IEC 60806

Edition 2.0 2022-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis

Détermination du champ de rayonnement maximal symétrique des gaines équipées et des ensembles radiogènes utilisés en diagnostic médical

IEC 60806:2022-11(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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DETERMINATION OF THE MAXIMUM SYMMETRICAL RADIATION FIELD OF X-RAY TUBE ASSEMBLIES AND X-RAY SOURCE ASSEMBLIES FOR MEDICAL DIAGNOSIS

FOREWORD

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IEC 60806 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is an International Standard.

This second edition cancels and replaces the first edition published in 1984. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition:

a) addition of solid state detectors as they have become more common since the first edition of 1984.

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

Draft	Report on voting
62B/1298/FDIS	62B/1305/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic 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: 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 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- withdrawn,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.

DETERMINATION OF THE MAXIMUM SYMMETRICAL RADIATION FIELD OF X-RAY TUBE ASSEMBLIES AND X-RAY SOURCE ASSEMBLIES FOR MEDICAL DIAGNOSIS

1 Scope

This document is applicable to X-RAY SOURCE ASSEMBLIES and X-RAY TUBE ASSEMBLIES.

NOTE 1 If, for certain MEDICAL ELECTRICAL SYSTEMS, special radiation fields are required such that the scope of IEC 60806 does not apply (e. g., using CT collimators with bow-tie filters), the appropriate system particular standard applies.

This document specifies a method for the determination of the greatest geometrically symmetrical RADIATION FIELD at a specified distance from the FOCAL SPOT for which the percentage AIR KERMA RATE along the major axes of the RADIATION FIELD does not fall below a permitted value.

NOTE 2 In practical use AIR KERMA or AIR KERMA RATE are the most practical physical measures to quantify X-RAY PATTERNS.

In case multiple FOCAL SPOTS are not super-imposed, each FOCAL SPOT has its own REFERENCE AXIS. Then the maximum RADIATION FIELD can be given for each FOCAL SPOT separately.

NOTE 3 The maximum symmetrical RADIATION FIELD can change from its initial value as the X-RAY TUBE ages through use.

2 Normative references

The following documents are referred to in the text in such a way that some or all 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 60336:2020, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Focal spot dimensions and related characteristics*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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 60601-1-3:2008/AMD2:2021

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, the terms and definitions given in IEC 60336:2020, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013, IEC 60601-1-3:2008/AMD2:2021, IEC 60613:2010, and IEC TR 60788:2004 apply.

NOTE 1 An Index of defined terms is to be found at the end of the document.

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

4 Maximum symmetrical RADIATION FIELD

4.1 Orientation of the maximum symmetrical RADIATION FIELD

For the determination of the maximum symmetrical RADIATION FIELD the distribution of AIR KERMA RATE shall be measured along two major axes in the measuring plane; see Figure 1.

