

Nadomešča:**SIST EN 60601-2-68:2015**

Medicinska električna oprema - 2-68. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenskih naprav pri slikovno vodeni radioterapiji z elektronskimi pospeševalniki, napravami za lahkoionsko radioterapijo in napravami za radionuklidno radioterapijo (IEC 60601-2-68:2025)

Medical electrical 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 (IEC 60601-2-68:2025)

Medizinische elektrische Geräte - Teil 2-68: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von röntgenstrahlungsbasierten Geräten für die bildgesteuerte Strahlentherapie zur Verwendung mit Elektronenbeschleunigern, Leichtionen-Strahlentherapiesystemen und Radionuklid-Strahlentherapiesystemen (IEC 60601-2-68:2025)

Appareils électromédicaux - Partie 2-68: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de radiothérapie à rayonnement X assistée par imagerie médicale, destinés à être utilisés avec les accélérateurs d'électrons, les appareils de thérapie par faisceau d'ions légers et les appareils de thérapie par faisceau de radionucléides (IEC 60601-2-68:2025)

Ta slovenski standard je istoveten z: EN IEC 60601-2-68:2025

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN IEC 60601-2-68:2025**en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-68

April 2025

ICS 11.040.60

Supersedes EN 60601-2-68:2015

English Version

Medical electrical 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
(IEC 60601-2-68:2025)

Appareils électromédicaux - Partie 2-68: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils de radiothérapie à rayonnement
X assistée par imagerie médicale, destinés à être utilisés
avec les accélérateurs d'électrons, les appareils de thérapie
par faisceau d'ions légers et les appareils de thérapie par
faisceau de radionucléides
(IEC 60601-2-68:2025)

Medizinische elektrische Geräte - Teil 2-68: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von
röntgenstrahlungsbasierten Geräten für die bildgesteuerte
Strahlentherapie zur Verwendung mit
Elektronenbeschleunigern, Leichtionen-
Strahlentherapiesystemen und Radionuklid-
Strahlentherapiesystemen
(IEC 60601-2-68:2025)

This European Standard was approved by CENELEC on 2025-03-11. 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

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

EN IEC 60601-2-68:2025 (E)**European foreword**

The text of document 62C/927/FDIS, future edition 2 of IEC 60601-2-68, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-68:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-04-30 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-04-30 document have to be withdrawn

This document supersedes EN 60601-2-68:2015 and all of its amendments and corrigenda (if any).

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The text of the International Standard IEC 60601-2-68:2025 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 standard indicated:

IEC 60336:2020	NOTE Approved as EN IEC 60336:2021 (not modified)
IEC 60364-7-710:2021	NOTE Approved as HD 60364-7-710:— ¹ (not modified) + A11:— ²
IEC 60601-1-9	NOTE Approved as EN 60601-1-9
IEC 60601-1-10	NOTE Approved as EN 60601-1-10
IEC 60601-2-4:2010	NOTE Approved as EN 60601-2-4:2011 (not modified)
IEC 60601-2-8	NOTE Approved as EN 60601-2-8
IEC 60601-2-11:2013	NOTE Approved as EN 60601-2-11:2015 (not modified)
IEC 60601-2-17	NOTE Approved as EN 60601-2-17
IEC 60601-2-28:2017	NOTE Approved as EN IEC 60601-2-28:2019 (not modified)
IEC 60601-2-44:2009	NOTE Approved as EN 60601-2-44:2009 (not modified) + A11:2011

¹ Under preparation. Stage at the time of publication: HD 60364-7-710:2025.

² Under preparation. Stage at the time of publication: HD 60364-7-710:2025/A11:2025.

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IEC 60601-2-44:2009/A1:2012	NOTE Approved as EN 60601-2-44:2009/A1:2012 (not modified)
IEC 60601-2-44:2009/A2:2016	NOTE Approved as EN 60601-2-44:2009/A2:2016 (not modified)
IEC 60601-2-54	NOTE Approved as EN IEC 60601-2-54
IEC 60601-2-64:2014	NOTE Approved as EN 60601-2-64:2015 (not modified)
IEC 60731:2011	NOTE Approved as EN 60731:2012 (not modified)
IEC 60976:2007	NOTE Approved as EN 60976:2007 (not modified)
IEC 61223-3-5:2019	NOTE Approved as EN IEC 61223-3-5:2019 (not modified)
IEC 61262-7:1995	NOTE Approved as EN 61262-7:1995 (not modified)
IEC 61674	NOTE Approved as EN IEC 61674
IEC 62083:2009	NOTE Approved as EN 62083:2009 (not modified)
IEC 62220-1-1:2015	NOTE Approved as EN 62220-1-1:2015 (not modified)
IEC 62274:2005	NOTE Approved as EN 62274:2005 (not modified)
IEC 62366-1:2015	NOTE Approved as EN 62366-1:2015 (not modified)

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[SIST EN IEC 60601-2-68:2025](https://standards.iteh.ai/catalog/standards/sist/75d97101-c2f8-4073-8061-37d002fc3347/sist-en-iec-60601-2-68-2025)

<https://standards.iteh.ai/catalog/standards/sist/75d97101-c2f8-4073-8061-37d002fc3347/sist-en-iec-60601-2-68-2025>

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.cencenelec.eu.

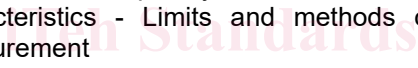
Clause 2 of EN 60601-1:2006³ applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<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
-	-		+ corrigendum Mar.	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
+ A2	2021		+ A2	2021
<i>Addition:</i>				
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
+ A2	2020		+ A2	2021
-	-		+ A13	2024

³ As impacted by EN 60601-1:2006/Corrigendum Mar. 2010, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A2:2021,

EN IEC 60601-2-68:2025 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-2-1	2020	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	EN IEC 60601-2-1	2021
IEC 60601-2-4	2010	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	EN 60601-2-4	2011
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
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	-
IEC 61217	2011	Radiotherapy equipment - Coordinates, movements and scales	EN 61217	2012
IEC 62563-1	2009	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	EN 62563-1	2010
CISPR 11	2024	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	-	-


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