IEC 60601-2-63

Edition 1.0 2012-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

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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.

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.

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*.

[1] The general standard is IEC 60601-1:2005, *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] and IEC 60601-1-11[3] 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.

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”

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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) 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

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 39.

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

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

Addition:

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

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, its applicable collateral standards, IEC/TR 60788:2004 and the following apply:

NOTE An index of defined terms is found beginning on page 42.

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

201.3.206
EXTRA-ORAL
related to DENTAL RADIOGRAPHY where the X-RAY IMAGE RECEPTOR is located outside the oral cavity

201.3.207
INTERLOCK
means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

[SOURCE:IEC 60601-2-54:2009, 201.3.207]

201.3.208
INTRA-ORAL
related to DENTAL RADIOGRAPHY where the X-RAY IMAGE RECEPTOR is located, wholly or partially, inside the oral cavity

201.3.209
NOMINAL SHORTEST IRRADIATION TIME
shortest LOADING TIME for which a required constancy of the controlled RADIATION QUANTIY is maintained

Note 1 to entry: The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

[SOURCE: IEC 60601-2-54:2009, 201.3.208]

201.3.210
ONE-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a single-phase supply that delivers an unrectified output voltage, or rectified output voltage with one peak during each cycle of the supply

[SOURCE: IEC 60601-2-65:2012, 201.3.208]

201.3.211
*** PANORAMIC**

related to DENTAL RADIOGRAPHY, produced by the coordinated motion of a scanning fan-shaped X-RAY BEAM, oriented parallel to the cranio-caudal axis of the PATIENT, and an X-RAY IMAGE RECEPTOR, both rotating around the head of the PATIENT

Note 1 to entry: A tomographic layer is produced with respect to the plane perpendicular to the rotational axis. The resulting image is a focused projection on a surface parallel to the rotational axis.

Note 2 to entry: The scanning axis is usually vertical.

201.3.212
TWO-PEAK HIGH-VOLTAGE GENERATOR
HIGH-VOLTAGE GENERATOR for operation on a single-phase supply that delivers a rectified output voltage with two peaks during each cycle of the supply

[SOURCE: IEC 60601-2-65:2012, 201.3.209]

201.3.213
X-RAY MONOBLOCK ASSEMBLY
X-RAY TUBE ASSEMBLY containing the HIGH-VOLTAGE TRANSFORMER ASSEMBLY

Note 1 to entry: The term X-RAY MONOBLOCK ASSEMBLY excludes the BEAM LIMITING DEVICE.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

The list in Table 201.101 is a list of potential ESSENTIAL PERFORMANCE to be considered by the MANUFACTURER in the RISK MANAGEMENT PROCESS.

NOTE Subclause 203.6.4.3.102 (Accuracy of LOADING FACTORS) specifies a limitation in applying subclause 203.6.4.3.102.3 (Accuracy of X-RAY TUBE VOLTAGE) and 203.6.4.3.102.4 (Accuracy of X-RAY TUBE CURRENT). This limitation is also valid for the ESSENTIAL PERFORMANCE list.

Table 201.101 – List of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT PROCESS

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.102
Reproducibility of the RADIATION output	203.6.3.2

201.4.10.1 Source of power for ME EQUIPMENT

Addition:

201.4.10.1.101 Connection to SUPPLY MAINS

ME EQUIPMENT shall be PERMANENTLY INSTALLED unless the INTENDED USE requires it to be MOBILE.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of ME EQUIPMENT if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

ME EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at a resistance of supply mains having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional test.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows: