ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA Máj 2021

STN	**Zdravotnícke elektrické prístroje Diagnostické röntgenové žiarenie Časť 1: Stanovenie ekvivalentnej filtrácie a permanentnej filtrácie**	**STN EN IEC 60522-1** 36 4729

Medical electrical equipment - Diagnostic X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/21

Obsahuje: EN IEC 60522-1:2021, IEC 60522-1:2020

132613

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60522-1

January 2021

ICS 11.040.50

English Version

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

Appareils électromedicaux - Rayonnements X de diagnostic - Partie 1: Détermination de la filtration de qualité équivalenteet de la filtration permanente (IEC 60522-1:2020)

Medizinische elektrische Geräte - Röntgendiagnostik - Teil 1: Bestimmung von qualitätsäquivalenter Filtration und Dauerfiltration (IEC 60522-1:2020)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 60522-1:2021 E

European foreword

The text of document 62B/1201/FDIS, future edition 1 of IEC 60522-1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60522-1:2021.

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) 2021-10-08
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-01-08

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60522-1:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-2-28:2017 NOTE Harmonized as EN IEC 60601-2-28:2019 (not modified)

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.cenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	—[1]
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	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
IEC 61674	2012	Medical electrical equipment - Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging	EN 61674	2013
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

[1] To be published. Stage at the time of publication: EN 60601-1:2006/FprA2:2020.

IEC 60522-1

Edition 1.0 2020-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Diagnostic X-rays – Part 1: Determination of quality equivalent filtration and permanent filtration

Appareils électromedicaux – Rayonnements X de diagnostic – Partie 1: Détermination de la filtration de qualité équivalenteet de la filtration permanente

IEC 60522-1:2020-12(en-fr)

IEC 60522-1

Edition 1.0 2020-12

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 1: Determination of 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.
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International Standard IEC 60522-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition cancels and replaces the second edition of IEC 60522 published in 1999. This edition constitutes a technical revision. This edition includes the following significant technical changes with respect to the IEC 60522:1999:

The scope of the IEC 60522-1 has been changed with respect to second edition of the IEC 60522 as follows:

a) As radiotherapy standards do not reference IEC 60522, radiotherapy is no longer in the scope. Consequently, the HIGH VOLTAGE is limited to 150 kV, and copper is no longer used as reference material.

b) While IEC 60522:1999 covers only PERMANENT FILTRATION, IEC 60522-1 also covers quite generally “material filtering the X-RAY BEAM incident on the PATIENT”. This concerns materials like ADDED FILTERS, table-tops, a breast COMPRESSION DEVICE, and materials in the BEAM LIMITING DEVICE. For these materials the defined term FILTERING MATERIAL has been introduced.

c) In order to provide technical and scientific background and rationale on the content of IEC 60522-1, IEC TR 60522-2 [2][1] was introduced.

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

FDIS	Report on voting
62B/1201/FDIS	62B/1213/RVD

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

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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;

– 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.

1 Numbers in square brackets refer to the Bibliography.

INTRODUCTION

The review of the second edition of IEC 60522 published in 1999 pointed to a number of technical issues. The analysis of these issues is laid down in the accompanying Technical Report, IEC TR 60522-2 [2]. This Technical Report identifies those items which are substantially modified in the first edition of IEC 60522-1 compared with the second edition of IEC 60522, and elucidates the analyses which led to the many new rationales and new approaches for the determination of the QUALITY EQUIVALENT FILTRATION.

While the second edition of IEC 60522 covers only PERMANENT FILTRATION, IEC 60522-1 also covers quite generally “material filtering the X-RAY BEAM incident on the PATIENT”. This concerns materials like ADDED FILTERS, a PATIENT table, a breast COMPRESSION DEVICE, and materials in the BEAM LIMITING DEVICE. For these materials the defined term FILTERING MATERIAL has been introduced.

With the extension by FILTERING MATERIAL, IEC 60522-1 now explicitly covers what IEC 60601-1-3:2008 requires in its Subclause 7.4 for irremovable materials, i.e. <Determine the represented FILTRATION by irremovable materials in an X-RAY SOURCE ASSEMBLY ..... If this information is not obtainable, determine the QUALITY EQUIVALENT FILTRATION in accordance with IEC 60522>.

MEDICAL ELECTRICAL EQUIPMENT – DIAGNOSTIC X-RAYS –

Part 1: Determination of quality equivalent filtration and permanent filtration

1 Scope

This document applies to X-RAY TUBE ASSEMBLIES and to FILTERING MATERIAL, in medical diagnostic applications up to a HIGH VOLTAGE of 150 kV. For HIGH VOLTAGES greater than 50 kV, this document applies to X-RAY TUBE ASSEMBLIES with tungsten or tungsten-alloy TARGETS only.

NOTE 1 The FILTERING MATERIAL in the X-RAY BEAM can be removable or irremovable; it can be positioned in any orientation or can have any shape (e.g. tapering thickness) – although usually plane-parallel material, perpendicular to the REFERENCE AXIS is applied. Examples of FILTERING MATERIALS are ADDED FILTERS, a PATIENT table (in case of an under-table X-RAY TUBE ASSEMBLY), materials in the BEAM LIMITING DEVICE, or a breast COMPRESSION DEVICE.

NOTE 2 The methodology and statement of compliance given in this document is for flat FILTERS only, but the methodology can be used for any kind of non-flat FILTER. In that case further data are included in order to produce useful results, e.g. field size, geometry/position of FILTER, etc.

This document defines the concept of PERMANENT FILTRATION of X-RAY TUBE ASSEMBLIES, and it defines the term FILTERING MATERIAL.

Methods are given to determine the PERMANENT FILTRATION of an X-RAY TUBE ASSEMBLY and for determining the QUALITY EQUIVALENT FILTRATION of FILTERING MATERIALS.

It contains requirements for statements of compliance of X-RAY TUBE ASSEMBLIES in ACCOMPANYING DOCUMENTS and for markings on X-RAY TUBE ASSEMBLIES, and for indications and statements of compliance of FILTERING MATERIAL.

NOTE 3 This document does not contain requirements for any specific values of PERMANENT FILTRATION. For X-RAY EQUIPMENT used for diagnostic purposes, FILTRATION requirements are given in e.g. IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 or in the applicable particular standard.

NOTE 4 The method of determination described in this document is suitable as a type test. It is not intended as a test to be applied by the USER.

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 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 TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61674:2012, *Medical electrical equipment – Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging*