IEC 61223-3-7

Edition 1.0 2021-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

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 61223-3-7:2021-12(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8322-1032-4

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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

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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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 41.

3.1
BASELINE VALUE
reference value used for constancy testing

Note 1 to entry: BASELINE VALUES are usually established by the completed ACCEPTANCE TEST.

3.2
CONE BEAM COMPUTED TOMOGRAPHY
CBCT
imaging procedure that generates a three-dimensional volumetric representation from the reconstruction of a number of two-dimensional, digital X-ray images

Note 1 to entry: DENTAL CBCT is a subset of DENTAL VOLUMETRIC RECONSTRUCTION (DVR) – see 201.3.203 of IEC 60601-2-63:2012.

3.3
ORIGINAL DATASET
result of the transformation of the PROJECTION data into a volumetric dataset, including the correction of known, reproducible inhomogeneity of the system and reconstruction

Note 1 to entry: The inhomogeneity is also referred to as "fixed-pattern-noise".

3.4
POSITIONING AIDS
feature that enables the correct positioning of the PATIENT

EXAMPLE: Scout view, presentation of the median sagittal plane, lasers, bite block, head holder, chair.