BS EN 61331-2:2014

BSI Standards Publication

Protective devices against diagnostic medical X-radiation

Part 2: Translucent protective plates

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 61331-2:2014. It is identical to IEC 61331-2:2014. It supersedes BS EN 61331-2:2002, which will be withdrawn on 11 June 2017.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2014.
Published by BSI Standards Limited 2014

ISBN 978 0 580 74634 5
ICS 11.040.50; 13.280

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2014.

Amendments/corrigenda issued since publication

Date	Text affected

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

© 2014 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

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

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*

IEC 61331-1:2014, *Protective devices against diagnostic medical X-radiation – Part 1: Determination of attenuation properties of materials*

ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

ISO 3534-1:2006, *Statistics – Vocabulary and symbols – Part 1: General statistical terms and terms used in probability*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC/TR 60788:2004, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, and the following apply.

3.1
PROTECTIVE GLASS PLATE
TRANSLUCENT PROTECTIVE PLATE consisting of mineral glass with SPECIFIED attenuation properties used for manufacturing of optically clear and optically transparent protective shielding

Note 1 to entry: Toughening impacts neither the attenuation properties nor optical and geometrical properties of the TRANSLUCENT PROTECTIVE PLATE consisting of mineral glass..

3.2
PROTECTIVE PLASTIC PLATE
TRANSLUCENT PROTECTIVE PLATE consisting of translucent plastic material with specified attenuation properties used for manufacturing of optically clear and optically transparent protective shielding

3.3
TRANSLUCENT PROTECTIVE PLATE
plate consisting of translucent material with SPECIFIED attenuation properties used for manufacturing of optically clear and optically transparent protective shielding

3.4
TRANSMITTANCE
τ
ratio of the transmitted radiant flux in the range of visible light to the incident flux in the range of visible light in the given conditions

Note 1 to entry: SI unit: 1. In the practice of the glass-industry it is usual to specify the transmittance in terms of %.

[SOURCE: IEC 60825-14:2004, 2.69, modified – the definition has been modified to specify the "range of visible light" and the note to entry has been expanded to address an aspect of the glass industry.]

4 Geometrical accuracy of translucent protective plates

4.1 Flatness and minimum thickness

On each of the two surfaces of a TRANSLUCENT PROTECTIVE PLATE all points shall be contained between two parallel planes 0,3 mm apart.

The actual thickness of a TRANSLUCENT PROTECTIVE PLATE shall not be less than the minimum thickness over its entire area.

The minimum thickness of TRANSLUCENT PROTECTIVE PLATES shall be indicated in units of millimetres (mm).

NOTE The minimum thickness of the plate over its entire area is relevant for the effectiveness of RADIATION PROTECTION.

4.2 Edges

The edges of PROTECTIVE GLASS PLATES shall be chamfered.

5 Optical quality of material

5.1 Inhomogeneities

Streaks, bubbles, inhomogeneities and faults of the surface which prevent optical clarity should not occur.

5.2 Transmittance

PROTECTIVE GLASS PLATES shall have a TRANSMITTANCE equal to or greater than 80 % at a glass thickness of 10 mm for light of a wavelength of 550 nm. The UNCERTAINTY of test methods for determination of TRANSMITTANCE shall not exceed 2 %. This UNCERTAINTY applies to a CONFIDENCE LEVEL of 95 %.

6 ATTENUATION properties

6.1 Determination of LEAD EQUIVALENT

NOTE The RADIATION PROTECTION shielding needed for a special purpose is usually estimated in thickness of lead. Therefore it is necessary to know the LEAD EQUIVALENT of the TRANSLUCENT PROTECTIVE PLATE.

The LEAD EQUIVALENT of a TRANSLUCENT PROTECTIVE PLATE shall be determined and specified according to the methods described in IEC 61331-1. LEAD EQUIVALENT shall be measured by use of the NARROW BEAM CONDITION or BROAD BEAM CONDITION for appropriate standard RADIATION QUALITIES chosen from Tables 1 and 2 of IEC 61331-1. If a measurement is not possible because of a lack of suitable radiation sources, e.g. for special photon-emitting RADIONUCLIDES, they shall be calculated according to the methods described in IEC 61331-1.

The chosen condition shall be indicated according to 6.4 and Clause 7, whereby N stands for NARROW BEAM CONDITION, B stands for BROAD BEAM CONDITION and C is used in case of calculated LEAD EQUIVALENT .

Both conditions are allowed, but the end user has to decide which condition is the most suitable one for its application for RADIATION PROTECTION shielding.

6.2 Homogeneity

The value of the LEAD EQUIVALENT shall not be less than the specified value over the entire area of a TRANSLUCENT PROTECTIVE PLATE.

