ELEKTRILISED MEDITSIINISEADMED. OSA 2-63: ERINÕUDED EKSTRAORAALSE DENTAALSE RÖNTGENSEADME ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-63:2015 +A1:2019 sisaldab Euroopa standardi EN 60601-2-63:2015 ingliskeelset teksti ja selle muudatuse A1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-63 :2015+A1:2019 consists of the English text of the European standard EN 60601-2-63:2015 and its amendment A1:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.05.2015, muudatus A1 11.10.2019.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 29.05.2015, for A1 11.10.2019.
Sellesse standardisse on muudatus A1 sisse viidud ja tehtud muudatused tähistatud topeltpüst-kriipsuga lehe välisveerisel. Selles standardis on rahvusvahelise standardi ühismuudatused tähistatud püstkriipsuga teksti välimisel veerisel. Standard on kättesaadav Eesti Standardi-keskusest.	The amendment A1 has been incorporated into this standard and changes have been marked by a double vertical line on the outer row of the page. Common modifications has been incorporated into this international standard and changes have been marked by a vertical line on the outer row of the page. The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-63 + A1

May 2015, October 2019

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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 + IEC 60601-2-63:2012/A1:2017)

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 + IEC 60601-2-63:2012/A1:2017)

Medizinische elektrische Geräte - Teil 2-63: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von extraoralen zahnärztlichen Röntgeneinrichtungen (IEC 60601-2-63:2012 + IEC 60601-2-63:2012/A1:2017)

This European Standard was approved by CENELEC on 2012-10-24. Amendment A1 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.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-63:2015 E + EN 60601-2-63:2015/A1:2019 E

Foreword

The text of document 62B/888/FDIS, future edition 1 of IEC 60601-2-63, 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.

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)	2015-11-29
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-05-29

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This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-63:2012 was approved by CENELEC as a European Standard without any modification.

IEC 60601-2-63/A1 European foreword

The text of document 62B/1049/FDIS, future IEC 60601-2-63/A1, 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/A1:2019.

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)	2020-04-11
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2022-10-11

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Endorsement notice

The text of the International Standard IEC 60601-2-63:2012/A1:2017 was approved by CENELEC as a European Standard without any modification.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 60601-2-63 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/888/FDIS	62B/898/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: in roman type.

– *Test specifications: in italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchange-d until the stability date indicated on the IEC web site 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

AMENDMENT 1 FOREWORD

This 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/1049/FDIS	62B/1058/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.

INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 (third edition), and its collaterals, a complete set of BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for DENTAL EXTRA-ORAL X-RAY EQUIPMENT. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of DENTAL EXTRA-ORAL X-RAY EQUIPMENT. Components and their functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of DENTAL EXTRA-ORAL X-RAY EQUIPMENT

The minimum safety requirements for DENTAL INTRA-ORAL X-RAY EQUIPMENT are specified in a separate particular standard IEC 60601-2-65 to simplify and improve the readability

Requirements particular to DENTAL X-RAY-EQUIPMENT which were included in previous editions of the collateral standard IEC 60601-1-3, the particular standards IEC 60601-2-28 IEC 60601-2-7, or IEC 60601-2-32 have been extracted and moved into this particular standard.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-63:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-63:2012 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL EXTRA-ORAL X-RAY EQUIPMENT, hereafter also called ME EQUIPMENT. The scope includes ME SYSTEMS containing such ME EQUIPMENT.

NOTE 1 This includes PANORAMIC equipment, CEPHALOMETRIC equipment, and equipment for dental volumetric reconstruction (hereafter DVR) as defined in 201.3.203 below.

NOTE 2 DVR includes dental CBCT (cone beam computed tomography), which is also known with other names in certain parts of the world, e.g. DVT (digital volumetric tomography); DVR also includes tomosynthesis.

NOTE 3 This may include the imaging of other anatomical parts (e.g. the hand) as long as required for dental treatment (e.g. orthodontic treatment).

NOTE 4 This may include anatomical objects of interest to the ENT (ear, nose, and throat) specialist.

The scope of this standard is restricted to X-RAY EQUIPMENT where:

- the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY and
- 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.

NOTE 5 DENTAL INTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard.

NOTE 6 FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and FOCAL SPOT to object distance are preset in the design of DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

NOTE 7 For DENTAL X-RAY EQUIPMENT not in the scope of this document because of the restriction above, applicable clauses of IEC 60601-2-54 may be used with this document.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45, IEC 60601-2-65 or IEC 60601-2-43 are excluded from the scope of this particular standard. The scope of this International Standard also excludes RADIOTHERAPY SIMULATORS and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME EQUIPMENT intended to be used for DENTAL RADIOSCOPY.

Within its specific scope, the clauses of this particular standard supersede and replace those of IEC 60601-2-7, *Medical electrical equipment – Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators* and of IEC 60601-2-32, *Medical electrical equipment – Particular requirements for the safety of associated equipment of X-ray equipment*.

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

NOTE 8 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or this particular standard. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the IEC 60601-1 3rd edition scheme for DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to ME EQUIPMENT in the scope of this International Standard with the exception of X-RAY TUBE ASSEMBLIES that are replaceable in the field.

NOTE 9 Requirements particular to DENTAL X-RAY-EQUIPMENT which were included in previous editions of the collateral standard IEC 60601-1-3 or the particular standard IEC 60601-2-28 have been extracted and moved into this particular standard.

NOTE 10 For X-RAY EQUIPMENT in the scope of this particular standard X-RAY TUBE ASSEMBLIES are X-RAY MONOBLOCK ASSEMBLIES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT for EXTRA-ORAL DENTAL RADIOGRAPHY.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10[2], IEC 60601-1-11[3] and IEC 60601-1-12[4] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE OPERATORS of DENTAL EXTRA-ORAL X-RAY EQUIPMENT are used to audible signals as required in this particular standard rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard or collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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[2] IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[3] IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[4] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 43.

Clause 2 of the general standard applies, except as follows:

Replacement:

deleted text

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*
IEC 60601-1-3:2008/AMD1:2013

Addition:

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-29:2008, *Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC/PAS 61910-1:2007, *Medical electrical equipment – Radiation dose documentation – Part 1: Equipment for radiography and radioscopy*

201.3 Terminology and definitions

Amendment:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, its applicable collateral standards, IEC/TR 60788:2004 and the following apply:

NOTE An index of defined terms is found beginning on page 46.

Addition:

201.3.201
CEPHALOMETRIC
related to PROJECTION RADIOGRAPHY of the whole dento-maxillo-facial anatomy, whereas the projection geometry is such to minimize geometrical image distortions

Note 1 to entry: This is usually achieved by setting a sufficiently large source-to-object-distance and source-to-detector-distance.

Note 2 to entry: Another term often used for CEPHALOMETRIC RADIOGRAPHY is teleradiography.

201.3.202
DENTAL
related to structures in the dento-maxillo-facial district of the PATIENT, including dentition

201.3.203
***DENTAL VOLUMETRIC RECONSTRUCTION**
DVR
reconstruction of the 3-dimensional attenuation distribution of the whole or part of the irradiated volume from a series of 2-dimensional projections produced by an X-RAY BEAM on an X-RAY IMAGE RECEPTOR moving around the head of the PATIENT

201.3.204
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$).

[SOURCE: IEC 60601-2-54:2009, 201.3.203]

201.3.205
ELECTRONIC X-RAY IMAGE RECEPTOR
X-RAY IMAGE RECEPTOR comprising an electrically-powered conversion method