Irish Standard
I.S. EN 60601-2-28:2010

Medical electrical equipment -- Part 2 -28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:2010 (EQV))

I.S. EN 60601-2-28:2010

Incorporating amendments/corrigenda issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:	*This document is based on:*	*Published:*
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Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-28

May 2010

ICS 11.040.55

Supersedes EN 60601-2-28:1993

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 60601-2-28:2010)

Appareils éléctromédicaux - Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical
(CEI 60601-2-28:2010)

Medizinische elektrische Geräte - Teil 2-28: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Röntgenstrahlern für die medizinische Diagnostik
(IEC 60601-2-28:2010)

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-28:2010 E

Foreword

The text of document 62B/778/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-28 on 2010-04-01.

This European Standard supersedes EN 60601-2-28:1993.

The second edition of this particular standard has been prepared to fit EN 60601-1:2006, which is referred to as the general standard.

When the first edition was developed, mainly X-RAY TUBE ASSEMBLIES holding a glass insert were considered and EN 60601-1:1990 was in place. While the variety of modern X-RAY TUBE ASSEMBLIES and technologies has increased, the third edition of the general standard requires the MANUFACTURER to perform RISK MANAGEMENT. The technical modifications versus the first edition of EN 60601-2-28 account for these changes.

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

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

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 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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-28:2010 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 referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

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

Publication	Year	Title	EN/HD	Year
Replacement:				
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
Addition:				
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 60613	2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis	EN 60613	2010
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 as given in Annex I of the EC Directive 93/42/EEC.

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

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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

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 60601-2-28 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 published in 1993. This edition constitutes a technical revision.

The second edition of this particular standard has been prepared to fit IEC 60601-1:2005 (the third edition of IEC 60601-1), which is referred to as the general standard.

When the first edition was developed, mainly X-RAY TUBE ASSEMBLIES holding a glass insert were considered and IEC 60601-1:1988 (the second edition of the general standard) was in place. While the variety of modern X-RAY TUBE ASSEMBLIES and technologies has increased, the third edition of the general standard requires the MANUFACTURER to perform RISK MANAGEMENT. The technical modifications versus the first edition of IEC 60601-2-28 account for these changes.

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

FDIS	Report on voting
62B/778/FDIS	62B/784/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:

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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 amendment and the base 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.