

INTERNATIONAL STANDARD

IEC 60522

Second edition
1999-02

Determination of the permanent filtration of X-ray tube assemblies

*Détermination de la filtration permanente
des gaines équipées*



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For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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International Electrotechnical Commission
Telefax: +41 22 919 0300

3, rue de Varembe Geneva, Switzerland
e-mail: inmail@iec.ch

IEC web site <http://www.iec.ch>



Commission Electrotechnique Internationale
International Electrotechnical Commission
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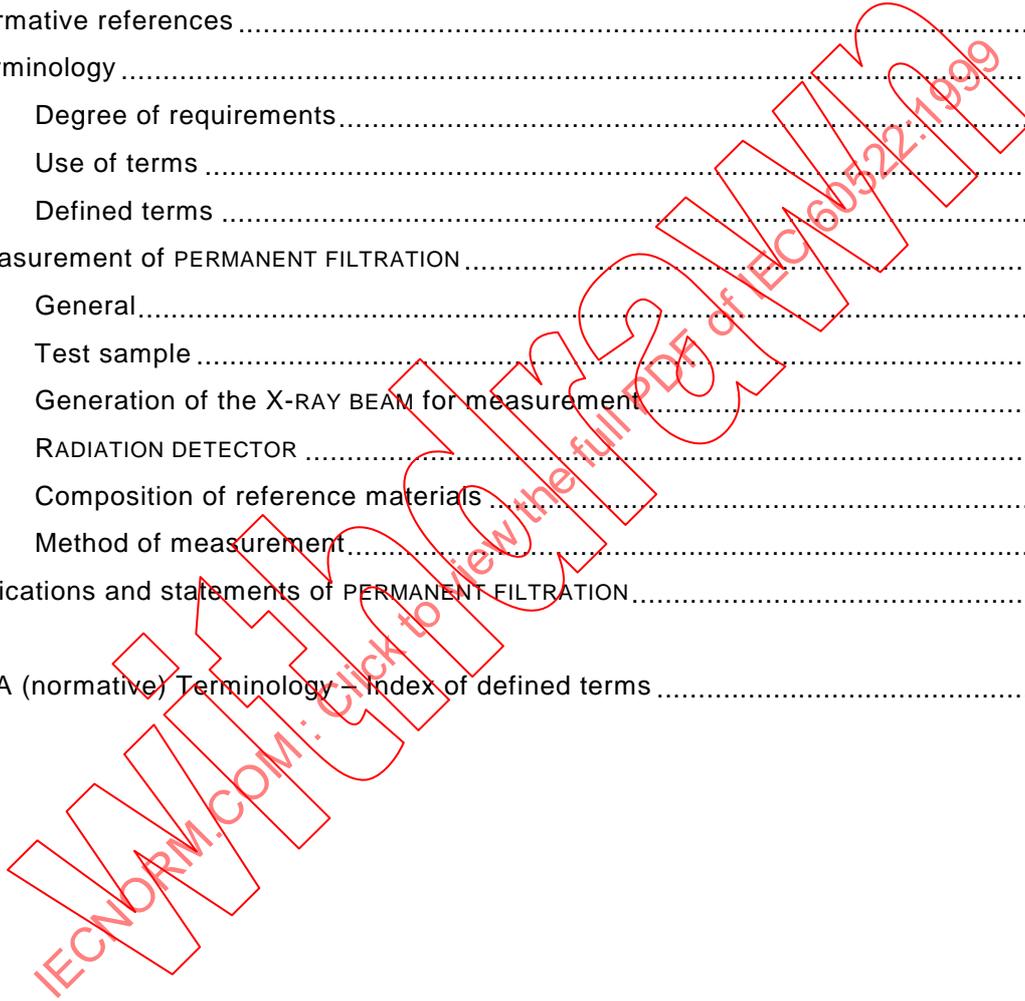
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

DETERMINATION OF THE PERMANENT FILTRATION OF X-RAY TUBE ASSEMBLIES

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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International Standard IEC 60522 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1976 and constitutes a technical revision.

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

FDIS	Report of voting
62B/359/FDIS	62B/363/RVD

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

Annex A forms an integral part of this standard.

In this standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: smaller type;
- *test specifications and headings of subclauses: italic type;*
- TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD, IN CLAUSE 2 OF IEC 60601-1, IN IEC 60788 OR IN ANNEX A: SMALL CAPITALS.

NOTE – Attention is drawn to the existence, in some countries, of legislation concerning RADIATION safety which may not align with the provisions of this standard.

A bilingual version of this standard may be issued at a later date.

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DETERMINATION OF THE PERMANENT FILTRATION OF X-RAY TUBE ASSEMBLIES

1 Scope and object

1.1 Scope

This International Standard applies to X-RAY TUBE ASSEMBLIES for medical diagnosis and RADIOTHERAPY.

1.2 Object

This standard defines the concept of PERMANENT FILTRATION in X-RAY TUBE ASSEMBLIES for medical diagnosis and RADIOTHERAPY and describes a method for its determination. It contains requirements for statements of compliance for ACCOMPANYING DOCUMENTS and for markings on X-RAY TUBE ASSEMBLIES.

Methods are given to determine the PERMANENT FILTRATION in an X-RAY TUBE ASSEMBLY with an accuracy that is sufficient to enable the appropriate ADDITIONAL FILTRATION to be provided in order to attain the desired TOTAL FILTRATION.

NOTE 1 – This standard does not contain requirements for any specific values of PERMANENT FILTRATION or TOTAL FILTRATION to be provided. For X-RAY TUBE ASSEMBLIES and X-RAY EQUIPMENT used for diagnostic purposes, appropriate requirements are given in IEC 60601-1-3.

NOTE 2 – The method of determination described in this standard is suitable as a type test. It is not intended as a test to be applied by the USER.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment No. 1 (1991)
Amendment No. 2 (1995)

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60788:1984, *Medical radiology – Terminology*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

3 Terminology

3.1 Degree of requirements

In this standard, certain terms which are not printed in SMALL CAPITALS have particular meanings, as follows:

- "shall" indicates a requirement that is mandatory for compliance;
- "should" indicates a strong recommendation that is not mandatory for compliance;
- "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
- "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;
- "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the equipment under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in this standard, in IEC 60601-1, or in IEC 60788.

NOTE – Where terms having definitions in the publication listed above are not printed in small capitals, the definitions do not apply and the meaning is determined by the context.

An index of defined terms used in this standard is given in annex A.

3.3 Defined terms

For the purpose of this standard, the following additional definition applies.

3.3.1 PERMANENT FILTRATION: The QUALITY EQUIVALENT FILTRATION effected in an X-RAY TUBE ASSEMBLY by permanently fixed materials intercepting the X-RAY BEAM, that are not intended to be removed for any application and are not provided with means for removal in NORMAL USE.

4 Measurement of PERMANENT FILTRATION

When, in accordance with the requirements in clause 5, the PERMANENT FILTRATION is to be expressed in terms of the actual filtering material (e.g. beryllium), the nature and thickness of the material present shall be determined or verified by inspection. In other cases, the following test shall be used to determine the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY to be indicated or stated in accordance with this standard.

4.1 General

The PERMANENT FILTRATION is determined by measuring the QUALITY EQUIVALENT FILTRATION of samples of the permanently fixed materials, used in the construction of the X-RAY TUBE ASSEMBLY, that intercept the X-RAY BEAM. Where appropriate, a composite sample replicating the combination of the various materials and their thicknesses, as actually used in the construction, can be tested. Alternatively, the PERMANENT FILTRATION can be computed from measurements on samples of the individual materials concerned, provided that:

- the reference material is the same for each sample and,
- the RADIATION QUALITY of the X-RAY BEAM used for the determination is adjusted to compensate for the absence of any components of the PERMANENT FILTRATION missing from the sample and normally located between the sample and the FOCAL SPOT.

NOTE – The result of the determination is valid only for a particular combination of materials, as tested. In manufacture, the composition and thicknesses of materials actually used must be controlled within appropriate limits, in order to maintain compliance with any stated value of PERMANENT FILTRATION.

4.2 Test sample

Use a test sample, replicating, in accordance with 4.1, either the complete composition of layers of different materials, or a layer of an individual material, as used in the construction of the X-RAY TUBE ASSEMBLY concerned to effect the whole or part of its PERMANENT FILTRATION.

