
Medicinska električna oprema - 2-63. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za ekstraoralni zobni rentgen - Dopolnilo A2 (IEC 60601-2-63:2012/A2:2021)

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)

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)

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)

Ta slovenski standard je istoveten z: EN 60601-2-63:2015/A2:2021

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.060.20	Zobotehnična oprema	Dental equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-63:2015/A2:2021 en

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EUROPEAN STANDARD

EN 60601-2-63:2015/A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2021

ICS 11.040.50

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

EN 60601-2-63:2015/A2:2021 (E)**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.

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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

[SIST EN 60601-2-63:2015/A2:2021](https://standards.iteh.ai/catalog/standards/sist/e175258a-6b5c-4afe-9438-6489ce3e986f/sist-en-60601-2-63-2015-a2-2021)
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IEC 60601-2-63

Edition 1.0 2021-05

INTERNATIONAL STANDARD

AMENDMENT 2

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

[SIST EN 60601-2-63:2015/A2:2021](https://standards.iteh.ai/catalog/standards/sist/e175258a-6b5c-4afe-9438-6489ce3e986f/sist-en-60601-2-63-2015-a2-2021)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-9629-5

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FOREWORD

This second amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1232/FDIS	62B/1237/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

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 website 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.

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201.1.1 Scope

Replace Note 1 with the following new note:

NOTE 1 An example of such equipment is an equipment designed to perform PANORAMIC, CEPHALOMETRIC and DENTAL VOLUMETRIC RECONSTRUCTION (hereafter DVR) as defined in 201.3.203.

Add, under Replacement, before Note 5, the following new paragraph:

DENTAL EXTRA-ORAL X-RAY EQUIPMENT are X-RAY EQUIPMENT designed for EXTRA-ORAL RADIOGRAPHY in which the geometrical relations between the X-RAY SOURCE, the anatomical object being imaged in the PATIENT, and the X-RAY IMAGE RECEPTOR, are preset in the design and cannot be arbitrarily altered by the OPERATOR during INTENDED USE. In such equipment, the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

Add, at the end of the existing fifth paragraph, between Note 8 and Note 9, "by entities other than the manufacturer".

201.2 Normative references

Replace, in this clause modified by Amendment 1, under Addition, the reference to IEC/PAS 61910-1:2007 with:

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

201.3 Terminology and definitions

Add, after definition 201.3.213, the following new terms and definitions:

201.3.214

DENTAL CONE BEAM COMPUTED TOMOGRAPHY

DENTAL CBCT

3-dimensional imaging of DENTAL anatomical structures, performed by reconstruction of a volume from a series of 2-dimensional projections produced by circular or rectangular collimated X-RAY BEAM on an X-RAY IMAGE RECEPTOR rotating around the head of the PATIENT

201.3.215

EXAMINATION PROTOCOL

full set of programmed LOADING FACTORS, control functions and settings, including image processing settings, designed to the image acquisition and DISPLAY

201.4.10.1 Source of power for ME EQUIPMENT

Delete the existing Addition and Subclause 201.4.10.1.101.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Add, under Addition, after the first paragraph, the following new text:

For this purpose, the APPARENT RESISTANCE OF SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

<https://standards.iteh.ai/catalog/standards/sist/e175258a-6b5c-4afe-9438-6489ce3e986f/sist-en-60601-2-63-2015-a2-2021>

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

201.7.9.1 General

Add, under Addition, after the second paragraph, the following new text:

If a test or a QUALITY CONTROL PROCEDURE recommended by the MANUFACTURER requires a device-specific arrangement (including a TOOL, a PHANTOM, a special software or a software setting); that is only available from the MANUFACTURER, the MANUFACTURER shall provide this arrangement for the RESPONSIBLE ORGANIZATION.

NOTE 103 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the ACCOMPANYING DOCUMENTS.

Add, after Note 102, the following new text and new note:

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

NOTE 104 The MANUFACTURER can provide PHANTOM with the equipment, if specified in the local regulations.

203.5.2.4.5 Deterministic effects

Add, under Addition, before the note, the following new subclause:

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the INSTRUCTIONS FOR USE shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the user.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE.

203.6 Radiation management

Add, before 203.6.2, the following new instruction and subclause:

Addition:

203.6.1.102 *Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For DVR (DENTAL CBCT, DVT) if EXAMINATION PROTOCOLS are preloaded and multiple EXAMINATION PROTOCOLS are intended for both the same clinical task and, if applicable, the same PATIENT size, then those EXAMINATION PROTOCOLS will be differentiated by qualitative indication of their effect on image resolution and dose.

Compliance is checked by inspection or by the appropriate functional tests.

203.6.4.3.102.4 *Accuracy of IRRADIATION TIME

Add, after the second paragraph, the following new text and new note:

For ME EQUIPMENT in which the RADIATION dose is using time-width modulation during the IRRADIATION EVENT, the MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS a description of the modulation pattern, including the NOMINAL duration(s) of single pulses, which are generated during the IRRADIATION EVENT.

NOTE These pulses are synchronized with the RADIATION cycle used for a single projection image within the DVT or DENTAL CBCT image acquisition sequence and are generated from CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR.

Replace the compliance statement with the following:

Compliance is checked based on calculation of the IRRADIATION TIME using the examination of typical pulse pattern according to the description provided in the ACCOMPANYING DOCUMENTS on data acquired by the test according to 203.6.4.3.102.2.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

Replace the second paragraph with the following note:

NOTE This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation (eg X-RAY TUBE CURRENT and X-RAY TUBE IRRADIATION TIME).