IEC 61223-3-7

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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

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*

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.

3.5
ARTEFACT
apparent structure, visible in the image, which does not represent a structure within the object

[SOURCE: IEC 61223-3-4:2000, 3.3.1]

3.6
X-RAY FIELD
surface of the field irradiated by X-rays at the plane of the image receptor, limited by the decay of the AIR KERMA to 25 % of the value present in the centre of the X-RAY FIELD

3.7
RESOLUTION INDEX 10
SPATIAL FREQUENCY at which the MODULATION TRANSFER FUNCTION takes the 10 % value

Note 1 to entry: MTF 10 term can also be used.

3.8
RESOLUTION INDEX 50
SPATIAL FREQUENCY at which the MODULATION TRANSFER FUNCTION takes the 50 % value

Note 1 to entry: MTF 50 term can also be used.

3.9
ACCEPTANCE INDEX
AI
index that describes the performance of the device in relation to image quality and AIR KERMA

3.10
HOMOGENEITY
H
consistency of voxel values across one tomographic slice of a specified uniformly dense material

3.11
CONTRAST TO NOISE RATIO
CNR
quantity describing the ability to distinguish the contrast of selected objects in the presence of noise

3.12
MODULATION TRANSFER FUNCTION
MTF
dimensional estimation of the three-dimensional modulation properties of the system

3.13
ACCEPTANCE TEST
test carried out after new ME EQUIPMENT has been installed, or a MAJOR SERVICE ACTION has been performed on existing ME EQUIPMENT, in order to verify compliance with MANUFACTURER's specifications or established requirements

3.14
CONSTANCY TEST
test carried out periodically in order to verify continued compliance with MANUFACTURER's specifications or established requirements

3.15
MAJOR SERVICE ACTION
action that may significantly affect RADIATION OUTPUT, image quality, or PATIENT positioning

EXAMPLE Replacement of the X-RAY GENERATOR, installation of a new BEAM LIMITING DEVICE, installation of a new image receptor, and reinstalling the DENTAL CBCT equipment.

Note 1 to entry: The MANUFACTURER may provide a list of MAJOR SERVICE ACTIONS.

Note 2 to entry: See IEC 61223-3-5:2019, 3.13.

3.16
DENTAL
related to structures in the dento-maxillo-facial region of the PATIENT, including dentition

[SOURCE: IEC 60601-2-63:2012, 201.3.202]

3.17
DOSE AREA PRODUCT
DAP
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section

Note 1 to entry: An alternative term for "DOSE AREA PRODUCT" (DAP) is "AIR KERMA AREA PRODUCT" (KAP) as used in ICRP 135.

[SOURCE: IEC 60601-2-54:2009, 201.3.203, modified – The abbreviated term "DAP" has been added, and the unit deleted.]

3.18
RADIATION OUTPUT
AIR KERMA per CURRENT TIME PRODUCT at a given distance from the FOCAL SPOT in the primary X-RAY BEAM

[SOURCE: IEC 61223-3-4:2000, 3.3.4, modified – The unit has been deleted from the definition.]

4 General aspects of ACCEPTANCE TESTS and CONSTANCY TESTS

4.1 Preconditions

ACCEPTANCE TESTS shall be performed on EQUIPMENT which has been installed, or received a MAJOR SERVICE ACTION, according to the ACCOMPANYING DOCUMENTS.

4.2 General conditions to be considered in testing

4.2.1 PHANTOM

The ACCEPTANCE and CONSTANCY TESTS are based on the evaluation of images acquired with the PHANTOM such as described in the Annex C.

The PHANTOM shall be positioned in such a way that the tests from 5.5 to 5.10 can be performed. Means for mounting the PHANTOM to the EQUIPMENT shall be made available by the MANUFACTURER.

The PHANTOM image data shall be acquired and reconstructed using standard parameters appropriate for a PATIENT. The same parameters established in ACCEPTANCE TESTS shall be used in CONSTANCY TESTS.

Means for analysing the ORIGINAL DATASET of the PHANTOM shall be made available by the MANUFACTURER.

NOTE 1 The MANUFACTURER can provide these parameters in the ACCOMPANYING DOCUMENTS.

NOTE 2 For finding issues before use, it is enough to perform this testing at just one volume/setting.