4.3 Generation of the X-RAY BEAM for measurement

To generate the X-RAY BEAM for measurement, use an X-RAY TUBE with a target of the same material as the X-RAY TUBE ASSEMBLY under test at an X-RAY TUBE VOLTAGE with a PERCENTAGE RIPPLE not exceeding 10 and a value chosen as follows:

- for X-RAY TUBE ASSEMBLIES in which the PERMANENT FILTRATION contains a material with a K-edge absorption energy at 19 keV or above, use an X-RAY TUBE VOLTAGE corresponding to the K-edge energy of the material, for example 20 kV for molybdenum with a K-edge at 19,99 keV; otherwise
- for X-RAY TUBE ASSEMBLIES designed for a narrow range of X-RAY TUBE VOLTAGE (e.g. CT-application), the NOMINAL X-RAY TUBE VOLTAGE; or
- for X-RAY TUBE ASSEMBLIES with a NOMINAL X-RAY TUBE VOLTAGE not exceeding 65 kV, the NOMINAL X-RAY TUBE VOLTAGE; or
- for X-RAY TUBE ASSEMBLIES with a NOMINAL X-RAY TUBE VOLTAGE exceeding 65 kV, 75 kV or approximately half the NOMINAL X-RAY TUBE VOLTAGE, whichever is the greater. It is desirable to avoid testing close to the absorption edge of tungsten.

For testing with a composite sample, use an X-RAY BEAM with negligible TOTAL FILTRATION (e.g. a beryllium window). For testing with a sample of a single material, add an appropriate thickness of the reference material between the material under test and the FOCAL SPOT. This is to compensate for the effect on the RADIATION QUALITY at the ENTRANCE SURFACE of the sample of omitting any layers of material forming part of the actual PERMANENT FILTRATION.

4.4 RADIATION DETECTOR

Use a RADIATION DETECTOR with a response that does not vary significantly over the energy range involved.

4.5 Composition of reference materials

Values of HALF-VALUE LAYER and QUALITY EQUIVALENT FILTRATION determined in accordance with this standard apply to reference materials of the following composition (designated by Cu 99,9 according ISO 2092):

- aluminium of 99,9 % purity or higher and density $2,70 \text{ g cm}^{-3}$;
- copper of at least 99,9 % purity or higher and a density of $8,90 \text{ g cm}^{-3}$.

4.6 Method of measurement

Measure the first HALF VALUE LAYER of the X-RAY BEAM under NARROW BEAM CONDITIONS, with the sample placed close to the FOCAL SPOT. Determine the thickness of the reference material

that is required to produce the same HALF VALUE LAYER under the same beam conditions. The resulting thickness of the reference material is the QUALITY EQUIVALENT FILTRATION of the sample.

If the sample is a composite one, representing all the materials comprising the PERMANENT FILTRATION, the result is also the value of the PERMANENT FILTRATION for the X-RAY TUBE ASSEMBLY concerned. Alternatively, add the values obtained (with the same reference material and primary beam conditions) for the QUALITY EQUIVALENT FILTRATION of samples representing all the different single materials forming part of the PERMANENT FILTRATION.

Compliance with a stated value of PERMANENT FILTRATION is achieved if the MEASURED VALUE determined in this test is not less than the stated value and does not exceed the stated value by more than 30 %.

5 Indications and statements of PERMANENT FILTRATION

For statements of compliance with this standard, the value of the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY shall be expressed in millimetres the thickness of:

- the material concerned, if the PERMANENT FILTRATION consists of a single material (e.g. beryllium), otherwise
- aluminium for X-RAY TUBE ASSEMBLIES with a NOMINAL X-RAY TUBE VOLTAGE not exceeding 150 kV, together with the X-RAY TUBE VOLTAGE used in the determination; or
- copper for X-RAY TUBE ASSEMBLIES with a NOMINAL X-RAY TUBE VOLTAGE exceeding 150 kV, together with the X-RAY TUBE VOLTAGE used for the determination.

Filtering or reference materials shall be described by their chemical symbols. The X-RAY TUBE VOLTAGE used for measurement, where applicable, shall be given in kilovolts.

If an indication or statement of compliance with this standard is to be given, it shall take the applicable form, as given below as an example, which applies to a stated value of 1,2 mm determined with aluminium as the reference material at an X-RAY TUBE VOLTAGE of 75 kV:

- a) for written statements, for example in ACCOMPANYING DOCUMENTS:

Permanent Filtration 1,2 mm Al/75 kV IEC 60522/1999;

- b) for markings on the X-RAY TUBE ASSEMBLY:

1,2 Al/75

NOTE 1 – In case a) above note that the units mm and kV are to be included.

NOTE 2 – Where the PERMANENT FILTRATION is to be stated in terms of the actual filtering material (e.g. beryllium) no X-RAY TUBE VOLTAGE is applicable. In all other cases, the voltage of determination is to be included.

Annex A (normative)

Terminology – Index of defined terms

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