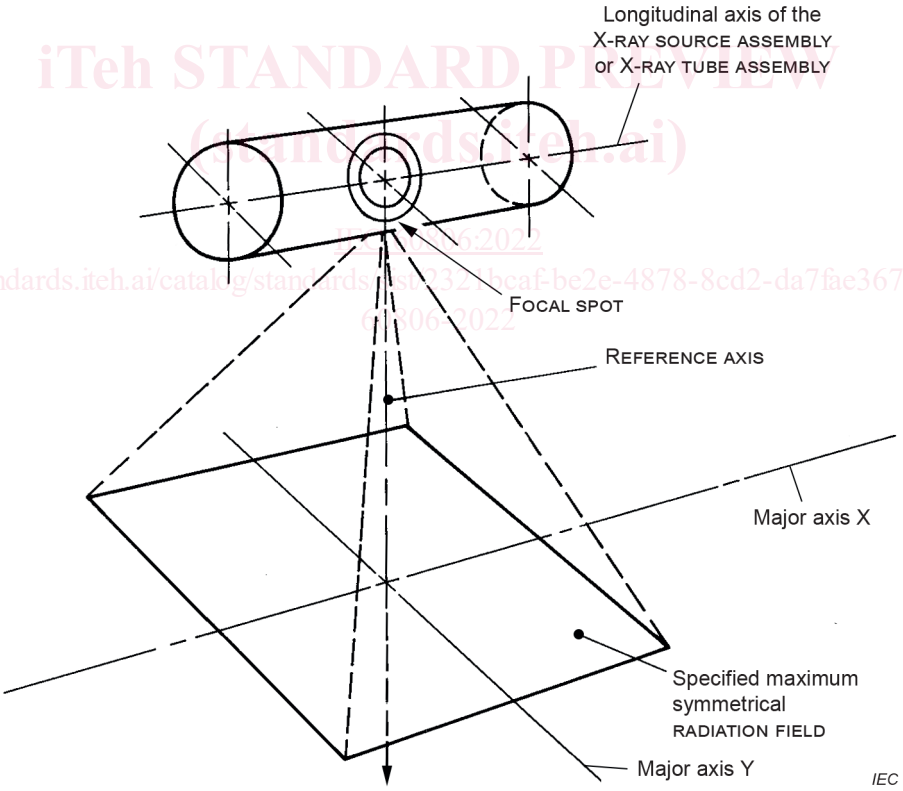

Figure 1 – Orientation of the maximum symmetrical RADIATION FIELD

The major axis *X* is the projection in REFERENCE DIRECTION of the longitudinal axis of the X-RAY TUBE ASSEMBLY or the X-RAY SOURCE ASSEMBLY onto the measuring plane. The major axis *Y* is normal to the axis *X*. Both major axes intersect on the REFERENCE AXIS.

NOTE 1 Usually, both major axes are normal to the REFERENCE AXIS (see also 5.2).

The orientation of the maximum symmetrical RADIATION FIELD is shown in Figure 1. The typical distribution in the direction of the *X* axis is given in Figure 2.

NOTE 2 The limitation of the RADIATION FIELD owing to the ANODE ANGLE is called the "ANODE heel effect". It refers to the relatively steep decline of the AIR KERMA RATE by ATTENUATION in the ANODE for angles close to the ANODE ANGLE.

