# SLOVENSKI STANDARD
# SIST EN 61223-3-1:2002

**01-februar-2002**

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**Evaluation and routine testing in medical imaging departments - Part 3-1: Acceptance tests - Imaging performance of X-ray equipment for radiographic and radioscopic systems**

Evaluation and routine testing in medical imaging departments -- Part 3-1: Acceptance tests - Imaging performance of X-ray equipment for radiographic and radioscopic systems



Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung -- Teil 3-1: Abnahmeprüfungen - Bildgebungsleistung der Röntgeneinrichtung bei radiographischen und Durchleuchtungs-Systemen



Essais d'évaluation et de routine dans les services d'imagerie médicale -- Partie 3-1: Essais d'acceptation - Performance d'imagerie des appareils à rayonnement X pour systèmes radiographiques et radioscopiques

**Ta slovenski standard je istoveten z:** **EN 61223-3-1:1999**

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**ICS:**

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| 11.040.50 | Radiografska oprema | Radiographic equipment |

**SIST EN 61223-3-1:2002** **en**

EUROPEAN STANDARD

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**EN 61223-3-1**

May 1999

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English version

# Evaluation and routine testing in medical imaging departments Part 3-1: Acceptance tests - Imaging performance of X-ray equipment for radiographic and radioscopic systems (IEC 61223-3-1:1999)

Essais d'évaluation et de routine dans les services d'imagerie médicale Partie 3-1: Essais d'acceptation Performance d'imagerie des appareils à rayonnement X pour systèmes radiographiques et radioscopiques (CEI 61223-3-1:1999)

Bewertung und routinemäßige Prüfung in Abteilungen für medizinische Bildgebung Teil 3-1: Abnahmeprüfungen Bildgebungsleistung der Röntgeneinrichtung bei radiographischen und Durchleuchtungs-Systemen (IEC 61223-3-1:1999)



This European Standard was approved by CENELEC on 1999-05-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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/361/FDIS, future edition 1 of IEC 61223-3-1, 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 61223-3-1 on 1999-05-01.

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) 2000-02-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2002-05-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes A and ZA are normative and annexes B, C, D and E are informative.
Annex ZA has been added by CENELEC.

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## Endorsement notice

The text of the International Standard IEC 61223-3-1:1999 was approved by CENELEC as a European Standard without any modification.

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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 | 1993 | X-ray tube assemblies for medical diagnosis Characteristics of focal spots | EN 60336 | 1995 |
| IEC 60417-1 | 1998 | Graphical symbols for use on equipment Part 1: Overview and application | EN 60417-1 | 199X |
| IEC 60522 | 1976[1)] | Inherent filtration of an X-ray tube assembly | - | - |
| IEC 60580 | 1977 | Area exposure product meter | HD 379 S1 | 1979 |
| IEC 60601-1 | 1988 | Medical electrical equipment Part 1: General requirements for safety | EN 60601-1 + corr. July + A13 | 1990 1994 1996 |
| | | NOTE: Amendments A11 and A12 are superseded by EN 60601-1/A2:1995. | | |
| IEC 60601-1-3 | 1994 | Medical electrical equipment Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment | EN 60601-1-3 | 1994 |
| IEC 60601-2-7 | 1998 | Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators | EN 60601-2-7 | 1998 |
| IEC 60601-2-28 | 1993 | Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis | EN 60601-2-28 | 1993 |
| IEC 60788 | 1984 | Medical radiology - Terminology | HD 501 S1 | 1988 |
| IEC 60878 | 1988 | Graphical symbols on electrical equipment in medical practice | - | - |





1) IEC 60522:1999, Determination of the permanent filtration of X-ray tube assemblies, is harmonized as EN 60522:1999.

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| IEC 61223-1 | 1993 | Evaluation and routine testing in medical imaging departments<br>Part 1: General aspects | - | - |
| IEC 61267 | 1994 | Medical diagnostic X-ray equipment<br>Radiation conditions for use in the determination of characteristics | EN 61267 | 1994 |
| ISO 2092 | 1981 | Light metals and their alloys - Code of designation based on chemical symbols | - | - |

# INTERNATIONAL STANDARD

# IEC 61223-3-1

First edition
1999-03

## Evaluation and routine testing in medical imaging departments –

## Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems



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



*Partie 3-1:*
*Essais d'acceptation –*
*Performance d'imagerie des appareils à rayonnement X pour systèmes radiographiques et radioscopiques*



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

# EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

## Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems

## FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.



3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.



