ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA December 2015

STN	**Diagnostické röntgenové zobrazovacie prístroje. Charakteristiky sekundárnych clôn na všeobecné použitie a na mamografiu.**	**STN EN 60627** 36 4722

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/15

Obsahuje: EN 60627:2015, IEC 60627:2013

Oznámením tejto normy sa od 14.04.2018 ruší
STN EN 60627 (36 4722) z mája 2003

121856

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60627

May 2015

ICS 11.040.50

Supersedes EN 60627:2001

English Version

Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids (IEC 60627:2013)

Équipements de diagnostic par imagerie à rayonnement X - Caractéristiques des grilles antidiffusantes d'usage général et de Mammographie (IEC 60627:2013)

Bildgebende Geräte für die Röntgendiagnostik - Kenngrößen von Streustrahlenrastern für die allgemeine Anwendung und für die Mammographie (IEC 60627:2013)

This European Standard was approved by CENELEC on 2015-04-14. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62B/914/FDIS, future edition 3 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 approved by CENELEC as EN 60627:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

This document supersedes EN 60627:2001.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60627:2013 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
+A1	2012		+A1 +A1/AC	2013 2014
			+A12	2014
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	EN 60601-1-3 + corr. March	2008 2010
+A1	2013		+A1 +A1/AC	2013 2014
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	EN 61267	2006

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

IEC 60627

Edition 3.0 2013-07

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 60627

Edition 3.0 2013-07

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX

V

ICS 11.040.50

ISBN 978-2-8322-0917-2

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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.
2) The formal decisions or agreements of 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 IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. 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 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*