

TECHNICAL REPORT



**Medical electrical equipment – Diagnostic X-rays –
Part 2: Guidance and rationale on quality equivalent filtration and permanent
filtration**



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

TECHNICAL REPORT



**Medical electrical equipment – Diagnostic X-rays –
Part 2: Guidance and rationale on quality equivalent filtration and permanent
filtration**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-8880-1

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	8
2 Normative references	8
3 Terms and definitions	8
4 Technical issues in IEC 60522:1999	9
4.1 General.....	9
4.2 Subclause 4.1, second dash, of IEC 60522:1999	9
4.3 Subclause 4.3, first paragraph, of IEC 60522:1999	9
4.4 Subclause 4.3, item a) of IEC 60522:1999	9
4.5 Subclause 4.3, item d), last phrase, of IEC 60522:1999	9
4.6 Subclause 4.3, last paragraph, of IEC 60522:1999.....	9
4.7 Subclause 4.6, second paragraph, second phrase of IEC 60522:1999	10
5 Influence of HIGH VOLTAGE and of atomic number of FILTER MATERIAL	10
5.1 General.....	10
5.2 RADIOGRAPHY – Atomic number of FILTERS ≤ 30	11
5.3 RADIOGRAPHY – Atomic number of FILTERS > 30	19
5.4 Mammography	20
5.5 Additivity	21
5.5.1 General	21
5.5.2 RADIOGRAPHY	21
5.5.3 Mammography	24
5.5.4 Decision process for the indirect determination of the permanent FILTRATION	24
6 Alignment of the REFERENCE AXES	25
6.1 General.....	25
6.2 RADIOGRAPHY – Atomic number ≤ 30	25
6.3 RADIOGRAPHY – Atomic number > 30	26
6.4 Mammography	26
7 Requirements on the HIGH VOLTAGE.....	27
7.1 General.....	27
7.2 RADIOGRAPHY – Determination at the K-edge – Requirement on constancy	27
7.3 Mammography – Requirement on constancy	28
7.4 Ripple	28
7.5 Choice of HIGH VOLTAGE	29
8 FILTERING MATERIAL – Representative TARGET ANGLE	30
8.1 General.....	30
8.2 RADIOGRAPHY – Atomic number ≤ 30	30
8.3 RADIOGRAPHY – Atomic number > 30	30
8.4 Mammography	31
9 RADIATION BEAM simulations	32
9.1 Simulation tool	32
9.2 Validation.....	32
10 Statement of QUALITY EQUIVALENT FILTRATION.....	33
10.1 Accuracy.....	33
10.2 PERMANENT FILTRATION	33

Bibliography.....	34
Figure 1 – Typical FILTER materials for mammography and RADIOGRAPHY	11
Figure 2 – QUALITY EQUIVALENT FILTRATION of elements as a function of HIGH VOLTAGE.....	12
Data adapted from reference [4]. Axes logarithmic.....	13
Figure 3 – Mass X-ray attenuation coefficients (μ/ρ) vs. photon energy.....	13
Figure 4 – Energetic location of discontinuities of the absorption coefficients (vertical axis) of elements vs. their atomic number, characteristic lines, L- and K-edge energies.....	14
Figure 5 – QEF of 0,1 mm Cu FILTER vs. thickness of an additional Al FILTER (at HIGH VOLTAGE of 75 kV).....	15
Figure 6 – QUALITY EQUIVALENT FILTRATION of elements with 1,0 mm Al pre-FILTRATION as a function of HIGH VOLTAGE (W TARGET with TARGET ANGLE 10°, thickness according to Figure 2).....	16
Figure 7 – QEF of 0,1 mm Cu as determined with various pre-FILTRATION materials as a function of HIGH VOLTAGE.....	17
Figure 8 – X-RAY spectra (12 ° W TARGET, 100 kV HIGH VOLTAGE) for FILTER materials Cu and Al with the same QEF	18
Figure 9 – X-RAY spectra from a 12° W TARGET with 1,0 mm additional FILTRATION	19
Figure 10 – QEF of a 0,025 mm W FILTER as a function of HIGH VOLTAGE	20
Figure 11 – Four typical examples of PERMANENT FILTRATION of mammographic X-RAY TUBE ASSEMBLIES as a function of HIGH VOLTAGE.....	21
Figure 12 – Inconsistent results from addition of the qefs according to IEC 60522:1999.....	23
Figure 13 – Example of failing additivity concept of IEC 60522:1999 in mammography	24
Figure 14 – Indirect determination of PERMANENT FILTRATION	25
Figure 15 – Dependency of the QEF of a 0,025 mm W FILTER on the TARGET ANGLE.....	31
Figure 16 – QEF for a range of practical TARGET ANGLES in mammography.....	32
Table 1 – QEF-variation of 0,1 mm Cu FILTER with Al pre-FILTRATION.....	16
Table 2 – Representative combinations of mammography TARGETS and FILTERS.....	20
Table 3 – Sample comparison of concepts of addition: IEC 60522:1999.....	22
Table 4 – Sample comparison of concepts of addition: IEC 60522-1	22
Table 5 – PERMANENT FILTRATION per order of the FILTERS – comparison of concepts.....	23
Table 6 – Impact of angular misalignment on PERMANENT FILTRATION.....	26
Table 7 – Impact of angular misalignment on PERMANENT FILTRATION.....	26
Table 8 – Impact of angular misalignment on PERMANENT FILTRATION.....	26
Table 9 – Impact of HIGH VOLTAGE shift (close to K-edge) on PERMANENT FILTRATION.....	27
Table 10 – Impact of HIGH VOLTAGE shift (distant from K-edge) on PERMANENT FILTRATION.....	27
Table 11 – Impact of shift of HIGH VOLTAGE on PERMANENT FILTRATION.....	28
Table 12 – Sensitivity for VOLTAGE RIPPLE.....	29
Table 13 – Influence on QEF of low-Z FILTRATION and of TARGET ANGLE	30
Table 14 – Comparison of simulated and measured PERMANENT FILTRATION.....	33

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –**Part 2: Guidance and rationale on quality equivalent
filtration and permanent filtration****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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

IEC TR 60522-2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice. It is a Technical Report.

