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

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FOREWORD

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This commented version (CMV) of the official standard IEC 61267:2025 edition 3.0 provides the user with comments from IEC SC 62C experts explaining the reasons for the most relevant changes made to the previous IEC 61267:2005 edition 2.0, or clarifying specific parts of the content.

Experts' comments are identified by a blue-background number. Mouse over a number to display a pop-up note with the comment.

This publication contains the CMV and the official standard. The full list of comments is available at the end of the CMV.

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 1
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
$\hat{U}$

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

where

$p(U)$	is the distribution function for the voltage U;
$w(U)$	is a weighting function;
U_{max}	is the highest voltage in the interval;
U_{min}	is the lowest voltage in the interval

Note 1 to entry: The unit of the quantity practical peak voltage is the volt (V).

[SOURCE: IEC 61676:2023, 3.16, modified - The second note to entry has been deleted.]

3.2.3
acceptance test
test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications

[SOURCE: IEC TR 60788:2004, rm-70-01]

3.2.4
accessory
additional component for use with an equipment in order:

– to perform its intended use;
– to adapt the equipment to some special use;
– to facilitate the use of the equipment;
– to enhance the performance of the equipment;
– to enable the functions of the equipment to be integrated with those of other equipment

[SOURCE: IEC TR 60788:2004, rm-83-06]

3.2.5
added filter
removable or irremovable filter positioned in the radiation beam to provide part or all of the additional filtration

[SOURCE: IEC TR 60788:2004, rm-35-02]

3.2.6
additional filtration
quality equivalent filtration due to added filters and other removable materials in the radiation beam which are between the radiation source and the patient or a specified plane

[SOURCE: IEC TR 60788:2004, rm-13-47]

3.2.7
air kerma
K

$$K = \frac{\mathrm{d}E_{\mathrm{tr}}}{\mathrm{d}m} \tag{2}$$

where

dE_{tr} is the sum of the initial kinetic energies of all the charged particles in a mass of air;

dm is the mass of air

Note 1 to entry: The unit of air kerma is J kg^{-1}. The special name for the unit of air kerma is gray (Gy) – see ICRU 60 [4].

[SOURCE: IEC TR 60788:2004, rm-13-11]

3.2.8
air kerma rate
$\dot{K}$

$$\dot{K} = \frac{dK}{dt} \tag{3}$$

where

dK is the increment of air kerma in the time interval dt;

dt is the time interval

Note 1 to entry: The unit is J kg-1 s-1.

Note 2 to entry: If the special name gray is used, the unit of air kerma rate is gray per second (Gy s^{-1}) - see [4].

[SOURCE: IEC TR 60788:2004, rm-13-54]

3.2.9
anti-scatter grid
device to be placed before the image reception area in order to reduce the incidence of scattered radiation upon that area and thus increase the contrast in the X-ray pattern

[SOURCE: IEC TR 60788:2004, rm-32-06]

3.2.10
associated equipment
<Radiological installation> equipment other than those for the production and control of ionizing radiation, but essential for its application

[SOURCE: IEC TR 60788:2004, rm-30-01]

3.2.11
attenuation
reduction of a radiation quantity upon passage of the radiation through matter resulting from all types of interaction with this matter.

Note 1 to entry: Attenuation does not include the geometric reduction of the radiation quantity with distance from the radiation source.

Note 2 to entry: The radiation quantity can be, for example, the particle flux density or the energy density.

[SOURCE: IEC TR 60788:2004, rm-12-08]

3.2.12
automatic exposure control
<X-ray generator> mode of operation in which one or more loading factors are controlled automatically in order to obtain at a pre-selected location a desired quantity of radiation

[SOURCE: IEC TR 60788:2004, rm-36-46]

3.2.13
broad beam condition
arrangement for the measurement of a radiation quantity in a broad beam of ionizing radiation

[SOURCE: IEC TR 60788:2004, rm-37-25]

3.2.14
diaphragm
beam limiting device with either a fixed or an adjustable aperture in practically one plane

[SOURCE: IEC TR 60788:2004, rm-37-29]

3.2.15
effective focal spot
focal spot
perpendicular projection of the actual focal spot on the reference plane

[SOURCE: IEC TR 60788:2004, rm-20-13, modified - The note has been deleted.]

