IEC 61331-2

Edition 2.0 2014-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Dispositifs de protection radiologique contre les rayonnements X pour diagnostic médical –
Partie 2: Plaques translucides de protection radiologique

IEC 61331-2:2014-05(en-fr)

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

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX L

ICS 11.040.50

ISBN 978-2-8322-1563-0

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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PROTECTIVE DEVICES AGAINST DIAGNOSTIC MEDICAL X-RADIATION –

Part 2: Translucent protective plates

FOREWORD

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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*

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.