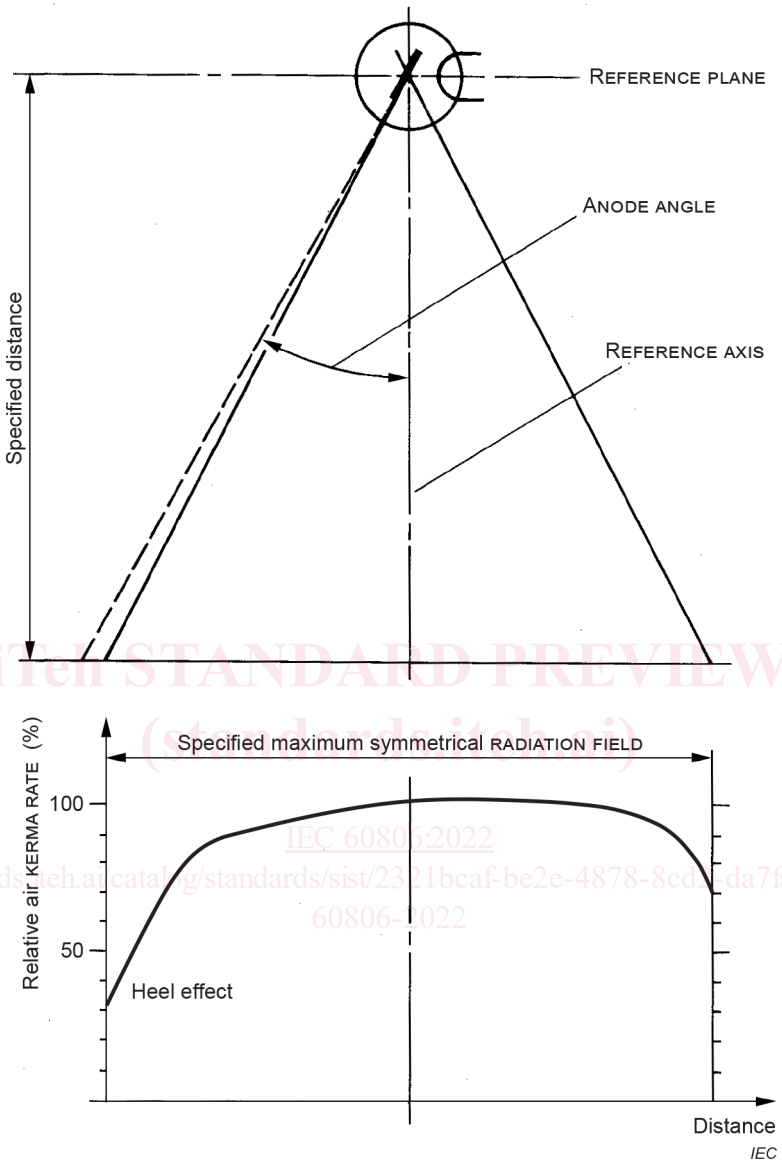

Figure 2 – Typical distribution of the relative AIR KERMA RATE along the major axis *X* of a maximum symmetrical RADIATION FIELD

4.2 Determination of the maximum symmetrical RADIATION FIELD

A maximum symmetrical RADIATION FIELD shall be determined as the dimensions of the greatest RADIATION FIELD at specified distance from the FOCAL SPOT symmetrical with respect to the specified REFERENCE AXIS, with its edges parallel to the major axes, in which the distribution of the relative AIR KERMA RATE along the major axes does not fall by more than 70 % of the AIR KERMA RATE on the REFERENCE AXIS.

5 Measurement of the distribution of AIR KERMA RATE

5.1 Detector

For the determination of the distribution of the AIR KERMA RATE, either an X-RAY IMAGE RECEPTOR, digital or RADIOGRAPHIC FILM, or a scanning method with a RADIATION DETECTOR shall be used.

The RADIATION FIELD shall be determined with an accuracy in width and length of 2 mm or better. By using the conversion function for the determination method, the individual measurement values shall be transformed into values of the AIR KERMA RATE.

5.2 Measuring arrangement

The required measuring arrangement is shown in Figure 3.

