SLOVENSKI STANDARD

SIST EN 61267:2006

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Medicinska diagnostična rentgenska oprema - Sevalni pogoji pri ugotavljanju karakteristik (IEC 61267:2005)

Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics (IEC 61267:2005)

ICS 11.040.50

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SIST EN 61267:2006(en)

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN 61267

January 2006

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Supersedes EN 61267:1994

English version

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

(IEC 61267:2005)

Equipement de diagnostic médical
à rayonnement X –
Conditions de rayonnement
pour utilisation dans la détermination
des caractéristiques
(CEI 61267:2005)

Medizinische diagnostische
Röntgeneinrichtung –
Bestrahlungsbedingungen zur
Bestimmung von Kenngrößen
(IEC 61267:2005)

This European Standard was approved by CENELEC on 2005-12-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

The text of document 62C/391/FDIS, future edition 2 of IEC 61267, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61267 on 2005-12-01.

This European Standard supersedes EN 61267:1994.

The main changes compared to EN 61267:1994 include:

a) introduction of “practical peak voltage” for measuring X-ray tube voltage;

b) introduction of a new procedure for establishing the radiation qualities;

c) inserting of an informative Annex B “Determination of the amount of additional filtration” and a normative Annex C “Measurement of the practical peak voltage”;

d) revision of radiation qualities and radiation conditions;

e) addition of term definitions.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2008-12-01

This European Standard makes reference to International Standards. Where the International Standard referred to has been endorsed as a European Standard or a home-grown European Standard exists, this European Standard shall be applied instead. Pertinent information can be found on the CENELEC web site.

In this standard, the following print types are used:

– requirements proper: roman type;

– *test specifications: italic type;*

– notes and explanatory matter: small roman type;

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT ARE DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 61267:2005 was approved by CENELEC as a European Standard without any modification.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
61267

Deuxième édition
Second edition
2005-11

Equipement de diagnostic médical à rayonnement X – Conditions de rayonnement pour utilisation dans la détermination des caractéristiques

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

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For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT – RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS

FOREWORD

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International Standard IEC 61267 has been prepared by subcommittee 62C: EQUIPMENT for RADIOTHERAPY, nuclear medicine and RADIATION dosimetry, of IEC technical committee 62: Electrical EQUIPMENT in medical practice.

This second edition cancels and replaces the first edition published in 1994. It constitutes a technical revision. The main changes of the second edition of this standard include:

a) introduction of "practical peak voltage" for measuring X-ray tube voltage;

b) introduction of a new procedure for establishing the radiation qualities;

c) inserting of an informative Annex B "Determination of the amount of additional filtration" and a normative Annex C "Measurement of the practical peak voltage";

d) revision of radiation qualities and radiation conditions;

e) addition of term definitions.

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

FDIS	Report on voting
62C/391/FDIS	62C/393/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.

In this standard, the following print types are used:

– requirements proper: roman type;
– *test specifications: italic type;*
– notes and explanatory matter: small roman type;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT ARE DEFINED IN CLAUSE 3, OR IN OTHER STANDARDS: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

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 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 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 RADIATION CONDITIONS (a dictionary of RADIATION CONDITIONS) to describe and judge the performance of X-RAY EQUIPMENT for the benefit of MANUFACTURERS, USERS, PATIENTS and health protection authorities;

– 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 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;

– determination of characteristics of ASSOCIATED EQUIPMENT.

Standard RADIATION CONDITIONS can benefit a number of potential users, such as:

– MANUFACTURERS of X-RAY EQUIPMENT;

– MANUFACTURERS of X-ray test instrumentation;

– research laboratories;

– testing institutes;

– USERS;

– government regulatory authorities;

– service organizations;

– standardization organizations.

Some provisions and statements in the body of this International Standard require additional information. Such information is presented in Annex A called "Rationale". An asterisk in the left-hand margin of a clause or subclause indicates the presence of such additional information.

In this standard the X-RAY TUBE VOLTAGE is measured as the PRACTICAL PEAK VOLTAGE. The rationale behind using this quantity is given in Annex C. A description of how the quantity PRACTICAL PEAK VOLTAGE is measured is given in Annex C.

