



SLOVENSKI STANDARD
SIST EN 61953:1998

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Diagnostic X-ray imaging equipment - Characteristics of mammographic anti-scatter grids (IEC 61953:1997)

Diagnostic X-ray imaging equipment - Characteristics of mammographic anti-scatter grids

Bildgebende Geräte für die Röntgendiagnostik - Kenngrößen von Streustrahler-Rastern für die Mammographie

Appareils d'imagerie de diagnostic à rayonnement X - Caractéristiques des grilles antidiffusantes pour la mammographie

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EUROPEAN STANDARD
NORME EUROPÉENNE
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January 1998

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English version

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rayonnement X - Caractéristiques
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Röntgendiagnostik - Kenngrößen
von Streustrahler-Rastern für die
Mammographie
(IEC 61953:1997)

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This European Standard was approved by CENELEC on 1997-07-01. 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/297/FDIS, future edition 1 of IEC 61953, 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 61953 on 1997-07-01.

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) 1998-07-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 1998-07-01

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

Endorsement notice

The text of the International Standard IEC 61953:1997 was approved by CENELEC as a European Standard without any modification.

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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 60417	1973	Graphical symbols for use on equipment Index, survey and compilation of the single sheets	HD 243 S12 ¹⁾	1995
IEC 60417N	1995		-	-
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1	1993
A2	1995		+ corr. July A2 ²⁾	1994 1995
			A13	1996
IEC 60627	1978	Characteristics of anti-scatter grids used in X-ray equipment	-	-
IEC 60788	1984	Medical radiology - Terminology	HD 501 S1	1988
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

1) HD 243 S12 includes supplements A:1974 to M:1994 to IEC 60417.

2) A2 includes corrigendum June 1995 to IEC 60601-1:1988/A2.

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**CEI
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61953

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**Appareils d'imagerie de diagnostic
à rayonnement X –**

**Caractéristiques des grilles antidiffusantes
pour la mammographie**

iTeh STANDARD PREVIEW

Diagnostic X-ray imaging equipment –

**Characteristics of mammographic
anti-scatter grids**

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**DIAGNOSTIC X-RAY IMAGING EQUIPMENT –
Characteristics of mammographic anti-scatter grids**

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 61953 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/297/FDIS	62B/320/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.

Annexes A and B form an integral part of this standard.

Annex C is 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 type;
- *test specifications and headings of subclauses: italic type;*
- TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN CLAUSE 3 OF THIS STANDARD OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX B: SMALL CAPITALS.

INTRODUCTION

X-ray mammography is an examination which is technically demanding because of the need to achieve high contrast and excellent resolution whilst limiting the absorbed dose to the female breast. Low energy X-rays, compression and a special geometry are needed to achieve these objectives. Therefore, only dedicated X-RAY EQUIPMENT should be used. While most of such equipment incorporates an ANTI-SCATTER GRID, the MAMMOGRAPHIC ANTI-SCATTER GRIDS used are not covered by IEC 60627.

ANTI-SCATTER GRIDS used in general radiology are covered by IEC 60627, and this standard follows the same outline. During the writing of this standard, it became clear that a revision of IEC 60627 was necessary, and work on this has started. It is intended that the two standards covering ANTI-SCATTER GRIDS will be merged together. To facilitate this, some subclauses are not used here and extra subclauses have been introduced.

Some of the differences between IEC 60627 and this standard are outlined below.

- The concept of a reference grid is now omitted. It was found that such grids were little used. It should be sufficient to unambiguously define the RADIATION DETECTOR and procedure.
- The geometry used here simulates a typical mammography examination.
- Only one PHANTOM is used for measurements of TRANSMISSION OF PRIMARY RADIATION and TRANSMISSION OF SCATTERED RADIATION.
- The FLUORESCENT SCREEN used for the measurements employs a thinner calcium tungstate phosphor. This is not a standard mammography phosphor, but this material is well defined, resulting in better uniformity of performance between different screens.
- The APPLICATION LIMITS needed to be reduced for mammography.
- The production tolerances have been narrowed, compared to the grids used in general radiology, in order to have meaningful characteristic data which allow the distinction between different grid types used in mammography. Consequently, the measuring tolerances have also been narrowed.

Special laboratory equipment and carefully controlled test conditions are needed for the measurements described here.

DIAGNOSTIC X-RAY IMAGING EQUIPMENT – Characteristics of mammographic anti-scatter grids

1 Scope and object

This International Standard deals with the definitions, determinations and indication of characteristics of MAMMOGRAPHIC ANTI-SCATTER grids used in diagnostic X-ray imaging equipment, in order to reduce the incidence of SCATTERED RADIATION, produced particularly in the body of the PATIENT, upon the IMAGE RECEPTION area and thus to improve the contrast of the X-RAY PATTERN.

At present only focused ANTI-SCATTER grids are used in mammography. The scope of this standard is therefore restricted to FOCUSED GRIDS.

This standard is not intended to be applied for ACCEPTANCE TESTS.

This standard does not cover the homogeneity of performance over the area of a grid.

This standard is not intended to be applied for the determination of the characteristics of MAMMOGRAPHIC ANTI-SCATTER GRIDS under conditions which can normally be found in installations of X-RAY EQUIPMENT at the USER's site.

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2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard 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 60417: 1973, *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets*

IEC 60417N: (1995), Thirteenth supplement

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

Amendment 1 (1991)

Amendment 2 (1995)

IEC 60627: 1978, *Characteristics of anti-scatter grids used in X-ray equipment*

IEC 60788: 1984, *Medical radiology – Terminology*

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*