SLOVENSKI STANDARD
SIST EN 61223-3-2:2008

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Ovrednotenje in rutinsko preskuġanje v medicinskih oddelkih za slikanje - 3-2. del: Preskusi sprejemljivosti - Slikovni uļ inek rentgenske opreme za mamografijo (IEC 61223-3-2:2007)

Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment (IEC 61223-3-2:2007)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-2: Abnahmeprüfungen - Leistungsmerkmale zur Bildgebung von Röntgen-Einrichtungen für die Mammographie (IEC 61223-3-2:2007)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-2: Essais d'acceptation - Performance d'imagerie des appareils de mammographie à rayonnement X (CEI 61223-3-2:2007)

Ta slovenski standard je istoveten z: EN 61223-3-2:2008

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11.040.50	Radiografska oprema	Radiographic equipment

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Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment

(IEC 61223-3-2:2007)

Essais d'évaluation et de routine dans les services d'imagerie médicale - Partie 3-2: Essais d'acceptation - Performance d'imagerie des appareils de mammographie à rayonnement X (CEI 61223-3-2:2007)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung - Teil 3-2: Abnahmeprüfungen - Leistungsmerkmale zur Bildgebung von Röntgen-Einrichtungen für die Mammographie (IEC 61223-3-2:2007)

This European Standard was approved by CENELEC on 2008-06-01. 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/651/FDIS, future edition 2 of IEC 61223-3-2, 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 61223-3-2 on 2008-06-01.

This European Standard supersedes EN 61223-3-2:1996.

EN 61223-3-2:2008 has been expanded by including tests of equipment properties depending on X-RAY IMAGE RECEPTORS, by putting emphasis on the aspect of image quality and dose and through harmonization, where possible, with other recognized standards. Annex L compares the specific content of EN 61223-3-2:1996 and EN 61223-3-2:2008.

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)	2009-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-06-01

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: smaller type;

– TERMS DEFINED IN IEC/TR 60788, EN 60601-1 OR IN CLAUSE 3 OF THIS STANDARD: SMALL CAPITALS (see index of defined terms).

NOTE 1 Where a defined term is used as a qualifier with another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a derived term without a definition.

NOTE 2 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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61223-3-2:2007 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 60601-1-3	NOTE	Harmonized as EN 60601-1-3:2008 (not modified).
IEC 60601-2-28	NOTE	Harmonized as EN 60601-2-28:1993 (not modified).
IEC 60627	NOTE	Harmonized as EN 60627:2001 (not modified).
IEC 61223-2-4	NOTE	Harmonized as EN 61223-2-4:1994 (not modified).
IEC 61223-2-5	NOTE	Harmonized as EN 61223-2-5:1994 (not modified).
IEC 61223-3-1	NOTE	Harmonized as EN 61223-3-1:1999 (not modified).
IEC 61223-3-3	NOTE	Harmonized as EN 61223-3-3:1996 (not modified).
IEC 61223-3-4	NOTE	Harmonized as EN 61223-3-4:2000 (not modified).
IEC 62220-1-2	NOTE	Harmonized as EN 62220-1-2:2007 (not modified).
ISO 3386-1	NOTE	Harmonized as EN ISO 3386-1:1997 (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.

Publication	Year	Title	EN/HD	Year
IEC 60336	2005	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005
IEC 60601	Series	Medical electrical equipment	EN 60601	Series
IEC 60601-1	-[1)]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006[2)]
IEC 60601-2-45	-[1)]	Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	EN 60601-2-45	2001[2)]
IEC/TS 61223-2-1	-[1)]	Evaluation and routing testing in medical imaging departments - Part 2-1: Constancy tests - Film processors	-	-
IEC 61674	-[1)]	Medical electrical equipment - Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging	EN 61674	1997[2)]
IEC 61676	2002	Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology	EN 61676	2002
ISO 4090	-[1)]	Photography - Medical radiographic cassettes/screens/films and hard-copy imaging films - Dimensions and specifications	-	-
ISO 9236-3	-[1)]	Photography - Sensitometry of screen/film systems for medical radiography - Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.

INTERNATIONAL STANDARD

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61223-3-2

Second edition
Deuxième édition
2007-07

Evaluation and routine testing in medical imaging departments –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

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

Partie 3-2: Essais d'acceptation – Performance d'imagerie des appareils de mammographie à rayonnement X

