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Utvärdering och rutinprovning i avdelningar för medicinsk bildframställning – Del 3-7: Leverans- och konstansprovning – Bildkvalitet hos dentalröntgenutrustning för cone beam-datortomografi (CBCT)

*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*

Som svensk standard gäller europastandarden EN IEC 61223-3-7:2022. Den svenska standarden innehåller den officiella engelska språkversionen av EN IEC 61223-3-7:2022.

Nationellt förord

Europastandarden EN IEC 61223-3-7:2022

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utarbetad inom International Electrotechnical Commission, IEC.

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English Version

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)

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)

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)

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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 (dop) 2022–10–11 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2025–01–11 document have to be withdrawn

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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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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. /A11	2010 2016
IEC 60336	-	Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots	EN/IEC 60336	-

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**

**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**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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**

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.

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

1 Scope and object

This part of IEC 61223 applies to DENTAL CONE-BEAM COMPUTED TOMOGRAPHY X-RAY EQUIPMENT, hereafter also called DENTAL CBCT EQUIPMENT, that conforms to IEC 60601-2-63:2012+AMD1:2017+AMD2:2021.

NOTE 1 DENTAL CBCT EQUIPMENT is a subset of DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

NOTE 2 DENTAL EXTRA-ORAL X-RAY EQUIPMENT can provide one or more of PANORAMIC, CEPHALOMETRIC, tomosynthesis and DENTAL CBCT imaging modalities, all of which are in the scope of the IEC 60601-2-63 basic safety and performance standard.

This document applies to ACCEPTANCE TESTS and CONSTANCY TESTS on DENTAL CONE-BEAM COMPUTED TOMOGRAPHY X-RAY EQUIPMENT.

The aim of ACCEPTANCE TESTS is to verify compliance of the installation or MAJOR SERVICE ACTION with specifications affecting the image quality, RADIATION OUTPUT and PATIENT positioning.

The requirements specified in this document are minimal requirements. The MANUFACTURER can establish criteria for the tests described here that exceed the levels contained in this document.

CONSTANCY TESTS are performed to ensure that the functional performance of ME EQUIPMENT meets established criteria and to enable the early recognition of changes in the properties of components of the ME EQUIPMENT, and to verify compliance with specifications affecting the image quality, RADIATION OUTPUT and PATIENT positioning.

This document also contains requirements for the ACCOMPANYING DOCUMENTS associated with ACCEPTANCE AND CONSTANCY TESTING of the DENTAL CBCT EQUIPMENT.

This document does not apply to:

- aspects of thermal, EMD (electromagnetic disturbances), mechanical and electrical safety;
- aspects of mechanical, electrical and software performance, unless they are essential for performing the ACCEPTANCE TESTS and CONSTANCY TESTS, and directly affect image quality, RADIATION OUTPUT and PATIENT positioning.

NOTE 3 Such aspects are generally addressed by IEC 60601-1 (all parts).

Equipment in the scope of IEC 61223-3-5 is excluded from the scope of this document.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT can provide modalities which are in the scope of IEC 61223-3-4. In this case, the respective clauses of the IEC 61223-3-4 apply.

The object of this document is to establish:

- the essential parameters which describe the performance of DENTAL CBCT EQUIPMENT with regard to the image quality, RADIATION OUTPUT and PATIENT positioning;
- methods of testing and whether measured quantities related to those parameters comply with the specified requirements.

These methods rely on non-invasive measurements performed once the installation or a MAJOR SERVICE ACTION is completed.

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 60601-1-3:2008, *Medical electrical equipment—Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*