SLOVENSKI STANDARD
oSIST prEN IEC 60806:2022

01-marec-2022

Določanje maksimuma simetričnega sevalnega polja rentgenskih cevi in rentgenskih žarkov za medicinsko diagnostiko

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 symétrique maximal des ensembles de tubes à rayons X ou des ensembles radiogène utilisés en diagnostic médical

Ta slovenski standard je istoveten z: prEN IEC 60806:2021

ICS:

11.040.50 Radiografska oprema Radiographic equipment

oSIST prEN IEC 60806:2022 en

62B/1267/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

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IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT	
SECRETARIAT: Germany	SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62C	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT	☒ QUALITY ASSURANCE ☒ SAFETY
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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TITLE:

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

PROPOSED STABILITY DATE: 2032

NOTE FROM TC/SC OFFICERS:

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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

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

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

This edition includes the following significant technical changes with respect to the previous edition: Since 1984, the first edition, considerable developments have been taken place in detector technology. So instead of RADIOGRAPHIC FILM, solid state detectors are generally used; the second edition thus applies such detectors, while keeping the alternative of RADIOGRAPHIC FILM.

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

FDIS	Report on voting
62B/XXX/FDIS	62B/XXX/RVD

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

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

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

reconfirmed,

withdrawn,

replaced by a revised edition, or

amended.

The National Committees are requested to note that for this publication the stability date is 2032. THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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

1 Scope

This International Standard is applicable to X-RAY SOURCE ASSEMBLIES and X-RAY TUBE ASSEMBLIES, for use in MEDICAL DIAGNOSTIC RADIOLOGY for techniques in which the X-RAY PATTERN will be received simultaneously in all points of the IMAGE RECEPTION AREA.

This standard 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 1 AIR KERMA or AIR KERMA RATE are the only practical verifiable physical quantities for X-RAY SOURCES. X-RAY SOURCES must be tested independently from MEDICAL ELECTRICAL SYSTEMS. Conversion to the characteristics of the X-RAY IMAGE RECEPTOR used in a MEDICAL ELECTRICAL SYSTEM may be done in addition.

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

NOTE 2 The maximum symmetrical RADIATION FIELD may change from its initial value as the X-RAY TUBE ages through use.

NOTE 3 If, for certain MEDICAL ELECTRICAL SYSTEMS the scope of IEC 60806 does not fit, then the special RADIATION FIELD requirements could be incorporated in the MEDICAL ELECTRICAL SYSTEM particular standard. However, a statement on the RADIATION FIELD while referring IEC 60806 is then no longer possible.

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 rotating anode X-ray tubes 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 TR 60788:2004, 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 60336:2020 apply.

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

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch

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

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.

