



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 60601-2-63:2015/A2:2021

**Medical electrical equipment - Part
2-63: Particular requirements for the
basic safety and essential performance
of dental extra-oral X-ray equipment**

Medizinische elektrische Geräte - Teil
2-63: Besondere Festlegungen für die
Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von

Appareils électromédicaux - Partie 2-63:
Exigences particulières pour la sécurité
de base et les performances essentielles
des appareils à rayonnement X dentaires

06/2021



National Foreword

This European Standard EN 60601-2-63:2015/A2:2021 was adopted as Luxembourgish Standard ILNAS-EN 60601-2-63:2015/A2:2021.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

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EUROPEAN STANDARD

ILNAS-EN 60601-2-63:2015/A2:2021

EN 60601-2-63:2015/A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2021

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English Version

**Medical electrical equipment - Part 2-63: Particular requirements
for the basic safety and essential performance of dental extra-
oral X-ray equipment
(IEC 60601-2-63:2012/A2:2021)**

Appareils électromédicaux - Partie 2-63: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils à rayonnement X dentaires extra-
oraux
(IEC 60601-2-63:2012/A2:2021)

Medizinische elektrische Geräte - Teil 2-63: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von extraoralen
zahnärztlichen Röntgeneinrichtungen
(IEC 60601-2-63:2012/A2:2021)

This amendment A2 modifies the European Standard EN 60601-2-63:2015; it was approved by CENELEC on 2021-06-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 amendment 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

European foreword

The text of document 62B/1232/FDIS, future IEC 60601-2-63/A2, 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 60601-2-63:2015/A2:2021.

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) 2022-03-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-06-16

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.

Endorsement notice

The text of the International Standard IEC 60601-2-63:2012/A2:2021 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 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.

Replace, in this clause modified by Amendment 1, under Addition, the reference to IEC/PAS 61910-1:2014 with:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61910-1	2014	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy	EN 61910-1	2014



INTERNATIONAL STANDARD

AMENDMENT 2

**Medical electrical equipment –
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