5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61223-3-1 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

| FDIS | Report on voting |
|---|---|
| 62B/361/FDIS | 62B/365/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.

Annex A forms an integral part of this standard.

Annexes B, C, D and E are for information only.

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 roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN IEC 60788, IN IEC 60601-1 OR IN THE IEC 61223 SERIES: SMALL CAPITALS (SEE ANNEX A).

A bilingual version of this standard may be issued at a later date.

# INTRODUCTION

This standard is part of a series of International Standards which give methods of acceptance testing and constancy testing for subsystems and systems (for example diagnostic X-RAY EQUIPMENT), including film processing, used in medical imaging departments.

Some provisions or statements in this standard require additional information. Such information is presented in annex D. An asterisk in the left margin of a clause or subclause indicates the presence of such additional information.

# EVALUATION AND ROUTINE TESTING IN MEDICAL IMAGING DEPARTMENTS –

## Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems

## 1 Scope and object

### 1.1 Scope

This part of IEC 61223 applies to those components of X-RAY EQUIPMENT which influence the image quality and PATIENT dose of diagnostic X-ray systems using radiographic and radioscopic imaging systems.

This standard applies to the performance of X-RAY EQUIPMENT in the ACCEPTANCE TEST on the following medical diagnostic X-RAY EQUIPMENT and ASSOCIATED EQUIPMENT:

– radiography equipment, for example:
  - stationary radiography EQUIPMENT;
  - mobile radiography EQUIPMENT;
  - skull radiography EQUIPMENT;
  - lung radiography EQUIPMENT;
  - TOMOGRAPHY EQUIPMENT – excluding COMPUTED TOMOGRAPHY;
  - radiography devices (SPOTFILM DEVICES) in RADIOSCOPY EQUIPMENT;
  - angiography EQUIPMENT (excluding DSA function);
  - CINERADIOGRAPHY equipment;

– RADIOSCOPY EQUIPMENT, including:
  - combined radiographic and radioscopic EQUIPMENT.



This standard applies to the generation of X-RADIATION and ACCESSORIES of digital systems. It does not apply to any digital image acquisition or image processing parts of the above mentioned diagnostic X-RAY EQUIPMENT.

NOTE – Since the characterization of digital detectors and image processing is still under development, this will be included in a later edition of this standard.

This standard does not apply to mammographic X-RAY EQUIPMENT, RADIOTHERAPY simulators, nor to dental X-RAY EQUIPMENT.

### 1.2 Object

This standard defines:

a) the parameters which describe the performance of X-RAY EQUIPMENT with regard to imaging properties and PATIENT dose;

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

These methods rely mainly on non-invasive measurements, using appropriate test equipment, performed during or after the installation is completed. Signed statements covering steps of product testing at the MANUFACTURER's site or during the installation procedure can be used as part of the acceptance testing.

The aim is to verify compliance of the installation with specifications relating to the image quality and PATIENT dose, and to detect malfunctions that are not in agreement with those specifications.

This standard does not specify tolerances for the parameters under investigation. Nor does it consider:

c) aspects of mechanical and electrical safety,

d) aspects of mechanical, electrical and software performance unless they are essential to the performance of the tests directly affecting image quality and PATIENT dose.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.



