

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

The European Standard EN 61953:1997 has the status of a
British Standard

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National foreword

This British Standard is the English language version of EN 61953:1998. It is identical with IEC 61953:1997.

The UK participation in its preparation was entrusted to Technical Committee CH/73, Radiation protection dose control and utilization, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional information. The following print types are used in this standard. Requirements, with which compliance can be tested, and definitions: in roman type.

Explanations, advice, general statements, exceptions and references: in small roman type.

Test procedures: in *italic* type.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 18 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

English version

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

(IEC 61953:1997)

Appareils d'imagerie de diagnostic à
rayonnement X — Caractéristiques
des grilles antidiffusantes pour la
mammographie
(CEI 61953:1997)

Bildgebende Geräte für die
Röntgendiagnostik — Kenngrößen
von Streustrahler-Rastern für die
Mammographie
(IEC 61953:1997)

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.

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CENELEC

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

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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, Annex A, Annex B and Annex 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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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.

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.

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*.

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, in IEC 60788, in clause 3 of this standard or in other standards referenced in Annex B

3.3 Defined terms

For the purpose of this International Standard, the following definitions apply.

NOTE Some of the defined terms given in this standard deviate from those given in the current edition (1984) of IEC 60788.

3.3.1

ANTI-SCATTER GRID

device with a fixed periodic arrangement of materials with different X-ray ATTENUATION properties to be placed in front of the IMAGE RECEPTION AREA in order to reduce the incidence of SCATTERED RADIATION upon that area and thus increase the contrast in the X-RAY PATTERN

3.3.2

LINEAR GRID

ANTI-SCATTER GRID composed of highly absorbing strips and highly transmitting interspaces which are parallel in their longitudinal direction

3.3.3

not used

3.3.4

FOCUSED GRID

LINEAR GRID in which the planes of the absorbing strips converge to a straight line at the FOCUSING DISTANCE