

# norm

# NEN-EN-IEC 61223-3-1

Evaluatie- en routinebeproevingen op afdelingen voor medische beeldweergave - Deel 3-1: Acceptatiebeproevingen - Gebruikseigenschappen van beeldweergave van röntgenapparatuur voor radiografische en radioscopische systemen (IEC 61223-3-1:1999)

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

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Als Nederlandse norm is aanvaard:

- EN 61223-3-1:1999
- IEC 61223-3-1:1999

Normcommissie 301 062 "Medische elektrische toestellen"

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<u>Vermelde norm</u>	<u>Nederlandse norm</u>	<u>Titel</u>
IEC 60336:1993	NEN 10336:1995	Medische elektrische toestellen - Röntgendiagnostiekbuizen - Kenmerken van brandpunten
IEC 60417-1:1998	-	-
IEC 60522:1976	NEN 10522:1977	Inherente filterverwerking van de omhulling van een röntgenbuis
IEC 60580:1977	NEN 10580:1978	Meetinstrument voor het produkt van bundeldoorsnede en exposie bij medisch onderzoek
IEC 60601-1:1988	NEN 10601-1:1990	Veiligheid van medisch-elektrische toestellen - Deel 1: Algemene eisen
IEC 60601-1-3:1994	NEN 10601-1-3:1994	Medische elektrische toestellen - Deel 1: Algemene veiligheidseisen - Sectie 3: Secundaire norm - Algemene eisen voor stralingsbeveiliging in diagnostische röntgentoestellen
IEC 60601-2-7:1998	NEN-EN-IEC 60601-2-7:1998	Medische elektrische toestellen - Deel 2-7: Bijzondere eisen voor de veiligheid van hoogspanningsgeneratoren van diagnostische röntgengeneratoren
IEC 60601-2-28:1993	NEN 10601-2-28:1993	Medische elektrische toestellen - Deel 2: Bijzondere eisen voor de veiligheid van röntgenbron- en röntgenbuis- samenstellingen voor medische diagnostiek
IEC 60788:1984	-	-
IEC 60878:1988	-	-
IEC 61223-1:1993	-	-
IEC 61267:1994	NEN 11267:1995	Medische diagnostische röntgentoestellen - Stralingsvoorwaarden voor het bepalen van kenmerken
ISO 2092:1981	-	-

English version

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

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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.

#### 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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 <sup>1)</sup>	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	-	-

Page 4

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	EN 61267	1994
ISO 2092	1981	Light metals and their alloys - Code of designation based on chemical symbols	-	-

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Preview

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*



Reference number  
IEC 61223-3-1:1999(E)

## Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

## Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

## Validity of this publication

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Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site\***
- **Catalogue of IEC publications**  
(Published yearly with regular updates  
(on-line catalogue))
- **IEC Bulletin**  
Available both at the IEC web site\* and as a printed periodical

## Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

\* See web site address on title page.



# INTERNATIONAL STANDARD

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**61223-3-1**

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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 radiosopic systems

FOREWORD

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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).

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