IEC 60336:1993, *X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*



IEC 60417-1:1998, *Graphical symbols for use on equipment – Part 1: Overview and application*

IEC 60522:1976, *Inherent filtration of an X-ray tube assembly*

IEC 60580:1977, *Area exposure product meter*

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-2-7:1998, *Medical electrical equipment – Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators*

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 60878:1988, *Graphical symbols for electrical equipment in medical practice*

IEC 61223-1:1993, *Evaluation and routine testing in medical imaging departments – Part 1: General aspects*

IEC 61267:1994, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

# 3 Terminology

## 3.1 Degree of requirements

In this standard, certain terms which are not printed in SMALL CAPITALS have particular meanings, as follows:

- "shall" indicates a requirement that is mandatory for compliance;
- "should" indicates a strong recommendation that is not mandatory for compliance;
- "may" indicates a permitted manner of complying with a requirement or of avoiding the need to comply;
- "specific" is used to indicate definitive information stated in this standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance;
- "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the EQUIPMENT under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

## 3.2 Use of terms

In this standard, terms printed in SMALL CAPITALS are used as defined in IEC 60601-1, IEC 60788, IEC 61223-1 and in 3.3 of this standard (see annex A).



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 Defined terms

### 3.3.1
**ARTIFACT**
apparent structure visible in the image which does not represent a structure within the object and which cannot be explained by noise or the MODULATION TRANSFER FUNCTION of the system

### 3.3.2
**LINE PAIR RESOLUTION**
highest spatial frequency of the specified line-group test pattern imaged under specified conditions which is distinguishable in the image. The unit is lp/mm

NOTE – LINE PAIR RESOLUTION is used here as a practical substitute for spatial resolution.

### 3.3.3
**LOW CONTRAST RESOLUTION**
lowest contrast detail object of a specified shape and area that can be resolved from an uniform background

### 3.3.4
**RADIATION OUTPUT**
AIR KERMA per CURRENT TIME PRODUCT (mGy/mAs) at a given distance from the FOCAL SPOT in the primary X-RAY BEAM

### 3.3.5
**TRANSMISSION KERMA (TRANSMISSION KERMA RATE)**
AIR KERMA (AIR KERMA RATE) in the central X-RAY BEAM behind the specified attenuating layer

## 4 General aspects of ACCEPTANCE TESTS

### 4.1 General conditions to be considered in test procedures

The aim of an ACCEPTANCE TEST is to demonstrate that the specified characteristics of the equipment lie within the specified tolerances. Some requirements are enforced by legislation. Other requirements and specifications may be in the order contract, in the supplier's brochure or in other standards, for example in the IEC 60601 series.

Before any ACCEPTANCE TEST according to this standard is carried out, the EQUIPMENT has to be installed and put into service according to the set-up procedure as given in the MANUFACTURER's documentation.

An inventory of the EQUIPMENT under test, the ACCOMPANYING DOCUMENTS, and the test protocols shall be compiled. Each item shall be identified by its MODEL OR TYPE REFERENCE (type number) and SERIAL NUMBER, and the entire inventory shall be compared with the order contract.

RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS, RADIOGRAPHIC FILMS and film processing are vital parts in the imaging chain. It is the responsibility of the USER to show that these components perform in an acceptable way, based upon information given by MANUFACTURERS of RADIOGRAPHIC FILMS and INTENSIFYING SCREENS, for example with respect to sensitivity, contrast and absence of ARTIFACTS.



Non-invasive measurements are preferred for ACCEPTANCE TESTS. Whenever invasive tests are part of the programme, it shall be shown that the EQUIPMENT has been restored to its pre-test condition after the test.



### 4.2 Documents and data for the tests



The following documentation is required:

- statements of compliance with applicable parts of IEC 60601;
- list of EQUIPMENT or EQUIPMENT parts ordered and the actual delivery list;
- performance specification as agreed upon between the purchaser and the supplier;
- results from tests performed at the MANUFACTURER's site or during installation covering items of importance to quality, such as NOMINAL FOCAL SPOT VALUE;
- INSTRUCTIONS FOR USE, including guidance for the operation of the EQUIPMENT;
- details of the actual operating conditions under which the X-RAY EQUIPMENT is to be used in medical practice and whether this results in a limitation of the scope of the tests or of the functionality of the EQUIPMENT. If certain functions are disabled, only those used need to be tested;
- guidance as to the extent and frequency of maintenance procedures;
- reports on previous tests where applicable;
- list of agreed technical modifications in the meantime between the order contract and the ACCEPTANCE TEST.

### 4.3 Test conditions

Different categories of tests can be identified:

- visual inspection;
- functional tests;
- system performance;
- check of the uncertainty in the values of variables.