Kaitseseadmed meditsiinidiagnostilise röntgenkiirguse vastu. Osa 2: Poolläbipaistvad kaitseplaadid

Protective devices against diagnostic medical X-radiation - Part 2: Translucent protective plates

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 61331-2:2014 sisaldab Euroopa standardi EN 61331-2:2014 inglisekeelset teksti.	This Estonian standard EVS-EN 61331-2:2014 consists of the English text of the European standard EN 61331-2:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.10.2014.	Date of Availability of the European standard is 24.10.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61331-2

October 2014

ICS 11.040.50

Supersedes EN 61331-2:2002

English Version

Protective devices against diagnostic medical X-radiation - Part 2: Translucent protective plates (IEC 61331-2:2014)

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical - Partie 2: Plaques translucides de protection radiologique (CEI 61331-2:2014)

Strahlenschutz in der medizinischen Röntgendiagnostik - Teil 2: Durchsichtige Schutzplatten (IEC 61331-2:2014)

This European Standard was approved by CENELEC on 2014-06-11. 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

Ref. No. EN 61331-2:2014 E

Foreword

The text of document 62B/937/FDIS, future edition 2 of IEC 61331-2, 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 61331-2:2014.

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)	2015-04-24
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2017-06-11

This document supersedes EN 61331-2:2002.

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.

Endorsement notice

The text of the International Standard IEC 61331-2:2014 was approved by CENELEC as a European Standard without any modification.

IEC 60601-2-17:2013	NOTE	Harmonised as EN 60601-2-17:2014.

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	2006
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
			+A11	2011
+A1	2012		+A1	2013
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	2008
			+EN 60601-1-3:2008/corrigendum Mar. 2010	2010
+A1	2013		+A1	2013
			+AC	2014
IEC 60601-2-8	2010	Medical electrical equipment -- Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	FprEN 60601-2-8	2010
IEC 61331-1	2014	Protective devices against diagnostic medical X-radiation -- Part 1: Determination of attenuation properties of materials	EN 61331-1	2014
ISO 3534-1	2006	Statistics_- Vocabulary and symbols_- Part_1: General statistical terms and terms used in probability	-	-
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
ISO/IEC Guide 99	2007	International vocabulary of metrology - Basic- and general concepts and associated terms (VIM)	-	-

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 2: Translucent protective plates

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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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 61331-2 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 of IEC 61331-2, published in 1994. It constitutes a technical revision. This second edition has been adapted to apply to the present technology.

The essential changes and extensions are:

extension of scope to cover all kinds of TRANSLUCENT PROTECTIVE PLATES and all kinds of RADIATION QUALITIES and GAMMA RADIATION;

removal of definition and requirements for TRANSLUCENT PROTECTIVE PLATES for visual imaging;

changes of requirements concerning geometrical accuracy and optical quality;

changes of requirements concerning determination of LEAD EQUIVALENT and minimal thickness;

changes of requirements concerning information and marking

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

FDIS	Report on voting
62B/937/FDIS	62B/943/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;

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

TERMS DEFINED IN CLAUSE 3 OF THIS STANDARD OR AS NOTED: SMALL CAPS.

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.

A list of all parts of the IEC 61331 series, published under the general title *Protective devices against diagnostic medical X-radiation,* can be found on the IEC website.

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.

PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 2: Translucent protective plates

1 Scope

This part of IEC 61331 applies to TRANSLUCENT PROTECTIVE PLATES used for RADIATION PROTECTION in X-ray diagnosis and in X-ray therapy. It also applies to TRANSLUCENT PROTECTIVE PLATES used for protection against GAMMA RADIATION in nuclear medicine and BRACHYTHERAPY with automatically-controlled AFTERLOADING equipment.

It does not cover other translucent RADIATION PROTECTION materials, e.g.

– leaded glasses or goggles for protection of the OPERATOR'S eyes (eye spectacles),
– leaded face shields, which cover the entire face of the OPERATOR,
– PATIENT eye protection, and
– thyroid/neck PROTECTIVE DEVICES.

This Part 2 deals with the requirements on

– geometrical accuracy;
– optical quality of the material;
– spectral TRANSMITTANCE;
– radiation ATTENUATION properties;
– marking;
– statement of compliance with this standard.

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*
IEC 60601-1:2005/AMD1:2012

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*
IEC 60601-1-3:2008/AMD1:2013

IEC 60601-2-8:2010, *Medical electrical equipment – Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

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