3.2.16
entrance surface
<Radiology> plane or curved surface through which the radiation enters an irradiated object including any bolus which is present

[SOURCE: IEC TR 60788:2004, rm-37-17]

3.2.17
half-value layer
thickness of a specified material which attenuates under narrow beam conditions X- radiation or gamma radiation with a particular radiation energy or with a particular spectrum to an extent such that the kerma rate, exposure rate or absorbed dose rate is reduced to one half of the value that is measured without the material

Note 1 to entry: The half-value layer is expressed in suitable submultiples of the metre together with the material.

[SOURCE: IEC TR 60788:2004, rm-13-42]

3.2.18
inherent filtration
quality equivalent filtration due to the irremovable materials through which the radiation beam passes before emerging from a radiation source assembly or from components thereof

Note 1 to entry: For an X-ray tube assembly, the inherent filtration is expressed in thickness of a reference material which, at a specified voltage and waveform, gives the same radiation quality in terms of first half-value layer.

[SOURCE: IEC TR 60788:2004, rm-13-46]

3.2.19
ionization chamber
ionization detector consisting of a chamber filled with a suitable gas, in which an electric field, insufficient to induce gas multiplication, is provided for the collection at the electrodes of charges associated with ions and the electrons produced in the sensitive volume of the detector by ionizing radiation

[SOURCE: IEC TR 60788:2004, rm-51-03]

3.2.20
manufacturer
organization or individual who produces an equipment

[SOURCE: IEC TR 60788:2004, rm-85-03]

3.2.21
narrow beam condition
arrangement for the measurement of a radiation quantity in a narrow beam of ionizing radiation

[SOURCE: IEC TR 60788:2004, rm-37-23]

3.2.22
patient
person or animal undergoing medical examination or treatment

Note 1 to entry: For purposes of radiological protection, a person or animal is a patient only during the intentional application of ionizing radiation to that person or animal.

[SOURCE: IEC TR 60788:2004, rm-62-03]

3.2.23
patient support
<Radiological equipment> component such as a table top or arm rest, serving to support the patient in order to allow the part of their body which is to be irradiated to be positioned or to be displaced

[SOURCE: IEC TR 60788:2004, rm-30-02]

3.2.24
percentage ripple
<High-voltage generator> ratio of the difference between the highest and the lowest values of a rectified voltage waveform during a cycle of the supply to the highest value, expressed as a percentage

[SOURCE: IEC TR 60788:2004, rm-36-17]

3.2.25
phantom
<Medical radiology> object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question

Note 1 to entry: Phantoms are used, for example, for simulating practical conditions of measurement:

– for purposes of radiation protection;
– for evaluation the performances of diagnostic systems with respect to the radiation or to the object;
– for dosimetry.

[SOURCE: IEC TR 60788:2004, rm-54-01]

3.2.26
quality control
operational techniques and activities that are used to fulfil requirements for quality

[SOURCE: IEC TR 60788:2004, rm-70-07]

3.2.27
quality equivalent filtration
quantitative indication of the filtration effected by one or several layer(s) of reference material(s) which, if substituted in a beam of specified radiation quality under narrow beam condition for the material under consideration, give(s) the same radiation quality as gives the material under consideration

Note 1 to entry: The quality equivalent filtration is expressed in suitable submultiples of the metre together with the reference material(s) and the radiation quality of the incident beam.

[SOURCE: IEC TR 60788:2004, rm-13-45]

3.2.28
radiation beam
<Radiology> spatial region limited in solid angle and containing a flux of ionizing radiation originating from a radiation source that is considered as a point source

EXAMPLE X-ray beam, gamma-ray beam, electron beam, neutron beam.

Note 1 to entry: Leakage radiation and scattered radiation are considered not to form a radiation beam.

[SOURCE: IEC TR 60788:2004, rm-37-05]

3.2.29
radiation beam axis
<Symmetrical radiation beam> line through the centre of the radiation source and half way between the effective edges of the beam limiting device

EXAMPLE X-ray beam axis, gamma-ray beam axis, neutron beam axis, electron beam axis.

Note 1 to entry: Usually, the radiation beam axis coincides within required tolerances with the reference axis of the radiation source.

[SOURCE: IEC TR 60788:2004, rm-37-06]

3.2.30
radiation detector
equipment, generally sub-assembly, or substance which, in the presence of radiation, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of the incident radiation

[SOURCE: IEC TR 60788:2004, rm-51-01]

3.2.31
radiation field
area on a surface intersected by a radiation beam within which the radiation intensity exceeds a specific or specified level

EXAMPLE X-ray field, gammy-ray field, electron field, neutron field.

[SOURCE: IEC TR 60788:2004, rm-37-07]