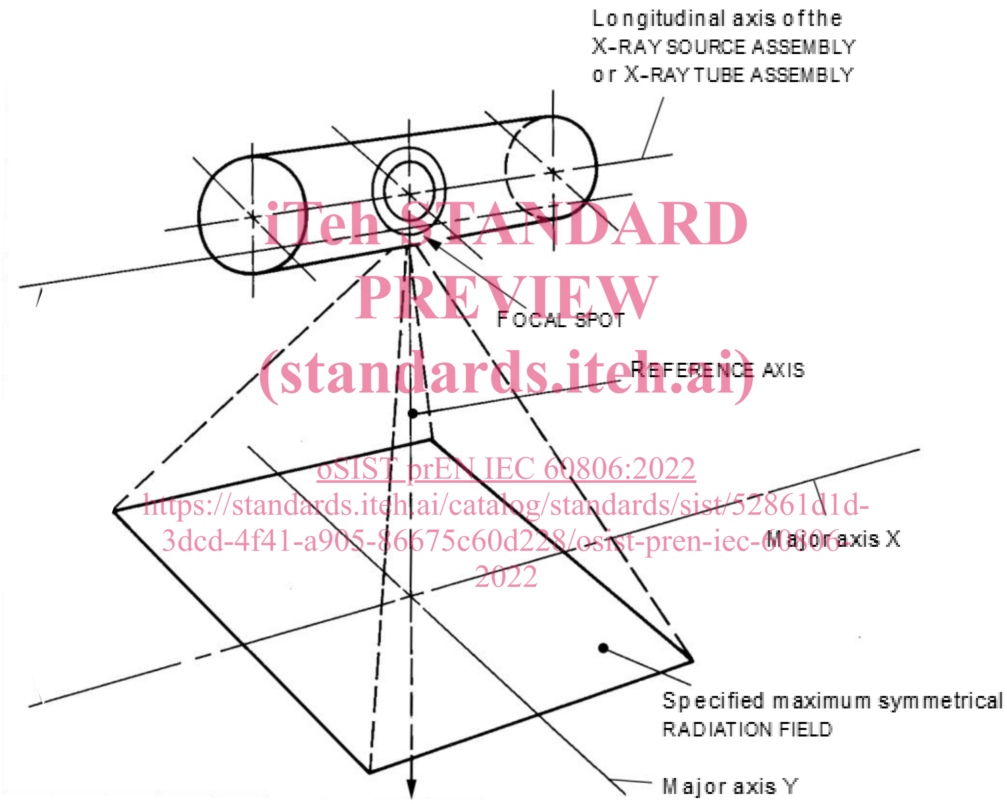

Figure 1 – Orientation of the maximum symmetrical RADIATION FIELD

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 subclause 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 AIR KERMA RATE by ATTENUATION in the ANODE for angles close to the ANODE ANGLE.

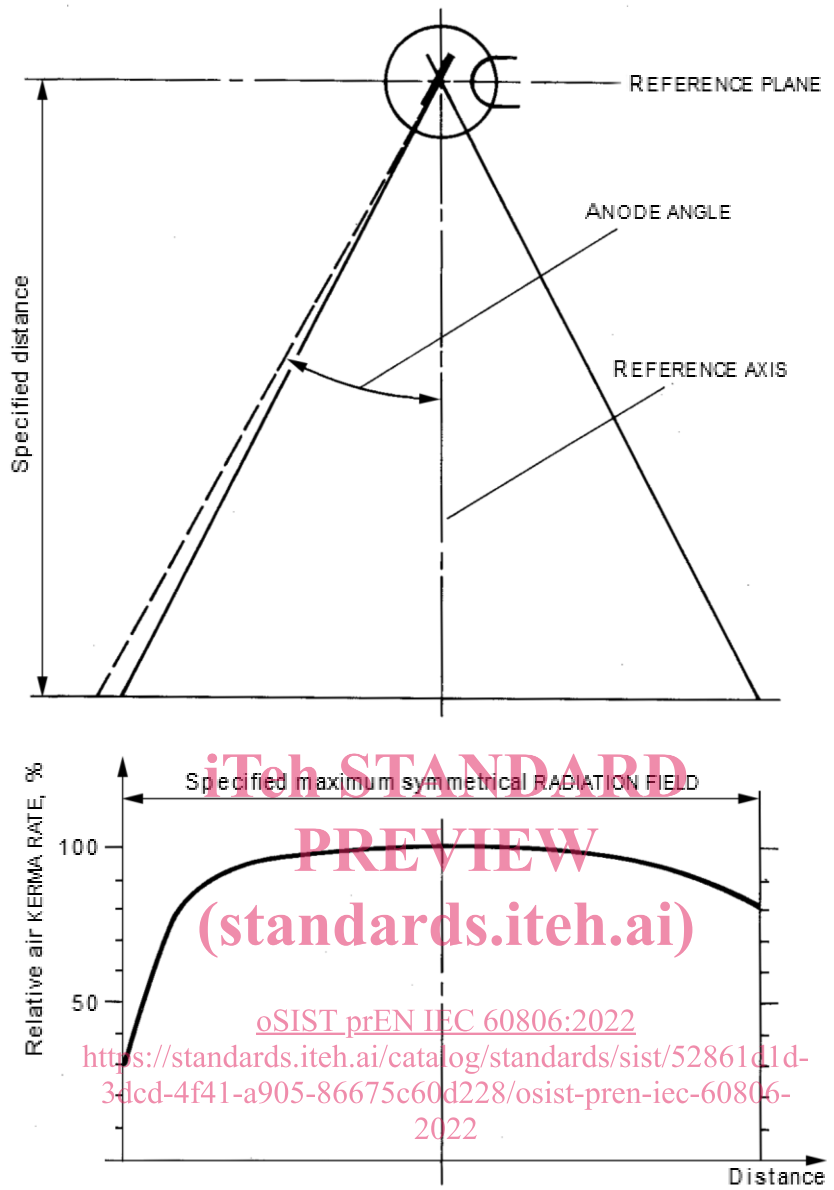

Figure 2 – Typical distribution of the relative AIR KERMA RATE along the major axis X of a maximum symmetrical RADIATION FIELD

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 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 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 a spatial resolution 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 linearized values of AIR KERMA RATE. Measuring arrangement

The required measuring arrangement is shown in Figure 3. At a distance of 75 % of the specified smallest distance a_{min} of the IMAGE RECEPTOR 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 it is recommended to apply the distance of 1000 mm.

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, the measuring arrangement shall be so as to minimize SCATTERING and BACK-SCATTERING.

5.2 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, in kV	FILTER thickness of aluminium, in mm	Required X-RAY TUBE VOLTAGE, in 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 may 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.