IEC 60627

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Diagnostic X-ray imaging equipment – Characteristics of general purpose and mammographic anti-scatter grids

Équipements de diagnostic par imagerie à rayonnement X – Caractéristiques des grilles antidiffusantes d'usage général et de mammographie

IEC 60627:2013

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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DIAGNOSTIC X-RAY IMAGING EQUIPMENT –

Characteristics of general purpose and mammographic anti-scatter grids

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 60627 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2001, and constitutes a technical revision.

In this revision calcium tungstate phosphor FLUORESCENT SCREENS, which are no longer available, have been replaced by gadolinium oxysulphide (GOS) FLUORESCENT SCREENS. Further, a new quality parameter is introduced: the IMAGE IMPROVEMENT FACTOR or Q-factor, which better describes the properties of the ANTI-SCATTER GRID, especially for digital detector applications.

Further differences between this third edition and the previous second edition are:

– some definitions have been modified and others added to improve clarity, harmonization or generality;

– new instrumentation is prescribed for measurements of the TRANSMISSION OF PRIMARY RADIATION, the TRANSMISSION OF SCATTERED RADIATION and the TRANSMISSION OF TOTAL RADIATION, because FLUORESCENT SCREENS made of calcium tungstate phosphors are outdated and are no longer available;

– the definition of the PHANTOM used for measurements of the TRANSMISSION OF PRIMARY RADIATION, the TRANSMISSION OF SCATTERED RADIATION and the TRANSMISSION OF TOTAL RADIATION is modified and references to IEC 61267 are omitted;

– the RADIATION CONDITIONS used for the measurements have been adapted and are now the RQR and RQR-M conditions specified in IEC 61267:2005;

– tolerances are specified for the dimensions in the arrangements for the measurements of the TRANSMISSION OF PRIMARY RADIATION, the TRANSMISSION OF SCATTERED RADIATION and the TRANSMISSION OF TOTAL RADIATION.

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

FDIS	Report on voting
62B/914/FDIS	62B/922/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.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR IN OTHER IEC PUBLICATIONS REFERENCED IN THIS STANDARD: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 5 includes subclauses 5.1, 5.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g., 5.1, 5.2 and 5.2.1 are all subclauses of Clause 5).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or”, so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

The committee has decided that the contents of this publication will remain unchanged until the stability 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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 36 months from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The first edition of IEC 60627 was intended for ANTI-SCATTER GRIDS used in general radiography and is not appropriate for ANTI-SCATTER GRIDS used in mammography. As a consequence, a complementary standard IEC 61953 was published. Later, it was decided to revise and merge together the two standards covering ANTI-SCATTER GRIDS. Wherever possible, a harmonized approach has been used. This constituted the second edition of IEC 60627 published in 2001.

This third edition is a revision of the second edition. This revision was initiated by the fact that calcium tungstate phosphors have become obsolete, and are no longer available. Instrumentation with FLUORESCENT SCREENS made of gadolinium oxysulphide (GOS) is the present state of the art.

Further, a new quality parameter is introduced: the IMAGE IMPROVEMENT FACTOR Q. This factor better describes the properties of ANTI-SCATTER GRIDS than the GRID EXPOSURE FACTOR B and the CONTRAST IMPROVEMENT FACTOR K, especially for digital detector applications. Namely, the signal-to-noise ratio (SNR) for digital X-ray detectors is increased proportionally with the square root of the factor Q when an ANTI-SCATTER GRID is applied. This effect is due to the efficient reduction of SCATTERED RADIATION and overcompensates the loss of PRIMARY RADIATION when using an ANTI-SCATTER GRID in situations where a considerable amount of SCATTERED RADIATION is present. The name IMAGE IMPROVEMENT FACTOR is chosen to reflect the improved image quality (characterized by SNR and other parameters) under equal RADIATION dose conditions.