In the development of this edition of this standard efforts were made to set up procedures that give a high degree of equivalence of standard RADIATION QUALITIES realized on different X-ray machines. In the first edition the RADIATION QUALITIES were established by adjusting, within given limits the X-RAY TUBE VOLTAGE to such a value that the required HALF-VALUE LAYER was achieved. Depending on the total INHERENT FILTRATION an X-RAY TUBE VOLTAGE had to be selected which could differ from the nominal value by as much as ±5 %. If the INHERENT FILTRATION of the X-RAY TUBE was relatively strong this could be compensated by choosing a lower X-RAY TUBE VOLTAGE and vice versa. For the example of a radiation quality with a nominal X-RAY TUBE VOLTAGE of 100 kV this procedure meant that the tube voltage could be set as low as 95 kV for a moderately filtered RADIATION QUALITY and as high as 105 kV for a heavily filtered X-RAY TUBE. These two RADIATION QUALITIES were considered to be equivalent as long as they both had the required HALF-VALUE LAYER.

This solution was not considered to be an ideal one. However, due to the lack of a suitable and agreed definition of what is usually termed peak voltage no alternative was available. With the arrival of the PRACTICAL PEAK VOLTAGE the situation has changed: With this quantity it is possible by means of an electrical measurement to set the tube voltage of the x-ray generator in question with any arbitrary shape of the ripple to a value that a radiograph taken with a tube connected to this generator has the same low level contrast as a radiograph taken with the same x-ray tube connected to a true constant potential generator operating at the 'correct' voltage.

Given the possibility of setting the tube voltage of any generator to the 'correct' value, irrespective of the shape of the ripple, it becomes difficult to justify the deliberate selection of a 'wrong' tube voltage to compensate for a below or an above average filtration of the x-ray tube. The procedure, by which the radiation qualities are realized in this second edition, consists of setting the X-RAY TUBE VOLTAGE to the 'correct' value and determining the amount of filtration needed to produce the required HALF-VALUE LAYER. The nature of this process implies that there is a certain maximum total INHERENT FILTRATION beyond which a given X-RAY TUBE may no longer be used to produce a given RADIATION QUALITY. This is not new in principle, but it is clearly expressed in this edition. In order not to exclude what are considered as standard X-RAY TUBES, the HALF-VALUE LAYERS of some of the RADIATION QUALITIES have been increased. The new HALF-VALUE LAYERS have been chosen in such a way that it is possible to establish all RADIATION QUALITIES in this standard with an X-RAY TUBE with 2,5 mm Al hardening-equivalent filtration and with ANODE ANGLES down to 9°.

The procedure to be followed according to this edition for producing the RADIATION QUALITIES of the RQR series does require a certain amount of additional effort. This additional effort is largely compensated when the more heavily filtered radiation qualities are realized. The great advantage of the new method lies in a much higher degree of equivalence of a given RADIATION QUALITY with X-RAY TUBES having different INHERENT FILTRATIONS.

MEDICAL DIAGNOSTIC X-RAY EQUIPMENT – RADIATION CONDITIONS FOR USE IN THE DETERMINATION OF CHARACTERISTICS

1 Scope and object

This International Standard applies to test procedures which, for the determination of characteristics of systems or components of medical diagnostic X-RAY EQUIPMENT, require well-defined RADIATION CONDITIONS.

Except for mammography, this standard does not apply to conditions where discontinuities in radiation absorption of elements are deliberately used to modify properties of the RADIATION BEAM (for example by rare earth filters).

RADIATION CONDITIONS as used for screen-film sensitometry are not covered in this standard.

NOTE Screen-film sensitometry is the subject of the ISO 9236 series.

This standard deals with methods for generating RADIATION BEAMS with 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.

Examples of such RADIATION QUALITIES are RADIATION BEAMS emerging through the filtration from the X-RAY SOURCE ASSEMBLY. RADIATION CONDITIONS represent the more general case, where SCATTERED RADIATION emerges from an EXIT SURFACE of a PATIENT or a PHANTOM. This requires a well defined geometrical arrangement.