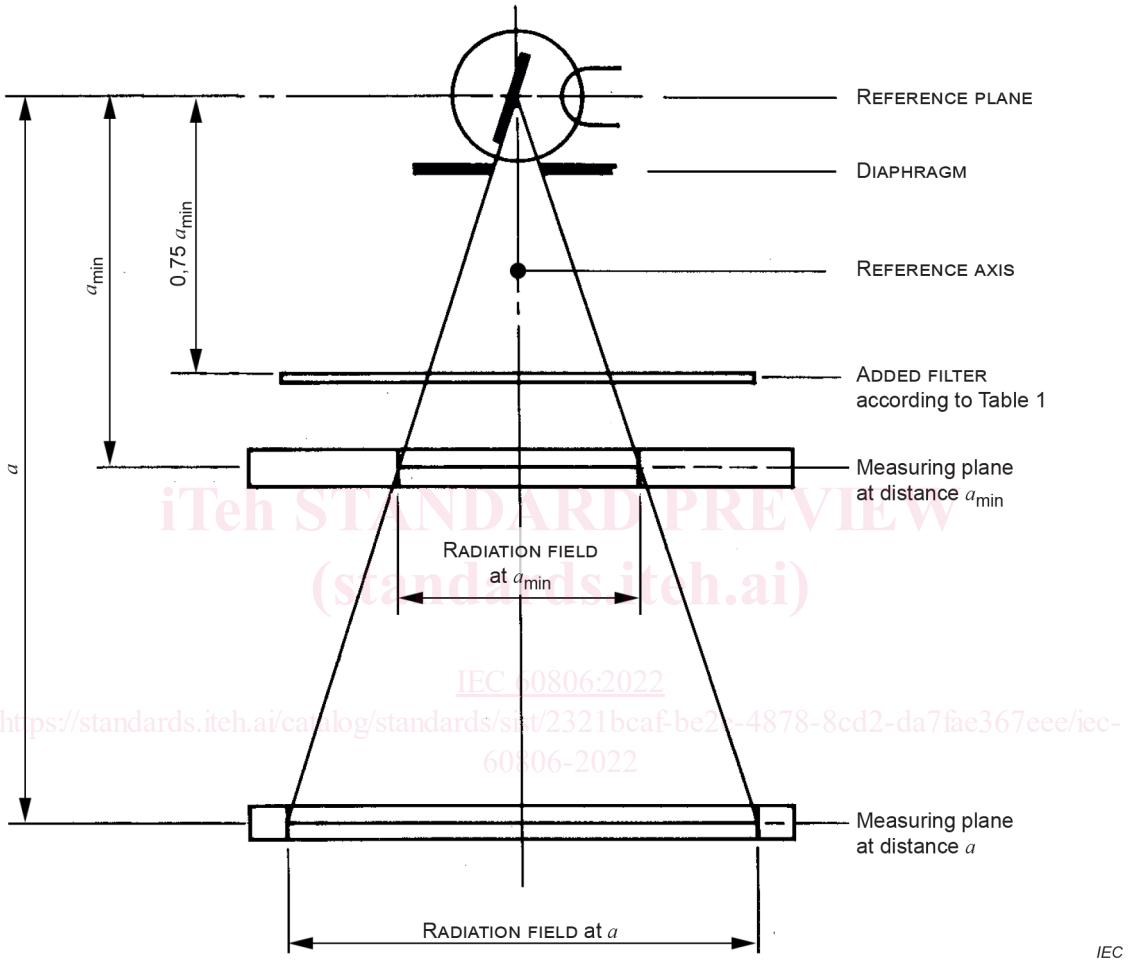

Figure 3 – Measuring arrangement

At a distance of 75 % of the specified smallest distance a_{min} of the IMAGE RECEPTION PLANE from the FOCAL SPOT, a FILTER according to Table 1 shall be placed of sufficient dimensions to intercept the entire RADIATION FIELD.

The measuring plane shall be at the specified distance a from the FOCAL SPOT and normal to the REFERENCE AXIS to within 2 degrees.

NOTE For referencing purposes, the distance of 1 000 mm is preferred.

If for a specified special radio-diagnostic technique the IMAGE RECEPTION PLANE is not normal to the REFERENCE AXIS, the measuring plane shall be adjusted to the direction specified for that technique to within 2 degrees.

In general, measurements should be performed under minimal SCATTERING and BACKSCATTERING conditions.

5.3 Measuring conditions

The X-RAY TUBE shall be operated as in INTENDED USE.

For securing a representative RADIATION QUALITY, the X-RAY TUBE VOLTAGE and the FILTER thickness shall be as given in Table 1.

Table 1 – RADIATION QUALITY

NOMINAL X-RAY TUBE VOLTAGE U_m	FILTER thickness of aluminium	Required X-RAY TUBE VOLTAGE
kV	mm	kV
$30 \leq U_m \leq 50$	5	30
$50 < U_m \leq 75$	10	50
$75 < U_m \leq 125$	20	75
$125 < U_m$	20	75 and 125

NOTE 1 The determination gives the base-line RADIATION FIELD. The FILTRATION in the relevant system can influence the effective maximal RADIATION FIELD and its uniformity.

NOTE 2 The ANODE heel-effect is more pronounced at the lower end of a given HIGH VOLTAGE range due to higher absorption. Therefore, for each HIGH VOLTAGE range in the table, the RADIATION FIELD is determined at that critical condition. For a large HIGH VOLTAGE range extending over 125 kV, 75 kV has thus been added to also cover this representative application.

6 Statement of compliance

The statement of a maximum symmetrical RADIATION FIELD complying with this document shall be as follows:

Maximum symmetrical RADIATION FIELD … mm/… mm for a HIGH VOLTAGE of … kV at a distance from the FOCAL SPOT of … mm according to IEC 60806:2022. For the assembly, the smallest distance from the FOCAL SPOT is … mm.

NOTE This statement can be given, if appropriate, for each FOCAL SPOT and each HIGH VOLTAGE.

The first value for a rectangular RADIATION FIELD shall be in the direction parallel to the longitudinal axis of the X-RAY SOURCE ASSEMBLY or X-RAY TUBE ASSEMBLY.

If applicable, the IMAGE RECEPTION PLANE angle shall be stated in case this plane is not normal to the REFERENCE AXIS (5.2).