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

DIAGNOSTIC X-RAY IMAGING EQUIPMENT –

Characteristics of general purpose and mammographic anti-scatter grids

1 Scope

This International Standard is applicable to ANTI-SCATTER GRIDS used in medical diagnostic X-ray imaging equipment. ANTI-SCATTER GRIDS are used 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. This International Standard specifies the definitions, determination and indication of characteristics of ANTI-SCATTER GRIDS.

In this standard only LINEAR GRIDS are considered.

Since at present only FOCUSED GRIDS are used in mammography, this standard is restricted to FOCUSED GRIDS where MAMMOGRAPHIC ANTI-SCATTER GRIDS are concerned.

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 intended to be applied for the determination of the characteristics of ANTI-SCATTER GRIDS under test conditions. These conditions are not usually available at the site of the RESPONSIBLE ORGANIZATION.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61267:2005, *Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-3:2008+A1:2013, IEC/TR 60788:2004 and the following apply.

3.1 Grid definitions

3.1.1
ANTI-SCATTER GRID
device to be placed before 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

3.1.2
LINEAR GRID
ANTI-SCATTER GRID composed of highly absorbing strips and highly transmitting interspaces which are parallel in their longitudinal direction

3.1.3
PARALLEL GRID
LINEAR GRID in which the planes of the absorbing strips are parallel to each other and perpendicular to the incident face

3.1.4
FOCUSED GRID
LINEAR GRID in which the planes of the absorbing strips converge to a straight line at the FOCUSING DISTANCE

3.1.5
TAPERED GRID
LINEAR GRID in which the height of the absorbing strips decreases as the distance between the absorbing strips and the TRUE CENTRAL LINE increases. This decrease is symmetrical about the TRUE CENTRAL LINE

3.1.6
CROSS-GRID

ANTI-SCATTER GRID composed of two LINEAR GRIDS built together in such a way that the directions of their absorbing strips form an angle

3.1.7
ORTHOGONAL CROSS-GRID
CROSS-GRID in which the directions of the absorbing strips form an angle of 90°

3.1.8
OBLIQUE CROSS-GRID
CROSS-GRID in which the directions of the absorbing strips form an angle other than 90°

3.1.9
STATIONARY GRID
ANTI-SCATTER GRID used in such a way that it does not move in relation to the RADIATION BEAM

3.1.10
MOVING GRID
ANTI-SCATTER GRID used in an ACCESSORY that enables the ANTI-SCATTER GRID to be moved, when irradiated by a RADIATION BEAM, in order to avoid the imaging of the absorbing strips and the consequent loss of information

3.1.11
MAMMOGRAPHIC ANTI-SCATTER GRID
FOCUSED GRID specially designed for mammography

Note 1 to entry: In this standard the term "general purpose ANTI-SCATTER GRID" is used to describe any ANTI-SCATTER GRID not specially designed for mammography.

3.2 Geometric characteristics

3.2.1
STRIP FREQUENCY
N
number of absorbing strips per unit length of a LINEAR GRID (unit: cm^{-1})

3.2.2
GRID RATIO
r
ratio between the height of the absorbing strips and the distance between the absorbing strips in the centre of a LINEAR GRID

3.2.3
FOCUSING DISTANCE
f_0
distance between the incident face of a FOCUSED GRID and the line into which the planes of the absorbing strips of the grid converge (unit: cm)

Note 1 to entry: Attention is drawn to the differences between "FOCUSING DISTANCE", "FOCAL SPOT to grid distance" and "FOCAL SPOT to film distance".

3.2.4
APPLICATION LIMITS
f_1, f_2
lower, f_1, and upper, f_2, limits of the distance from the FOCAL SPOT to the incident face of a FOCUSED GRID or a PARALLEL GRID between which the obtained radiological information can be considered acceptable for many purposes (unit: cm)

Note 1 to entry: See Annex A for details on the calculation of the APPLICATION LIMITS.

