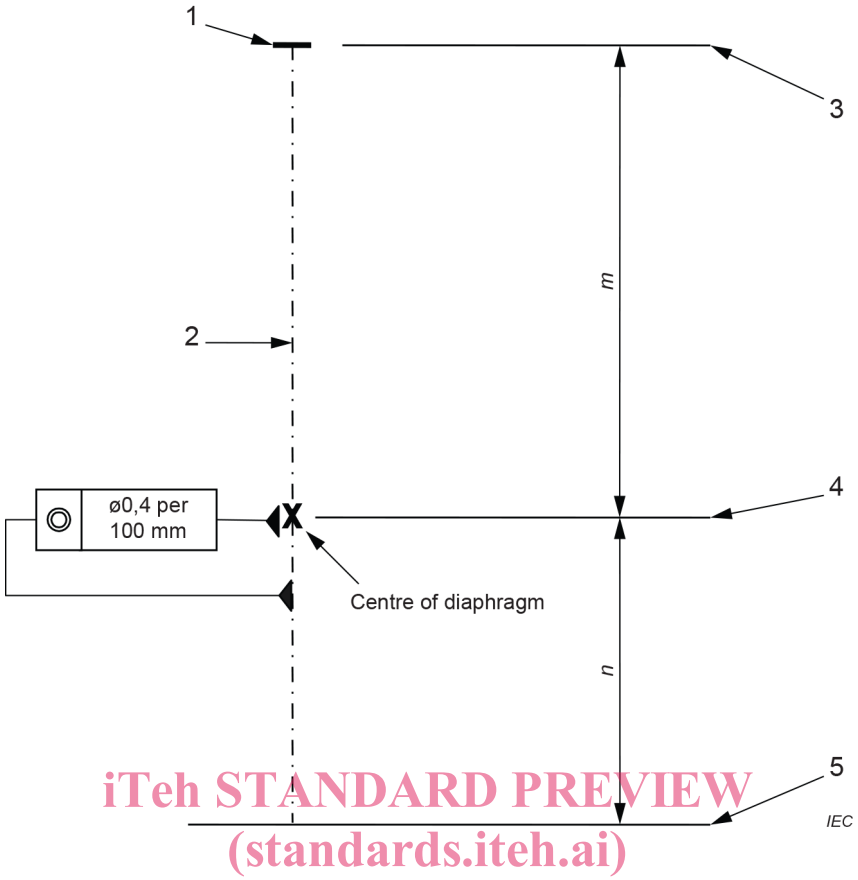
  NOTE The 1D-detector is sometimes referred to as "line-detector".

– 2D-detector; the receptor consists of a two-dimensional matrix of pixels. This detector may be applied to obtain the FOCAL SPOT SLIT RADIOGRAMS (see 6.3.1), and it shall be applied to obtain the FOCAL SPOT PINHOLE RADIOGRAM (see 6.3.2).

5.5 Test arrangement

5.5.1 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 4).



Key

1 EFFECTIVE FOCAL SPOT

2 REFERENCE AXIS

3 REFERENCE PLANE

4 incident face of the slit or pinhole diaphragm

5 IMAGE RECEPTION PLANE

Figure 4 – Position of the centre of the slit or pinhole diaphragm (marked as x in the figure) with respect to the REFERENCE AXIS

5.5.2 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 along the REFERENCE AXIS does not exceed ±5 %.

In Figure 5, the determining parameters are indicated, namely:

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*.

NOTE Whether the requirement on the variation of the enlargement is met depends on the values of *p*, *k* and *m* – whereas *p* and *k* depend in turn on the ANODE ANGLE and the ACTUAL FOCAL SPOT length. As an example, for *m* = 100, maximum *p* and *k* is 5 mm.