



NSAI
Standards

Irish Standard
I.S. EN IEC 60601-2-28:2019

Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

I.S. EN IEC 60601-2-28:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN IEC 60601-2-28:2019 is the adopted Irish version of the European Document EN IEC 60601-2-28:2019, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

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EUROPEAN STANDARD

EN IEC 60601-2-28

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2019

ICS 11.040.55

Supersedes EN 60601-2-28:2010 and all of its
amendments and corrigenda (if any)

English Version

**Medical electrical equipment - Part 2-28: Particular requirements
for the basic safety and essential performance of X-ray tube
assemblies for medical diagnosis
(IEC 60601-2-28:2017)**

Appareils électromédicaux - Partie 2-28 : Exigences
particulières pour la sécurité de base et les performances
essentielles des gaines équipées pour diagnostic médical
(IEC 60601-2-28:2017)

Medizinische elektrische Geräte - Teil 2-28: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Röntgenstrahlern für
die medizinische Diagnostik
(IEC 60601-2-28:2017)

This European Standard was approved by CENELEC on 2019-08-07. 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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 60601-2-28:2019 (E)

European foreword

The text of document 62B/1040/FDIS, future edition 3 of IEC 60601-2-28, 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 IEC 60601-2-28:2019.

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) 2020-05-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-08-07

This document supersedes EN 60601-2-28:2010.

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Endorsement notice

The text of the International Standard IEC 60601-2-28:2017 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010 (not modified)
ISO 13732-1	NOTE	Harmonized as EN ISO 13732-1

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

NOTE 1 Where 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.

The annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition</i>				
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
IEC 60522	-	Determination of the permanent filtration of X-ray tube assemblies	EN 60522	-
IEC TR 60788	2004	Medical electrical equipment - Glossary of-defined terms		-
<i>Replacement</i>				
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 60601-1-2010	
			3:2008/corrigendum	
			Mar. 2010	
			+A11	2016

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IEC 60601-2-28

Edition 3.0 2017-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-28: Particular requirements for the basic safety and essential performance
of X-ray tube assemblies for medical diagnosis**

**Appareils électromédicaux –
Partie 2-28: Exigences particulières pour la sécurité de base et les performances
essentielles des gaines équipées pour diagnostic médical**



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IEC 60601-2-28

Edition 3.0 2017-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

**Part 2-28: Particular requirements for the basic safety and essential performance
of X-ray tube assemblies for medical diagnosis**

Appareils électromédicaux –

**Partie 2-28: Exigences particulières pour la sécurité de base et les performances
essentielles des gaines équipées pour diagnostic médical**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
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INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

FOREWORD

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International Standard IEC 60601-2-28 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 2010. This edition constitutes a technical revision.

The third edition of this particular standard has been prepared to fit IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (the amended third edition of IEC 60601-1), which is referred to as the general standard. Apart from the changes related to the amendment of IEC 60601-1, changes related to technical improvements are also included.

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

FDIS	Report on voting
62B/1040/FDIS	62B/1051/RVD

Full information on the voting for the approval of this particular 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: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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 Clause 7 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 60601 series, published under the general title *Medical electrical equipment*, 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-RAY TUBE ASSEMBLIES and to components thereof, intended for medical diagnosis and imaging.

Where the general standard IEC 60601-1 and the collateral standard IEC 60601-1-3 refer to ME EQUIPMENT, this is interpreted as X-RAY TUBE ASSEMBLIES in this particular standard. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE This document is also applicable to the X-RAY TUBE ASSEMBLY aspects of X-RAY SOURCE ASSEMBLIES and X-RAY TUBE HEADS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-RAY TUBE ASSEMBLIES for medical diagnosis.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 applies as modified in Clause 203. IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 101 IEC 60601-1-2 does not apply because RISKS for the X-RAY TUBE ASSEMBLY outside the system may only be indicative of RISKS for the system due to the difference in electromagnetic environment.

NOTE 102 IEC 60601-1-6 and IEC 60601-1-8 do not apply because X-RAY TUBE ASSEMBLIES are not operated as a stand-alone device.

NOTE 103 X-RAY TUBE ASSEMBLIES are not in the scope of IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12.

¹ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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