SLOVENSKI STANDARD
SIST EN 60627:2002

01-junij-2002

Nadomešča:
SIST EN 61953:1998

Diagnostična oprema za rentgensko slikanje – Značilnosti splošnonamenske in mamografske protirazpršilne mrežice (IEC 60627:2001)

Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids (IEC 60627:2001)

Bildgebende Geräte für die Röntgendiagnostik - Kenngrößen von Streustrahlenrastern für die allgemeine Anwendung und für die Mammographie (IEC 60627:2001)

Equipements de diagnostic par imagerie à rayonnement X - Caractéristiques des grilles antidiffusantes d'usage général et de mammographie (IEC 60627:2001)

Ta slovenski standard je istoveten z: **EN 60627:2001**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60627:2002 **en**

EUROPEAN STANDARD **EN 60627**

NORME EUROPÉENNE

EUROPÄISCHE NORM November 2001

ICS 11.040.50

English version

Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
(IEC 60627:2001)

Equipements de diagnostic par imagerie à rayonnement X - Caractéristiques des grilles antidiffusantes d'usage général et de mammographie (CEI 60627:2001)

Bildgebende Geräte für die Röntgendiagnostik - Kenngrößen von Streustrahlenrastern für die allgemeine Anwendung und für die Mammographie (IEC 60627:2001)

This European Standard was approved by CENELEC on 2001-11-01. 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, Malta, 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

Ref. No. EN 60627:2001 E

Foreword

The text of document 62B/436A/FDIS, future edition 2 of IEC 60627, 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 60627 on 2001-11-01.

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)	2002-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2004-11-01

Annexes designated "normative" are part of the body of the standard.
In this standard, annexes A, B and ZA are normative.
Annex ZA has been added by CENELEC.

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: in roman type;
– explanations, advice, notes, general statements, exceptions and references: in smaller roman type;
– *test specifications: in italic type;*
– TERMS DEFINED IN EN 60601-1, IN EN 60788, IN CLAUSE 3 OF THIS STANDARD OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX B: IN SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60627:2001 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 60417	Series	Graphical symbols for use on equipment	EN 60417	Series
IEC 60601-1	- [1]	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A13	1990 [2] 1994 1996
IEC 60788	- [1]	Medical radiology - Terminology	HD 501 S1	1988 [2]
IEC 61223-1	- [1]	Evaluation and routine testing in medical imaging departments Part 1: General aspects	-	-
IEC 61267	- [1]	Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics	EN 61267	1994 [2]

[1] Undated reference.

[2] Valid edition at time of issue.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60627

Deuxième édition
Second edition
2001-08

Equipements de diagnostic par imagerie à rayonnement X –

Caractéristiques des grilles antidiffusantes d'usage général et de mammographie

Diagnostic X-ray imaging equipment –

Characteristics of general purpose and mammographic anti-scatter grids

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International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE U

Pour prix, voir catalogue en vigueur
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Characteristics of general purpose and 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 specifications, 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 60627 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1978, and constitutes a technical revision. It also cancels and replaces IEC 61953 published in 1997 which is incorporated in this standard technically unchanged.

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

FDIS	Report on voting
62B/436A/FDIS	62B/441/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.

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

In this standard, the following print types are used:

– requirements, compliances with which can be tested, and definitions: in roman type;
– explanations, advice, notes, general statements, exceptions and references: in smaller roman type;
– *test specifications: in italic type;*
– TERMS DEFINED IN IEC 60601-1, IN IEC 60788, IN CLAUSE 3 OF THIS STANDARD OR IN OTHER IEC PUBLICATIONS REFERENCED IN ANNEX B: IN SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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. During the preparation of this latter standard, it became clear that a revision of IEC 60627 itself was necessary, and it was decided to merge together the two standards covering ANTI-SCATTER GRIDS. Wherever possible, a harmonized approach has been used. Where there are differences in this standard between general purpose ANTI-SCATTER GRIDS and MAMMOGRAPHIC ANTI-SCATTER GRIDS, these are listed as items a) and b) respectively.

Some of the differences for general purpose ANTI-SCATTER GRIDS between this second edition and the first edition of IEC 60627 are outlined below:

– some definitions have been modified and others added to improve clarity, harmonization or generality;
– the concept of a reference ANTI-SCATTER GRID is now omitted. It was found that such ANTI-SCATTER GRIDS were little used. It should be sufficient to define unambiguously the RADIATION DETECTOR and the measuring procedure;
– the same PHANTOM is used for measurements of TRANSMISSION OF PRIMARY RADIATION and TRANSMISSION OF SCATTERED RADIATION;
– the RADIATION QUALITIES used for the measurement have been changed and are now qualities specified in IEC 61267;
– a lower energy X-RAY SPECTRUM than before is used to measure the performance of general purpose ANTI-SCATTER GRIDS. This was considered to be more appropriate than the spectrum previously used;
– where a general purpose ANTI-SCATTER GRID is specified for low-energy use, additional measurements have now to be made with appropriate, specified RADIATION QUALITIES;
– the diameter of the measuring field is reduced;
– the TRANSMISSION OF PRIMARY RADIATION is now given on the ANTI-SCATTER GRID or in the ACCOMPANYING DOCUMENTS;
– information on the nature of the material used for the grid interspace and on the nature of the grid covers is now given in the ACCOMPANYING DOCUMENTS;
– application limits are now given for PARALLEL GRIDS;
– the position of the grid centre is now indicated.

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 and object

This International Standard deals with the definitions, determination and indication of characteristics of 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.

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 for MAMMOGRAPHIC ANTI-SCATTER 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 intended to be applied for the demonstration of the characteristics of ANTI-SCATTER GRIDS under test conditions. These conditions are not usually available at the USER's site.

2 Normative references

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

IEC 60417 (all parts), *Graphical symbols for use on equipment*

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

IEC 60788, *Medical radiology – Terminology*

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

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