SLOVENSKI STANDARD
SIST EN IEC 61223-3-7:2022

01-april-2022

Vrednotenje in rutinsko preskušanje v medicinskih oddelkih za slikanje - 3-7. del: Preskusi sprejemljivosti in konstantnosti - Slikovni učinek rentgenske opreme za računalniško tomografijo s stožčastim snopom (IEC 61223-3-7:2021)

Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography (IEC 61223-3-7:2021)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-7: Abnahmeprüfung und Qualitätssicherung von zahnärztlichen extraoralen Röntgengeräten in Verwendung mit zahnärztlichen Volumentomografiegeräten (IEC 61223-3-7:2021)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-7: Essais d'acceptation et de constance - Performance d'imagerie des appareils à rayonnement X pour la tomodensitométrie dentaire à faisceau conique (IEC 61223-3-7:2021)

Ta slovenski standard je istoveten z: **EN IEC 61223-3-7:2022**

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11.040.50	Radiografska oprema	Radiographic equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography (IEC 61223-3-7:2021)

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CENELEC

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/1249/FDIS, future edition 1 of IEC 61223-3-7, 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 61223-3-7:2022.

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) 2022–10–11
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025–01–11

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61223-3-7:2021 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1 (series)	NOTE	Harmonized as EN 60601-1-9 (series)
IEC 60601-2-44:2009	NOTE	Harmonized as EN 60601-2-44:2009 (not modified) +A11:2011
IEC 60601-2-54:2009	NOTE	Harmonized as EN 60601-2-54:2009 (not modified)
IEC 60601-2-63:2012	NOTE	Harmonized as EN 60601-2-63:2015 (not modified)
IEC 61223-3-4:2000	NOTE	Harmonized as EN 61223-3-4:2000 (not modified)
IEC 61223-3-5:2019	NOTE	Harmonized as EN IEC 61223-3-5:2019 (not modified)
IEC 61910-1	NOTE	Harmonized as EN 61910-1
IEC 62220-1-1:2015	NOTE	Harmonized as EN 62220-1-1:2015 (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 60601-1-3	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
			/A11	2016
IEC 60336	-	Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots	EN/IEC 60336	-

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INTERNATIONAL STANDARD

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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 61223-3-7 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
62B/1249/FDIS	62B/1255/RVD

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 International Standard 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.

In this document, the following print types are used:

– requirements and definitions: roman type.
– test specifications: *italic type*.
– informative material appearing outside of tables, such as notes, examples and references: smaller type; normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

A list of all parts of the IEC 61223 series, published under the general title *Evaluation and routine testing in medical imaging departments,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under 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 provides methods for acceptance testing and constancy testing for DENTAL CONE-BEAM COMPUTED TOMOGRAPHY X-RAY EQUIPMENT.

The complete set of ACCEPTANCE TESTS is to be carried out after the EQUIPMENT has been installed, or a subset of the tests is to be carried out after each MAJOR SERVICE ACTION that is made to installed EQUIPMENT. This is done to facilitate verification of applicable safety and performance standards, regulations, and published and/or contractual specifications that influence the image quality, RADIATION OUTPUT and PATIENT positioning.

The complete set of CONSTANCY TESTS is to be carried out periodically at installed EQUIPMENT. This is done to facilitate verification of stability of the EQUIPMENT according to the applicable safety and performance standards, regulations, and published and/or contractual specifications that influence the image quality, RADIATION OUTPUT and PATIENT positioning.

To maintain the homogeneity of this IEC standard with the other IEC standards addressing DENTAL EXTRA-ORAL X-RAY EQUIPMENT, the measuring methods and the terminology are taken as applicable from the safety standard IEC 60601-2-63:2012+AMD1:2017+AMD2:2021.

Some provisions or statements in this document require additional information, which is presented in the annexes.