SLOVENSKI STANDARD
SIST EN IEC 60522-1:2021

01-marec-2021

Medicinska električna oprema - Diagnostični rentgenski žarki - 1. del: Določanje enakovredne kakovosti filtracije in trajne filtracije (IEC 60522-1:2020)

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

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

Ta slovenski standard je istoveten z: **EN IEC 60522-1:2021**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN IEC 60522-1:2021 **en**

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)

This European Standard was approved by CENELEC on 2021-01-08. 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 CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-9036-1

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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>.