The most complete specification of RADIATION FIELDS is given by the spectral distribution of the photon fluence. Since the measurement of X-RAY SPECTRA is a demanding task, this standard expresses RADIATION QUALITIES in terms of the X-RAY TUBE VOLTAGE, the first and second HALF-VALUE LAYER. In the case of RADIATION CONDITIONS, specifications are performed additionally in terms of PHANTOM properties and geometry.

The attempt to characterize a spectral distribution just by means of the X-RAY TUBE VOLTAGE, the first and possibly the second HALF-VALUE LAYER is thus a compromise between the mutually conflicting requirements of avoiding excessive efforts for establishing a RADIATION QUALITY and of the complete absence of any ambiguity in the definition of a RADIATION QUALITY. Due to differences in the design and the age of X-RAY TUBES in terms of anode angle, anode roughening and INHERENT FILTRATION, two RADIATION QUALITIES produced at a given X-RAY TUBE VOLTAGE having the same first HALF-VALUE LAYER can still have quite different spectral distributions. Given the inherent ambiguity in the characterization of RADIATION QUALITY, it is essential that further tolerances introduced by allowing certain ranges of values, e.g. for X-RAY TUBE VOLTAGE and first HALF-VALUE LAYER, must be sufficiently small not to jeopardise the underlying objective of this standard. This standard is to ensure that measurements of the properties of medical diagnostic equipment should produce consistent results if RADIATION QUALITIES or RADIATION CONDITIONS in compliance with this standard are used.

To achieve this objective, certain degrees of freedom in the way in which a RADIATION CONDITION could be established in the framework of the first edition of this standard have been removed. The essential restriction introduced in this second edition is that the X-RAY TUBE VOLTAGE is measured and set to its 'correct' value. The second step is to attempt to establish the prescribed first HALF-VALUE LAYER by adding into the beam the necessary amount of ADDITIONAL FILTRATION. If the INHERENT FILTRATION provided by the X-RAY TUBE alone is so strong that the HALF-VALUE LAYER of the RADIATION BEAM emerging from the X-RAY TUBE ASSEMBLY as such is larger than that to be established, the X-RAY TUBE ASSEMBLY used is not suited for producing the desired RADIATION CONDITION. This may occur if the anode angle of the X-RAY TUBE ASSEMBLY is too small and/or in the case of excessive anode roughening due to tube ageing.

In the approach outlined in the two preceding paragraphs the X-RAY TUBE VOLTAGE plays a decisive role. It is therefore essential that the 'correct' X-ray tube voltage is chosen irrespective of the type of high voltage generator connected to the X-RAY TUBE. The way in which this is realized in this standard is by measuring the X-RAY TUBE VOLTAGE in terms of the PRACTICAL PEAK VOLTAGE. This quantity is a weighted mean of all values of the X-RAY TUBE VOLTAGE occurring during an exposure. The weighting is done in such a way that identical values of the PRACTICAL PEAK VOLTAGE give identical values of the low level contrast on a radiograph irrespective of the waveform supplied by the generator.

Although the PRACTICAL PEAK VOLTAGE can be measured non-invasively, the level of uncertainty required in this standard demands the use of invasive techniques. The design and age of the X-RAY TUBE ASSEMBLY influence the result of non-invasive measurements. When PRACTICAL PEAK VOLTAGE is measured invasively, tube design and age have no influence on the result of such a measurement.

In the framework of what is physically feasible, differences in tube design and ageing are taken into account by adding the appropriate amount of ADDITIONAL FILTRATION.

In Annex C further explanations with regard to the PRACTICAL PEAK VOLTAGE are given.

This standard describes both primary RADIATION QUALITIES, which to a good approximation are free of SCATTERED RADIATION (RQR, RQA, RQC, RQT, RQR-M and RQA-M) and, for PATIENT simulation, RADIATION CONDITIONS containing SCATTERED RADIATION (RQN, RQB, RQN-M and RQB-M).

It is crucial to be aware that in the presence of SCATTERED RADIATION the characteristics of X-radiation in terms of fractions of AIR KERMA associated with the PRIMARY RADIATION and the SCATTERED RADIATION depend on the position and nature of any ADDED FILTER or PHANTOM. It is therefore obvious that AIR KERMA measurements in such RADIATION BEAMS need careful consideration.

Clauses 5 to 9 deal with RADIATION CONDITIONS which are essentially free of SCATTERED RADIATION. Due to the spatial homogeneity of these RADIATION CONDITIONS, the APPLICATION DISTANCE does not influence the RADIATION CONDITIONS to a significant extent. These RADIATION CONDITIONS are called RADIATION QUALITIES.

- Clause 5 deals with RADIATION QUALITIES of the RADIATION BEAM emerging from the X-RAY SOURCE ASSEMBLY. Such RADIATION QUALITIES can be used for determining ATTENUATION properties of ASSOCIATED EQUIPMENT.
- Clause 6 deals with RADIATION QUALITIES of the RADIATION BEAM emerging from an irradiated object, that simulates a PATIENT under the conditions that:

  - the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
  - exact simulation of the spectral distribution of the RADIATION BEAM emerging from the PATIENT is not a prerequisite

- Clauses 7 and 8 deal with RADIATION QUALITIES derived from those dealt with in Clause 6 in view of special applications like automatic exposure and automatic brightness control systems and computed tomographs. The radiation transmitted through the irradiated object has properties similar to those of the radiation transmitted through a PATIENT under the conditions that:
  - the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
  - exact simulation of the spectral distribution of the RADIATION BEAM emerging from the PATIENT is not a prerequisite.
- Clauses 9 and 10 deal with RADIATION CONDITIONS where SCATTERED RADIATION is taken into account. This is done either by limiting the amount of SCATTERED RADIATION by appropriate means and/or providing specific additional information.
- Clause 9 deals with measuring arrangements primarily intended in combination with RADIATION CONDITIONS RQB of Clause 10 to be used for those measurements where the contribution of SCATTERED RADIATION to the detected signal is minimal and is known as NARROW BEAM CONDITION.
- Clause 10 deals with RADIATION CONDITIONS to be used for measurements where the contribution of SCATTERED RADIATION to the detected signal is significant and is known as BROAD BEAM CONDITION.

For the RADIATION QUALITIES specified in Clauses 5 to 10 it is assumed that an X-RAY TUBE is available with an anode angle of not less than about 9 degrees. For x-ray tubes with smaller anode angles it may not be possible to realize some or all RADIATION QUALITIES of Clause 5. If some or all RADIATION QUALITIES of the RQR series cannot be realized with a given X-RAY TUBE due to a too strong INHERENT FILTRATION, some special provisions have been made to establish nevertheless the more heavily filtered RADIATION QUALITIES in Clauses 6 to 10 which are in principle based on the RADIATION QUALITIES of the RQR series.

In order to make allowance for the use of X-RAY TUBES with ANODE ANGLES down to 9°, the HALF-VALUE LAYERS of RADIATION QUALITIES RQR 4 to RQR 10 have been increased with respect to the values specified in the first edition of this standard (1994).

Clauses 11 to 14 deal with RADIATION CONDITIONS applicable to mammography.

- Clause 11 deals with RADIATION QUALITIES of the RADIATION BEAM emerging from the X-RAY SOURCE ASSEMBLY. Such RADIATION QUALITIES can be used for determining ATTENUATION properties of ASSOCIATED EQUIPMENT.
- Clause 12 deals with RADIATION QUALITIES transmitted through an irradiated object, that simulates a PATIENT under the conditions that:
  - the contribution of SCATTERED RADIATION in the RADIATION BEAM is not significant;
  - exact simulation of the spectral distribution of the RADIATION BEAM emerging from the PATIENT is not a prerequisite.
- CLAUSE 13 deals with RADIATION CONDITIONS to be used for studies in mammography under NARROW BEAM CONDITION. These RADIATION CONDITIONS are achieved by applying a special tissue-equivalent PHANTOM.