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Medicinska diagnostična rentgenska oprema - Sevalni pogoji pri določanju karakteristik (IEC 61267:2025)

Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics (IEC 61267:2025)

Medizinische diagnostische Röntgeneinrichtung - Bestrahlungsbedingungen zur Bestimmung von Kenngrößen (IEC 61267:2025)

Equipement de diagnostic médical à rayonnement x - Conditions de rayonnement pour utilisation dans la détermination des caractéristiques (IEC 61267:2025)

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Medizinische diagnostische Röntgeneinrichtung - Bestrahlungsbedingungen zur Bestimmung von Kenngrößen (IEC 61267:2025)

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European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 62C/958/FDIS, future edition 3 of IEC 61267, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61267:2026.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2027-02-28
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2029-02-28

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The text of the International Standard IEC 61267:2025 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60731:2011	NOTE	Approved as EN 60731:2012 (not modified)
IEC 61676:2023	NOTE	Approved as EN IEC 61676:2023 (not modified)
IEC 61267:2005	NOTE	Approved as EN 61267:2006 (not modified)
IEC 62220-1-1	NOTE	Approved as EN 62220-1-1
IEC 62220-1-3	NOTE	Approved as EN 62220-1-3

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 61674	-	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	EN IEC 61674	-
IEC 61676	-	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN IEC 61676	-

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Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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IEC 61267 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published 2005. This edition constitutes a technical revision.

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

a) removing former Annex C "Measurement of the practical peak voltage";
b) inserting informative Annex C "Tabulated values for the squared signal-to-noise ratio per air kerma (SNR^2_{in})" and normative Annex D "Additional X-ray radiation conditions as used in mammography and determination of the corresponding nominal aluminium half-value layers";
c) revision of X-ray radiation conditions;
d) new method for verification of X-ray radiation conditions;
e) change of term definitions.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62C/958/FDIS	62C/965/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 ww.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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, or
– revised.

INTRODUCTION

To establish characteristics, aspects or properties of associated equipment or to have available radiation beams for physical and medical investigations, sets of well-defined X-ray radiation conditions can offer an important tool in many situations.

From a regulation and standardization point of view, there is a need

– to have available well-defined X-ray radiation conditions that can be used internationally to specify standards of operation of X-ray equipment,
– to provide a basis for the harmonization of existing national standards,
– to provide uniform sets of X-ray radiation conditions (a dictionary of X-ray radiation conditions) to describe and judge the performance of X-ray equipment for the benefit of manufacturers, users, patients and health protection authorities, and
– to solve communication problems between manufacturers, users and regulatory authorities, stemming from a lack of internationally accepted definitions and test methods.

From an application point of view, commonly accepted sets of X-ray radiation conditions would in general find use in

– quality control tests by manufacturers,
– installation and acceptance tests,
– calibration of test instrumentation,
– type approval tests (where required),
– inspection and tests by regulatory authorities and testing institutes,
– physical and medical studies in physical laboratories and medical facilities, and
– determination of characteristics of associated equipment.

Standardized X-ray radiation conditions can benefit a range of potential users, such as

– manufacturers of X-ray equipment,
– manufacturers of X-ray test instrumentation,
– research laboratories,
– testing institutes,
– government regulatory authorities,
– service organizations, and
– standardization organizations.

The X-ray radiation conditions defined in this document are intended to represent the range of typical X-ray radiation beams encountered in medical diagnostic X-ray equipment. This includes X-ray radiation beams passing through the filtration of an X-ray source assembly whereby the radiation field includes only an insignificant amount of scattered radiation. It also includes the more general case, where scattered radiation emerges from an exit surface of a patient or a phantom. An overview of the X-ray radiation conditions defined in this document and of possible applications can be found in Annex E.

Potential applications include studies for devices used in specific imaging modalities such as mammography. However, the clauses of this document are not intended to represent specific imaging modalities in general. For example, the X-ray radiation conditions described in Clause 5 can be useful for examinations of equipment found in dental radiography but also for examinations of equipment related to chest radiography. In addition, some X-ray radiation conditions can only partially cover the range of equipment for a particular imaging task. Therefore, imaging modalities are not explicitly included or excluded from the scope of this document.

1 Scope

This document applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-ray equipment, require well-defined X-ray radiation conditions.

This document deals with methods for generating X-ray radiation conditions which can be used under test conditions typically found in test laboratories or in manufacturing facilities for the determination of characteristics of medical diagnostic X-ray equipment.

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 61674, *Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676, *Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 61674, IEC 61676 and the following apply.

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

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

3.1 Terms defined in this document

3.1.1
application distance
distance from the effective focal spot to the application plane

3.1.2
application plane
plane perpendicular to the central beam axis, where the X-ray radiation condition is defined

3.1.3
central beam axis
line from the effective focal spot through the centre of the diaphragm

3.1.4
exit surface
<radiology> plane or curved surface through which the radiation beam emerges from an irradiated object

3.1.5
homogeneity coefficient
ratio of first to second half-value layer

Note 1 to entry: The first HVL gives the thickness of a specified material which reduces the air kerma rate to half the value without this material; the second HVL gives the additional thickness to reduce the air kerma rate to a quarter.

3.1.6
X-ray radiation condition
selection of the following parameters to achieve specific X-ray beam characteristics:

– material of the emitting target;
– X-ray tube voltage;
– specific total filtration consisting of that of
  • the X-ray tube assembly, and
  • additional filtration;
– first half-value layer;
– homogeneity coefficient;
– application distance;
– properties of diaphragms;
– properties of a phantom used

Note 1 to entry: In the scope of this document the additional filtration is a result of added filters, phantoms and a monitor chamber.

3.1.7
X-ray tube voltage
potential difference applied to an X-ray tube between the anode and the cathode

Note 1 to entry: The X-ray tube voltage can vary as a function of time. The practical peak voltage is a weighted value of the X-ray tube voltage over a time period.

Note 2 to entry: The unit of this quantity is the volt (V).

3.1.8
reference direction
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

3.2 Terms defined in other standards

3.2.1
reference point
point of a radiation detector which, during the calibration of the detector, is brought to coincidence with the point at which the conventional true value is specified

[SOURCE: IEC 60731:2011, 3.16, modified – The words "of the chamber" have been removed from the preferred term; "an ionization chamber" has been replaced with a "radiation detector" in the definition.]

3.2.2
practical peak voltage
$\hat{U}$

$$\hat{U} = \frac{\int_{U_{\min}}^{U_{\max}} p(U) \times w(U) \times U dU}{\int_{U_{\min}}^{U_{\max}} p(U) \times w(U) dU} \text{ with } \int_{U_{\min}}^{U_{\max}} p(U) dU = 1 \quad (1)$$