

Evaluation and routine testing in medical imaging departments —

Part 2: Constancy tests —

Section 2.6 Method for X-ray equipment for computed tomography

The European Standard EN 61223-2-6:1994 has the status of a British Standard

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- British Institute of Radiology
- College of Radiographers
- Department of Health
- Institute of Physical Sciences in Medicine (IPSM)
- Society of X-ray Technology

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National foreword

This British Standard has been prepared by Technical Committee HCC/73, Interchangeable X-ray components, and is the English language version of EN 61223-2-6:1994 *Evaluation and routine testing in medical imaging departments — Part 2-6: Constancy tests — X-ray equipment for computed tomography*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 1223-2-6:1994 published by the International Electrotechnical Commission (IEC).

Cross-references

Publication referred to	Corresponding British Standard
IEC 788	BS 6641:1985 <i>Glossary of medical radiology terms</i> BS 7725 <i>Evaluation and routine testing in medical imaging departments</i>
IEC 1223-1:1993	Part 1:1994 <i>General</i> Part 2 <i>Constancy tests</i>
IEC 1223-2-1:1993	Section 2.1:1994 <i>Method for film processors</i>
IEC 1223-2-2:1994	Section 2.2:1993 <i>Method for radiographic cassettes and film changers and film-screen contact and relative sensitivity of the screen-cassette assembly</i>
IEC 1223-2-3:1993	Section 2.3:1994 <i>Method for darkroom safelight conditions</i>

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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Descriptors: Electromedical equipment, image display, medical imaging, constancy test, evaluation testing, routine testing

English version

Evaluation and routine testing in medical imaging
departments
Part 2-6: Constancy tests — X-ray equipment for
computed tomography

(IEC 1223-2-6:1994)

Essais d'évaluation et de routine dans les
services d'imagerie médicale
Partie 2-6: Essais de constance
Appareils de tomodensitométrie
(CEI 1223-2-6:1994)

Bewertung und routinemäßige Prüfung in
Abteilungen für medizinische Bildgebung
Teil 2-6: Konstanzprüfungen
Röntgeneinrichtungen für
Computertomographie
(IEC 1223-2-6:1994)

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B(CO)107, as prepared by Sub-Committee 62B, Diagnostic imaging equipment, of IEC Technical Committee 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in May 1993.

The reference document was approved by CENELEC as EN 61223-2-6 on 8 March 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-04-01
- latest date of withdrawal of conflicting national standards (dow) 2000-04-01

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given only for information. In this standard, Annex A and Annex ZA are normative and Annex B, Annex C and Annex D are informative.

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Introduction

Some provisions or statements in the body of this part of IEC 1223 require additional information. Such information is presented in Annex D, Rationale. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

1 Scope and object

1.1 Scope

This part of IEC 1223 applies to RADIOLOGICAL INSTALLATIONS with diagnostic X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY.

This standard is intended to assist in the establishment and operation of a QUALITY ASSURANCE PROGRAMME in the diagnostic X-ray department.

This standard is a part of a series of Particular Publications (standards and technical reports) which give methods of tests for the constancy of properties of diagnostic imaging systems as described in IEC 1223-1 (see clause 2).

1.2 Object

This part of IEC 1223 defines:

- variables which describe the imaging performance of the above RADIOLOGICAL INSTALLATIONS;
- methods of checking whether variations in measured variables meet ESTABLISHED CRITERIA;

in order to ensure that the conditions for adequate imaging performance of the X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY are maintained whilst unnecessary IRRADIATION of the PATIENT is avoided.

The methods are based upon either simple measurements using appropriate test equipment or assessments of other information.

The aim of the methods is to detect any significant variation in the level of variables with respect to reference levels of performance. These reference levels are determined following an ACCEPTANCE TEST or a STATUS TEST.

Guidance is given to indicate the degree of variation in any variable which might require appropriate remedial action.

Because RADIOLOGICAL INSTALLATIONS differ widely from each other, it is not possible to specify target values and criteria for the variables in this standard, which are generally applicable.

This standard is not intended to deal with:

- aspects of mechanical or electrical safety;
- optimization of imaging performance;
- special applications of COMPUTED TOMOGRAPHY, for instance quantitative COMPUTED TOMOGRAPHY.

With regard to the measurements, reference is made to methods described in related publications, which for practical reasons should be carried out prior to the application of the methods described in this standard (see clause 2).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of IEC 1223. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this part of IEC 1223 are encouraged to investigate the possibility of applying the most recent editions of the normative documents listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 788:1984, *Medical radiology — Terminology*.

IEC 1223-1:1993, *Evaluation and routine testing in medical imaging departments — Part 1: General aspects*.

IEC 1223-2-1:1993, *Evaluation and routine testing in medical imaging departments — Part 2-1: Constancy tests — Film processors*.

IEC 1223-2-2:1993, *Evaluation and routine testing in medical imaging departments — Part 2-2: Constancy tests — Radiographic cassettes and film changers — Film-screen contact and relative sensitivity of the screen-cassette assembly.*

IEC 1223-2-3:1993, *Evaluation and routine testing in medical imaging departments — Part 2-3: Constancy tests — Darkroom safelight conditions.*

IEC 1223-2-12:19XX, *Evaluation and routine testing in medical imaging departments — Part 2-12: Constancy tests — Film illuminators (under consideration).*

3 Terminology

3.1 Degree of requirements

In this part of IEC 1223 the verbal form:

- “shall” implies that compliance with a requirement is mandatory for compliance with the standard;
- “should” implies that compliance with a requirement is strongly recommended but is not mandatory for compliance with the standard;
- “may” implies that compliance with a requirement is permitted to be accomplished in a particular manner, for compliance with the standard.

The term:

- “specific” when used with parameters or conditions: refers to a particular value or standardized arrangement, usually to those required in an IEC publication or a legal requirement.
- “specified” when used with parameters or conditions: refers to a value or arrangement to be chosen for the purpose under consideration and indicated usually in ACCOMPANYING DOCUMENTS.

3.2 Use of terms

In this part of IEC 1223, terms printed in SMALL CAPITALS are used as defined in IEC 788, 3.3 of this standard or other IEC publications referenced in Annex A. Where a defined term is used as a qualifier in another defined or undefined term it is not printed in capital letters, unless the concept thus qualified is defined, or recognized as a derived term without definition.

NOTE Attention is drawn to the fact that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower-case letters.

3.3 Definitions

3.3.1

COMPUTED TOMOGRAPHY DOSE INDEX (CTDI)

integral of the DOSE PROFILE along a line perpendicular to the tomographic plane from -7 times T to $+7$ times T (where T is the NOMINAL TOMOGRAPHIC SLICE THICKNESS), divided by the product of the NOMINAL TOMOGRAPHIC SLICE THICKNESS and the number of tomograms N produced in a single scan

$$CTDI = \frac{1}{N \times T} \int_{-7 \times T}^{+7 \times T} D(z) dz$$

where

T is the NOMINAL TOMOGRAPHIC SLICE THICKNESS;

N is the number of tomograms produced in a single scan;

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the tomographic plane

NOTE A scan can consist of a number of tomograms (slices).