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CONTENTS

FOREWORD 4
INTRODUCTION 6

1 Scope 7
2 Normative references 8
3 Terms and definitions 9
4 General aspects of the ACCEPTANCE TEST 12
4.1 Levels of compliance 12
4.2 General conditions in test procedures 12
4.3 Documents and data for the tests 13
4.4 Test conditions 14
4.5 Scope of tests 14
4.6 Test EQUIPMENT 15
4.7 Evaluating the test results 16
5 Test methods for mammographic X-RAY EQUIPMENT 17
5.1 Initial test and inventory 17
5.2 X-RAY TUBE VOLTAGE 17
5.3 HALF VALUE LAYER (HVL) 18
5.4 NOMINAL FOCAL SPOT VALUE 19
5.5 X-RAY FIELD limitation and beam alignment 19
5.6 Radiation output 20
5.7 AUTOMATIC EXPOSURE CONTROL (AEC) 20
5.8 Reproducibility of the AIR KERMA 26
5.9 ATTENUATION RATIO of material between the upper surface of the PATIENT SUPPORT and the IMAGE RECEPTION PLANE 26
5.10 Breast COMPRESSION DEVICE 27
5.11 Uniformity 28
5.12 Dynamic range of mammographic X-RAY EQUIPMENT using digital X-ray image receptors, including storage phosphor systems 30
5.13 Spatial resolution 31
5.14 LOW CONTRAST DETECTABILITY 34
5.15 Entrance surface AIR KERMA 35
5.16 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES 36
6 Baseline values for CONSTANCY TESTS 37
7 Test report and statement of compliance 37

Annex A (informative) TEST DEVICES and arrangements for testing the automatic exposure control system with a digital X-RAY IMAGE RECEPTOR 39
Annex B (informative) TEST DEVICE for testing the dynamic range of systems with a digital X-RAY IMAGE RECEPTOR 43
Annex C (informative) Test methods for screen-film X-ray image receptor 44
Annex D (informative) Test methods for storage phosphor system 46

Annex E (informative) Example of a method for the determination of the AVERAGE GLANDULAR DOSE 49
Annex F (informative) Example of TEST DEVICES and arrangements for testing the system contrast transfer function for systems with a digital X-RAY IMAGE RECEPTOR 51
Annex G (informative) LOW CONTRAST DETECTABILITY test for mammographic X-RAY EQUIPMENT using an integrated digital X-RAY IMAGE RECEPTOR or storage phosphor plates 52
Annex H (informative) Example of a mammographic stereotactic TEST DEVICE 54
Annex I (normative) Set-up for HALF-VALUE LAYER measurements 55
Annex J (informative) Definition of the ROIs for testing lag effects 56
Annex K (informative) ARTIFACTS and other non-uniformities 57
Annex L (informative) Cross reference and history 59

Bibliography 60

Terminology – Index of defined terms 62

Figure A.1 – Basic ATTENUATION Plates 39
Figure A.2 – Alternative design for the top attenuating plate 40
Figure A.3 – Alternative design for the two additional attenuating plates (two pieces required) 41
Figure A.4 – Measurement of CNR: 2-step methods 42
Figure B.1 – Test object for the dynamic range (to be used together with a 20 mm PMMA plate placed on top) 43
Figure F.1 – Example of 45° test pattern for the evaluation of the system contrast transfer function 51
Figure H.1 – Example of a mammographic stereotactic TEST DEVICE 54
Figure I.1 – Set-up for HALF-VALUE LAYER measurements 55
Figure J.1 – Definition of the ROIs for testing lag effects 56

Table 1 – Symbols, physical quantities, abbreviations and units used in this standard 11
Table 2 – Examples of typical HALF-VALUE LAYERS (HVL) in millimetres of aluminium (mm Al) for mammographic X-RAY EQUIPMENT with different TARGET FILTER combinations operated at different X-RAY TUBE VOLTAGES 18
Table E.1 – *g* for breasts simulated with PMMA 50
Table E.2 – *c* for breasts simulated with PMMA 50
Table E.3 – Typical HVL measurements for different tube voltage and TARGET FILTER combinations 50
Table E.4 – *s* for clinically used spectra [Dance et al. 2000] 50
Table L.1 – Cross reference list for Editions 1 and 2 of this standard 59

INTERNATIONAL ELECTROTECHNICAL COMMISSION

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

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 61223-3-2 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 1996. It constitutes a technical revision. This second edition has been expanded by including tests of equipment properties depending on X-RAY IMAGE RECEPTORS, by putting emphasis on the aspect of image quality and dose and through harmonization, where possible, with other recognized standards. Annex L compares the specific content of the first and second editions.

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

FDIS	RVD
62B/651/FDIS	62B/659/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.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: smaller type;

– TERMS DEFINED IN IEC 60788, IEC 60601-1 OR IN CLAUSE 3 OF THIS STANDARD: SMALL CAPITALS (see Index of defined terms).

NOTE 1 Where a defined term is used as a qualifier with another defined or undefined term, it is not printed in SMALL CAPITALS, unless the concept thus qualified is defined, or recognized as a derived term without a definition..

NOTE 2 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.

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

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for diagnostic X-RAY EQUIPMENT.

This second edition of the particular standard for the ACCEPTANCE TEST of mammographic X-RAY EQUIPMENT describes test methods for EQUIPMENT using RADIOGRAPHIC FILMS, EQUIPMENT using storage phosphor plates, EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS, and MAMMOGRAPHIC STEREOTACTIC DEVICES.

EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment

1 Scope

This part of IEC 61223 applies to the effectiveness of mammographic X-RAY EQUIPMENT, with respect to image quality and dose, in combination with aspects of EQUIPMENT safety.