6.3 Minimum thickness and LEAD EQUIVALENT

NOTE 1 TRANSLUCENT PROTECTIVE PLATES are usually ordered by their LEAD EQUIVALENT. Therefore it is useful to know the relation between a given minimum thickness and the corresponding LEAD EQUIVALENT.

The ratio of the LEAD EQUIVALENT as determined according to 6.1 and the minimum thickness as determined according to 4.1 of a PROTECTIVE GLASS PLATE shall not be less than 0,22 for all RADIATION QUALITIES listed in Table 1 of IEC 61331-1 with X-RAY TUBE VOLTAGES 50 kV to 150 kV. Examples of minimum thicknesses and their LEAD EQUIVALENT are given in Table 1.

NOTE 2 The exact value of the ratio of the LEAD EQUIVALENT and the minimum thickness of a PROTECTIVE GLASS PLATE depends on the RADIATION QUALITY.

Table 1 – Ratio of LEAD EQUIVALENT and minimum thickness for PROTECTIVE GLASS PLATES

Minimum thickness mm	**LEAD EQUIVALENT** mm Pb	**Ratio of LEAD EQUIVALENT and minimum thickness**
3,5	0,77	0,22
5	1,10	0,22
6	1,32	0,22
7	1,54	0,22
8,5	1,87	0,22
10	2,20	0,22

6.4 Information

Information about the LEAD EQUIVALENT shall be provided in mm Pb together with the method used for the determination and the RADIATION QUALITY or radionuclide for which it is SPECIFIED to be used.

Either the information shall be provided in the form of ACCOMPANYING DOCUMENTS or it shall be ensured that the information can be obtained by using the marking according to Clause 7.

If care must be taken in the use of cleaning agents, sufficient guidance for proper cleaning shall be contained in the ACCOMPANYING DOCUMENTS.

7 Marking

PROTECTIVE GLASS PLATE shall be permanently marked on one surface with the information as indicated in Table 2. The marking shall be legible and recognizable from the other surface and shall be affixed at a distance of not less than 10 mm from one corner.

Table 2 – Information and data for marking PROTECTIVE GLASS PLATES

	INFORMATION	**Data**
a	Name of MANUFACTURER or supplier	ABC
b	Trade mark or type of glass or identification corresponding with ACCOMPANYING DOCUMENTS	DEF
c	Minimal thickness in brackets as determined according to 4.2	(uvw)
d	LEAD EQUIVALENT expressed in thickness of lead followed by the symbol Pb	xy mmPb
e	Key indicator of beam condition for measurement or calculation of LEAD EQUIVALENT	N: NARROW BEAM B: BROAD BEAM C. calculated
f	X-RAY TUBE VOLTAGE or GAMMA RADIATION energy or code of RADIONUCLIDE respectively according to 6.1	See IEC61331-1
g	Statement of compliance with this International Standard according to Clause 9.	

8 ACCOMPANYING DOCUMENTS

If PROTECTIVE GLASS PLATES are provided with ACCOMPANYING DOCUMENTS, the ACCOMPANYING DOCUMENTS shall clearly state the identification of the PROTECTIVE GLASS PLATE to which they refer.

All markings required in Clause 7 shall be stated in the ACCOMPANYING DOCUMENTS.

9 Statement of compliance

If for a PROTECTIVE GLASS PLATE compliance with this part of the International Standard shall be stated, this shall be indicated as in the following example:

protective glass plate ABC[1)] DEF[2)] (8,5)[3)] 2,5 mm Pb[4)] N[5)] 150 kV[6)] IEC 61331-2:2014[7)]

1) name of MANUFACTURER or supplier ;

2) trademark or type of glass;

3) minimum thickness;

4) LEAD EQUIVALENT;

5) indicator for beam condition of measurement or calculation of LEAD EQUIVALENT;

6) X-RAY TUBE VOLTAGE in kV or GAMMA RADIATION energy in keV or code of RADIONUCLIDE;

7) year of publication of this standard.

Bibliography

IEC 60050-393:2003, *International Electrotechnical Vocabulary – Part 393: Nuclear instrumentation – Physical phenomena and basic concepts* (withdrawn)

IEC 60601-2-17:2013, *Medical electrical equipment – Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment*

IEC 60825-14:2004, *Safety of laser products – Part 14: A user's guide*

Index of defined terms used in this International Standard

NOTE In the present document terms defined either in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, IEC 60601-2-8:2010, ISO/IEC guide 99, IEC/TR 60788:2004, ISO 3534-1:2006 or in this International Standard have been used. These defined terms can be looked up at the IEC website http://std.iec.ch/glossary .

This page deliberately left blank

This page deliberately left blank

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. Details and advice can be obtained from the Copyright & Licensing Department.

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™