The text of this Technical Report is based on the following documents:

Draft	Report on voting
62B/1136/DTR	62B/1159/RVDTR

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 Technical Report 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 www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

A list of all parts in the IEC 60522 series, published under the general title *Medical electrical equipment – Diagnostic X-rays*, can be found on the IEC website.

In this document, the following print types are used:

- requirements and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR LISTED IN THE INDEX: SMALL CAPITALS.

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

This document supports IEC 60522-1.

The purpose of this document is to identify those items which are substantially modified in IEC 60522-1 versus the 2nd Edition of IEC 60522, published in 1999, as well as to elucidate the technical analyses which led to the many new rationales and new approaches for the determination of the QUALITY EQUIVALENT FILTRATION (abbreviated, where appropriate, like in figures and tables, by “QEF”).

The review of IEC 60522:1999 pointed to several technical issues, as discussed in Clause 4. These issues have been investigated with the help of a RADIATION BEAM HALF-VALUE LAYER simulation tool, based on the SRS-78 code (see [2]¹) and the NIST X-ray mass ATTENUATION COEFFICIENTS [4]. On this basis, HALF-VALUE LAYER values can reliably be obtained (see [3]). (For further confirmation of the tool's accuracy, the tool has been validated against laboratory measurements, with good results – see 9.2).

With this tool, the properties of the RADIATION BEAM can be analysed as a function of the TARGET material, TARGET ANGLE, HIGH VOLTAGE and FILTER material.

It appears then that the following statements in the IEC 60522:1999 are not always true:

- 1) on the concept of adding individual values of QEF to obtain the total QEF value, i.e. the concept of “additivity” (see 5.5 for details);
- 2) on the relevance of the K-edge for RADIOGRAPHY, and
- 3) on the method for determining the PERMANENT FILTRATION on the basis of a composite sample of the materials.

Further, it appears that the method of choice for the determination depends on the class of FILTER material and HIGH VOLTAGE. Two ranges of HIGH VOLTAGE are discerned:

- 1) up to 50 kV;
- 2) from 50 to 150 kV.

In this document, for ease of use, the term “RADIOGRAPHY” is used for applications within the HIGH VOLTAGE range 50 kV to 150 kV, although strictly speaking the defined term “RADIOGRAPHY” does not limit the HIGH VOLTAGE. So “RADIOGRAPHY”, i.e. if it is *not* written in small capitals in order to discern it from the IEC defined term, thus covers applications in the scope of [6] IEC 60601-2-43 (INTERVENTIONAL PROCEDURES), [7] IEC 60601-2-44 (CT), [9] IEC 60601-2-54 (RADIOGRAPHY and RADIOSCOPY), [10] IEC 60601-2-63 and [11] IEC 60601-2-65 (dental applications).

For RADIOGRAPHY, three groups of FILTER materials are discerned, see a) to c).

The term “mammography” is used in this document, for applications up to 50 kV HIGH VOLTAGE. (If mammographic applications go beyond 50 kV, then these are considered to fall within RADIOGRAPHY).

For RADIOGRAPHY, three groups of FILTER materials are discerned, see a) to c).

- a) atomic number not larger than 26 e.g. the materials Cr (Z=22), Ti (Z=24) and Fe (Z=26); these materials may FILTER like aluminium, so they are designated in this document as “Al-like”;

¹ Numbers in square brackets refer to the Bibliography.

- b) atomic number larger than 26, but not larger than 30; in *combination with* the materials of the former group, i.e. “atomic number not larger than 26”, these materials may also act “Al-like”. An important example in this group of materials is copper ($Z=29$);
- c) atomic number larger than 30.

Due attention is given to relatively new FILTERS (Au, W, Ta, Ag, Sn) as applied in RADIOGRAPHY and in mammography.

Recommendations are given for the HIGH VOLTAGE to be used per type of application, HIGH VOLTAGE stability, VOLTAGE RIPPLE; for the alignment of the X-RAY TUBE ASSEMBLIES for the determination of the PERMANENT FILTRATION and for the choice of a representative TARGET ANGLE for the determination of the QUALITY EQUIVALENT FILTRATION of FILTERING MATERIAL.

The results of this document are based on the analyses of error-propagation of many parameters (see e.g. Clauses 6, 7, 8 and Table 1; see also 10.1). In general, the prediction of the total error of a QEF determination is beyond the scope of this document – as each measurement system will be designed with its own balance in parameters and their accuracy. It is thus left up to the manufacturers to analyse the total error of their measurement system, while using, where appropriate, the error-propagation as analysed in this document.

MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration

1 Scope

This document provides guidance on quality equivalent filtration and permanent filtration with regards to the requirements of IEC 60522-1 and its modifications versus IEC 60522:1999.

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 60522:1999, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60522-1:2020, *Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of quality equivalent filtration and permanent filtration*

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 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies 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 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60613:2010, IEC 60522-1:2020, and IEC TR 60788:2004 apply.