This standard applies to mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

The tests described in this standard require the quality and performance of the X-RAY IMAGE RECEPTORS to be assured prior to the acceptance testing when they are not an integral part of the mammographic X-RAY EQUIPMENT. This includes RADIOGRAPHIC FILMS, INTENSIFYING SCREENS, RADIOGRAPHIC CASSETTES, storage phosphor plates and ASSOCIATED EQUIPMENT such as film processors or storage phosphor plate readers, IMAGE DISPLAY DEVICES and HARD COPY CAMERAS.

For testing RADIOGRAPHIC CASSETTES and INTENSIFYING SCREENS, this standard makes reference to ISO 4090. Sensitivity and contrast for the screen-film image receptors are considered to be stated according to ISO 9236-3.

NOTE Currently there exists no IEC standard for acceptance testing of HARD COPY CAMERAS or IMAGE DISPLAY DEVICES.

By the measurements described in this standard, data for AVERAGE GLANDULAR DOSE calculation can be determined.

When the results of the ACCEPTANCE TEST are in compliance with the expected values, the baseline values for the subsequent CONSTANCY TESTS are established.

This part of IEC 61223 defines

a) the essential parameters which describe the performance of the above-mentioned mammographic X-RAY EQUIPMENT with regard to image quality and dose; and

b) the methods of testing whether measured quantities related to those parameters comply with specified tolerances.

These methods mainly rely on non-invasive measurements that use appropriate test EQUIPMENT and are performed during or after the installation. Signed statements covering steps in the installation procedure can be used as part of the ACCEPTANCE TEST. Tests required by a higher level of compliance take precedence over similar tests with a lower level of compliance. This concept is described in 4.1.

This standard does not in itself specify limiting values or tolerances for the parameters under investigation.

A difficulty may arise with regard to the responsibility for acceptance testing when the film/screen combination, film processing chemistry or computed radiography system is changed. This arises from a combination of causes. Firstly, the image receptor MANUFACTURER and the X-RAY EQUIPMENT MANUFACTURER may be different. Secondly a change in image receptor or film processing chemistry may alter the system performance. When system integration such as the above occurs, it is important that acceptance testing is performed. When a change occurs which could alter system performance, it is essential that the system integrator (i.e. whoever is responsible for this change) discusses the implication of their change with the X-RAY EQUIPMENT MANUFACTURER so that the latter can adjust the imaging system if necessary.

ACCEPTANCE TESTING of mammographic X-RAY EQUIPMENT requires average skill in medical physics. However, the decision concerning who performs the test is determined by local rules (e.g. contract, regulation, law).

2 Normative references

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.

IEC 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601 (all parts), *Medical electrical equipment*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-45, *Medical electrical equipment – Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices*

IEC 61223-2-1, *Evaluation and routine testing in medical imaging departments – Part 2-1: Constancy tests – Film processors*

IEC 61674, *Medical electrical equipment – Dosimeters with ionization chambers and/or semi-conductor detectors as used in X-ray diagnostic imaging*

IEC 61676:2002, *Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

ISO 4090, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

ISO 9236-3, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

3 Terms and definitions

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

NOTE Symbols, physical quantities, abbreviations and units used in this standard are given at the end of this clause in Table 1.

3.1
ACCEPTANCE TEST
test carried out after new EQUIPMENT has been installed, or major modifications have been made to existing EQUIPMENT, in order to verify compliance with MANUFACTURER's specifications or requirements

[IEC 61223-1, definition 3.2.4, modified]

3.2
ARTIFACT
apparent structure, visible in the image, which does not represent a structure within the object

[IEC 61223-3-4, definition 3.3.1]

3.3
CONSTANCY TEST
each of a series of tests, carried out:

– to ensure that the functional performance of the EQUIPMENT meets ESTABLISHED CRITERIA; or

– to enable the early recognition of changes in the properties of components of the EQUIPMENT

[IEC 61223-1, definition 3.2.6]

3.4
DIRECT FOCAL DISTANCE
shortest distance from the FOCAL SPOT to the axis of symmetry of the effective IMAGE RECEPTION AREA perpendicular to the chest wall edge of the X-RAY IMAGE RECEPTOR

[IEC 60601-2-45, definition, 2.101.4, modified]

3.5
(DIAGNOSTIC) DOSIMETER
EQUIPMENT which uses IONIZATION CHAMBERS and/or semi-conductor detectors for the measurement of AIR KERMA, air kerma length and/or AIR KERMA RATE in the beam of an X-ray machine used for diagnostic medical radiological examinations

A DIAGNOSTIC DOSIMETER contains the following components:

– one or more detector assemblies which may or may not be an integral part of the measuring assembly;

– a measuring assembly; and/or

– one or more stability check devices (optional)

[IEC 61674, definition 3.1]

3.6
LOW CONTRAST DETECTABILITY
capability of an imaging system to differentiate a low contrast object from a uniform background