4.2.2 AIR KERMA

The AIR KERMA exposure conditions shall be the same as the parameters used for the PHANTOM based testing.

4.3 Documents and data for the tests in the ACCOMPANYING DOCUMENTS

Additional requirements for PROCEDURES in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Table 1.

The ACCOMPANYING DOCUMENTS shall contain quality control PROCEDURES to be performed on the ME EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include ACCEPTANCE TEST and CONSTANCY TEST criteria for the tests.

Table 1 – Additional requirements in ACCOMPANYING DOCUMENTS

Title	Subclause
Preconditions	4.1
General conditions to be considered in testing	4.2
Establishment of BASELINE VALUES and TEST frequencies	4.6
Visual inspection	5.1
ACCEPTANCE INDEX	5.8
ARTEFACTS	5.10

4.4 Measuring INSTRUMENTS

The DIAGNOSTIC DOSIMETER used for ACCEPTANCE or CONSTANCY TESTS shall be calibrated to applicable regulatory requirements.

NOTE There might be local regulations regarding calibration requirements.

4.5 MAJOR SERVICE ACTION

After a MAJOR SERVICE ACTION, an ACCEPTANCE TEST shall be performed.

4.6 Record and establishment of BASELINE VALUES and TEST frequencies

The testing conditions and results of performed ACCEPTANCE and CONSTANCY TESTS shall be recorded. The records shall be maintained by the RESPONSIBLE ORGANISATION.

For the AIR KERMA, CNR and RESOLUTION INDEX 50 tests, the baseline values shall be established during the ACCEPTANCE TESTS.

The ACCOMPANYING DOCUMENTS shall provide recommended frequencies for CONSTANCY TESTS.

The minimum frequency for CONSTANCY TESTS of CNR, RESOLUTION INDEX 10 and 50, HOMOGENEITY and geometric accuracy shall be every 6 months. The minimum frequency for CONSTANCY TESTS of AIR KERMA and alignment of X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA shall be every 5 years.

NOTE It is possible national regulations specify a different frequency of testing.

5 Performance tests for DENTAL CBCT EQUIPMENT

5.1 Visual inspection

The presence of the following declarations shall be checked as part of the visual inspection of the marking on the outside of the ME EQUIPMENT and ACCOMPANYING DOCUMENTS:

– characteristics such as X-RAY TUBE VOLTAGE (kV), X-RAY TUBE CURRENT (mA), IRRADIATION TIME (s);

– NOMINAL VALUE of the FOCAL SPOT according to IEC 60336;

– value of the TOTAL FILTRATION according to IEC 60601-1-3.

5.2 Functional test

The following functionality shall be checked:

– positioning aids as described by the MANUFACTURER;

– display of the DOSE AREA PRODUCT.

The functionalities of the system shall be tested according to the procedure provided by the ACCOMPANYING DOCUMENTS.

NOTE 1 Local regulatory requirements can require specific tests.

NOTE 2 Examples of functional tests can be positioning aids, display devices, mechanical movement supporting the X-RAY TUBE ASSEMBLY and X-RAY IMAGE RECEPTOR.

5.3 Relationship between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

5.3.1 Requirement

The X-RAY FIELD shall not over-radiate the EFFECTIVE IMAGE RECEPTION AREA at the surface of the X-RAY IMAGE RECEPTOR more than 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 3 % in both directions. In the case of the X-RAY IMAGE RECEPTOR having an active surface side length below 8 cm, the over-RADIATION shall not be larger than 1 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 2 % in two directions.

5.3.2 Test

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELD, the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.

The maximum size available of the X-RAY FIELD is determined by examination of at least one appropriate image from the DENTAL CBCT EQUIPMENT or use of a test instrument at the location of the X-RAY IMAGE RECEPTOR and compared with the EFFECTIVE IMAGE RECEPTION AREA.

NOTE Examples of test verification methods can be: the presentation of an image from the DENTAL CBCT EQUIPMENT with collimation edges visible or measurement with a device that can detect the boundary of a RADIATION field.

5.4 Reproducibility of the AIR KERMA

5.4.1 Requirement

The deviation of any individual measurement from a set from at least three measurements of incident AIR KERMA K_d from their mean K_d shall not exceed ±5 %.