3.2.5
TRUE CENTRAL LINE

– for a PARALLEL GRID: line on the incident face in the direction of the absorbing strips and passing through the centre of the grid area

– for a FOCUSED GRID: perpendicular projection onto the incident face of the grid, of the line into which the planes of the absorbing strips converge

– for a TAPERED GRID: line on the incident face in the direction of the absorbing strips and lying within a symmetry plane of the grid structure

Note 1 to entry: A CROSS-GRID has two TRUE CENTRAL LINES.

3.2.6
CENTRAL-LINE INDICATION
marking on the incident face of a LINEAR GRID, which is intended to indicate the position and direction of the TRUE CENTRAL LINE

Note 1 to entry: In most cases, this marking coincides with the geometric centre line of the grid's incident face.

3.3 Physical characteristics

3.3.1
TRANSMISSION OF PRIMARY RADIATION
T_p
characteristic of an object, evaluated as the ratio of the MEASURED VALUE of the quantity or rate of PRIMARY RADIATION with the object placed in a RADIATION BEAM to that with the object removed from the beam, under specific measuring conditions

3.3.2
TRANSMISSION OF SCATTERED RADIATION
T_s
characteristic of an object, evaluated as the ratio of the MEASURED VALUE of the quantity or rate of SCATTERED RADIATION with the object placed in a RADIATION BEAM to that with the object removed from the beam, under specific measuring conditions

3.3.3
TRANSMISSION OF TOTAL RADIATION
T_t
characteristic of an object, evaluated as the ratio of the MEASURED VALUE of the quantity or rate of total RADIATION with the object placed in a RADIATION BEAM to that with the object removed from the beam, under specific measuring conditions

3.3.4
GRID SELECTIVITY
Σ
characteristic of an ANTI-SCATTER GRID, evaluated as the ratio of the TRANSMISSION OF PRIMARY RADIATION to the TRANSMISSION OF SCATTERED RADIATION

3.3.5
CONTRAST IMPROVEMENT RATIO
K
characteristic of an ANTI-SCATTER GRID, evaluated as the ratio of the TRANSMISSION OF PRIMARY RADIATION to the TRANSMISSION OF TOTAL RADIATION

3.3.6
GRID EXPOSURE FACTOR
B
characteristic of an ANTI-SCATTER GRID, evaluated as the reciprocal value of the TRANSMISSION OF TOTAL RADIATION

3.3.7
IMAGE IMPROVEMENT FACTOR
Q
characteristic of an ANTI-SCATTER GRID, evaluated as the ratio of the square of the TRANSMISSION OF PRIMARY RADIATION to the TRANSMISSION OF TOTAL RADIATION

3.4 Other terms

3.4.1
DECENTRING
distance between the TRUE CENTRAL LINE of a FOCUSED GRID and the perpendicular projection of the FOCAL SPOT of an X-RAY TUBE onto the incident face of the grid

3.4.2
DEFOCUSING
difference between the distance from the FOCAL SPOT of an X-RAY TUBE to the incident face of a FOCUSED GRID and the FOCUSING DISTANCE of that grid

Note 1 to entry: See Clause A.1 for an explanation of DECENTRING and DEFOCUSING.

3.4.3
SERIAL NUMBER
number and/or other designation to identify an individual unit of a certain model of equipment or ACCESSORY

4 Structure of ANTI-SCATTER GRIDS

ANTI-SCATTER GRIDS usually consist of strips of highly absorbent material, of thickness *d* and height *h*, arranged at regular intervals *D* from each other; see Figure 1.

The height *h* of the strips is either constant over the area of the ANTI-SCATTER GRID or decreases in TAPERED GRIDS from the highest strip – with height h_0 – towards two edges.

NOTE *D* and *d* are measured at the incident face of the grid.

The interspaces between the strips are usually filled with highly transmitting material. The ANTI-SCATTER GRID may have a frame and covers to protect against mechanical damage and to ensure the rigidity of the grid.

The STRIP FREQUENCY shall be determined according to the formula

$$N = \frac{1}{(d + D)}$$

The GRID RATIO shall be determined according to one of the following formulae

– for a PARALLEL GRID and for a FOCUSED GRID:

$$r = \frac{h}{D}$$

– for a TAPERED GRID:

$$r_0 = \frac{h_0}{D_0}$$

– for a CROSS-GRID:

$$r_1 = \frac{h_1}{D_1}$$

$$r_2 = \frac{h_2}{D_2}$$

Letter symbols without index designate general properties of a LINEAR GRID. The index "0" designates quantities at the TRUE CENTRAL LINE. Indices "1" or "2" designate quantities for the LINEAR GRIDS forming a CROSS-GRID.

5 Measurement and determination of physical characteristics

5.1 Method and arrangement for measurement

5.1.1 Determination of physical characteristics

For the purpose of this standard, the values of the TRANSMISSION OF PRIMARY RADIATION, the TRANSMISSION OF SCATTERED RADIATION and the TRANSMISSION OF TOTAL RADIATION shall be determined as the ratio of the two MEASURED VALUES obtained with the instrumentation described in 5.1.2 and the PHANTOM described in 5.1.3, in the arrangements described in 5.1.4, and with the RADIATION CONDITIONS described in 5.1.5.

5.1.2 Instrumentation

5.1.2.1 General

A RADIATION DETECTOR shall be used which incorporates a FLUORESCENT SCREEN and a photo-detector; see Figure 2. The FLUORESCENT SCREEN shall be made from a terbium-activated gadolinium oxysulphide (GOS, Gd_2O_2S:Tb) scintillator, preferably without dye.

The area density of the scintillator shall be

a) for general purpose ANTI-SCATTER GRIDS 75 mg · cm^{-2} ± 10 mg · cm^{-2};

b) for MAMMOGRAPHIC ANTI-SCATTER GRIDS 30 mg · cm^{-2} ± 3 mg · cm^{-2}.

NOTE The previously specified scintillator material, calcium tungstate, is no longer commercially available. Current state-of-the-art is GOS, which is non-toxic and non-hygroscopic as opposed to thallium-doped cesium iodide (CsI:Tl). Experimental results show equivalent outcome for calcium tungstate and GOS scintillators.

The diameter of the measuring field shall be 6,0 mm ± 0,5 mm.

The luminance produced at the FLUORESCENT SCREEN shall be measured with the photo-detector, which shall be sensitive in the energy range of the light photons produced.

The ADDITIONAL FILTRATION between the supporting plane of the ANTI-SCATTER GRID and the active layer of the FLUORESCENT SCREEN shall be not more than

a) for general purpose ANTI-SCATTER GRIDS 0,5 mm Al;

b) for MAMMOGRAPHIC ANTI-SCATTER GRIDS 0,1 mm Al

for the RADIATION CONDITION applied.

The dark current and the direct IRRADIATION of the photo-detector shall not significantly affect the result of the measurements.

The response of the photo-detector shall be linearly proportional to the RADIATION intensity.

5.1.2.2 Test for dark current and direct IRRADIATION

Use the following test PROCEDURE *to check the effects of the dark current and the direct* IRRADIATION *of the photo-detector:*

a) *use an arrangement as described in 5.2.3, except that the* ANTI-SCATTER GRID *is removed, and apply a* RADIATION CONDITION *as specified in 5.1.5;*

b) *measure the detector signal at the maximum* X-RAY TUBE CURRENT *used for the grid measurements with the photo-detector shielded by X-ray transparent material against the visible light excited in the* FLUORESCENT SCREEN *and with the photo-detector unshielded;*

c) *measure the detector signal without* IRRADIATION *(this is the dark-current value of the* RADIATION DETECTOR*);*

d) *calculate the ratio of the* MEASURED VALUES *for the shielded and unshielded measurements after subtraction of the dark-current value;*

e) *this ratio shall not exceed 0,002.*

5.1.2.3 Test for linearity

Use the following test PROCEDURE *to check the linearity of the photo-detector:*

a) *use an arrangement as described in 5.2.3, except that the* ANTI-SCATTER GRID *is removed, and apply a* RADIATION CONDITION *as specified in 5.1.5;*