



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 61223-2-6:2007

ICS 11.040.50

**EVALUATION AND ROUTINE TESTING IN
MEDICAL IMAGING DEPARTMENTS --
PART 2-6: CONSTANCY TESTS - IMAGING
PERFORMANCE OF COMPUTED
TOMOGRAPHY X-RAY EQUIPMENT (IEC
61223-2-6:2006 (EQV))**

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*This Irish Standard was
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Authority of Ireland and
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8 June 2007*

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 61223-2-6

May 2007

ICS 11.040.50

Supersedes EN 61223-2-6:1994

English version

**Evaluation and routine testing in medical imaging departments -
Part 2-6: Constancy tests -
Imaging performance of computed tomography X-ray equipment
(IEC 61223-2-6:2006)**

Essais d'évaluation et de routine
dans les services d'imagerie médicale -
Partie 2-6: Essais de constance -
Performance d'imagerie des équipements
de tomodensitométrie à rayonnement X
(CEI 61223-2-6:2006)

Bewertung und routinemäßige Prüfung
in Abteilungen
für medizinische Bildgebung -
Teil 2-6: Konstanzprüfungen -
Röntgeneinrichtungen
für die Computertomographie
(IEC 61223-2-6:2006)

This European Standard was approved by CENELEC on 2007-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62B/629/FDIS, future edition 2 of IEC 61223-2-6, 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 was approved by CENELEC as EN 61223-2-6 on 2007-03-01.

This European Standard supersedes EN 61223-2-6:1994.

EN 61223-2-6:2007 is harmonized with the content of EN 60601-2-44:2001 + A1:2003 and with EN 61223-3-5:2004. Instead of harmonizing test procedures for all modalities of X-ray equipment, as intended in EN 61223-2-6:1994, this EN 61223-2-6:2007 comprises part of a set of standards covering all of the particular requirements for CT scanners.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2007-12-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2010-03-01 |

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- explanations, advice, notes, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN EN 60601-1, IN EN 60788, IN EN 61223-1 OR IN OTHER PUBLICATIONS REFERENCED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-2-6:2006 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 61223-2-5	NOTE Harmonized as EN 61223-2-5:1994 (not modified).
IEC 61223-2-4	NOTE Harmonized as EN 61223-2-4:1994 (not modified).
IEC 60336	NOTE Harmonized as EN 60336:2005 (not modified).
IEC 60522	NOTE Harmonized as EN 60522:1999 (not modified).
IEC 60601-1	NOTE Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-2-28	NOTE Harmonized as EN 60601-2-28:1993 (not modified).
IEC 60601-2-32	NOTE Harmonized as EN 60601-2-32:1994 (not modified).
IEC 61267	NOTE Harmonized as EN 61267:2006 (not modified).

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-2-44 A1	2001 2002	Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography	EN 60601-2-44 A1	2001 2003
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	EN 61223-3-5	2004

**NORME
INTERNATIONALE
INTERNATIONAL
STANDARD**

**CEI
IEC**

61223-2-6

Deuxième édition
Second edition
2006-11

**Essais d'évaluation et de routine dans
les services d'imagerie médicale –**

**Partie 2-6:
Essais de constance –
Performance d'imagerie des équipements
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**Evaluation and routine testing in
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Numéro de référence
Reference number
CEI/IEC 61223-2-6:2006

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International Electrotechnical Commission
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

FOREWORD

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International Standard IEC 61223-2-6 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994. It constitutes a technical revision. This second edition is harmonized with the content of IEC 60601-2-44:2001 and its Amendment 1 (2002) and with IEC 61223-3-5. Instead of harmonizing test procedures for all modalities of X-ray equipment, as intended in the first edition, this second edition comprises part of a set of standards covering all of the particular requirements for CT scanners.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/629/FDIS	62B/639/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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.

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The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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