Norma Española

UNE-EN IEC 60601-2-1:2021

Idioma: Inglés

Equipos electromédicos. Parte 2-1: Requisitos particulares para la seguridad básica y funcionamiento esencial de los aceleradores de electrones en el rango de 1 MeV a 50 MeV. (Ratificada por la Asociación Española de Normalización en septiembre de 2021.)

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Equipos electromédicos. Parte 2-1: Requisitos particulares para la seguridad básica y funcionamiento esencial de los aceleradores de electrones en el rango de 1 MeV a 50 MeV. (Ratificada por la Asociación Española de Normalización en septiembre de 2021.)

Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV (Endorsed by Asociación Española de Normalización in September of 2021.)

Appareils électromédicaux - Partie 2-1: Exigences particulières pour la sécurité de base et les performances essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV (Entérinée par l'Asociación Española de Normalización en septembre 2021.)

En cumplimiento del punto 11.2.5.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de documento normativo español UNE al documento normativo europeo EN IEC 60601-2-1:2021 (Fecha de disponibilidad 2021-07-16)

Este documento está disponible en los idiomas oficiales de CEN/CENELEC/ETSI.

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE.

La correspondiente versión oficial de este documento se encuentra disponible en la Asociación Española de Normalización (Génova 6 28004 MADRID, www.une.org).

Las observaciones a este documento han de dirigirse a:

Asociación Española de Normalización

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-1

July 2021

ICS 11.040.60

Supersedes EN 60601-2-1:2015 and all of its amendments and corrigenda (if any)

English Version

Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV (IEC 60601-2-1:2020)

Appareils électromédicaux - Partie 2-1: Exigences particulières pour la sécurité de base et les performances essentielles des accélérateurs d'électrons dans la gamme de 1 MeV à 50 MeV (IEC 60601-2-1:2020)

Medizinische elektrische Geräte - Teil 2-1: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektronenbeschleunigern im Bereich von 1 MeV bis 50 MeV (IEC 60601-2-1:2020)

This European Standard was approved by CENELEC on 2020-12-02. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 60601-2-1:2021 E

European foreword

The text of document 62C/770/FDIS, future edition 4 of IEC 60601-2-1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-1:2021.

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) 2022-01-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-07-16

This document supersedes EN 60601-2-1:2015 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

Endorsement notice

The text of the International Standard IEC 60601-2-1:2020 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 60601-1-3:2008	NOTE	Harmonized as EN 60601-1-3:2008 (not modified)
IEC 60601-1-3:2008/A1:2013	NOTE	Harmonized as EN 60601-1-3:2008/A1:2013 (not modified)
IEC 60601-1-9:2007	NOTE	Harmonized as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Harmonized as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-10:2007	NOTE	Harmonized as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Harmonized as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-2-11:2013	NOTE	Harmonized as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17:2013	NOTE	Harmonized as EN 60601-2-17:2015 (not modified)
IEC 60601-2-64:2014	NOTE	Harmonized as EN 60601-2-64:2015 (not modified)
IEC 60976:2007	NOTE	Harmonized as EN 60976:2007 (not modified)
IEC 62083:2009	NOTE	Harmonized as EN 62083:2009 (not modified)
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
IEC 62680-2-1:2015	NOTE	Harmonized as EN 62680-2-1:2015 (not modified)

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/A1:2013 applies with the following replacements:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015

The Annex ZA of EN 60601-1:2006/A1:2013 applies with the following additions:

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
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-2-68	2014	Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	EN 60601-2-68	2015
IEC 61000-4-3	-	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN IEC 61000-4-3	-

Publication	Year	Title	EN/HD	Year
IEC 61217	2011	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	2012
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
CISPR 11	-	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	-

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IEC 60601-2-1:2020-10(en-fr)

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