



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-28:2019. It is identical to IEC 60601-2-28:2017. It supersedes BS EN 60601-2-28:2010, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee 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.

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Amendments/corrigenda issued since publication

Date	Text affected
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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.

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.

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

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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