

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 2-65: Particular requirements for the basic safety and essential performance
of dental intra-oral X-ray equipment**

[IEC 60601-2-65:2012](https://standards.iteh.ai/catalog/standards/sist/4f6aea8f-71f0-4317-9816-cd9fa4dd05eb/iec-60601-2-65-2012)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

FOREWORD

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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-65 edition 1.2 contains the first edition (2012-09) [documents 62B/889/FDIS and 62B/897/RVD], its amendment 1 (2017-05) [documents 62B/1006/CDV and 62B/1039/RVC] and its amendment 2 (2021-05) [documents 62B/1233/FDIS and 62B/1238/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-2-65 has been prepared by IEC subcommittee 62B: Diagnostic Imaging Equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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: roman type.
- *Test specifications: 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.

IEC 60601-2-65:2012

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.

The committee has decided that the contents of the base publication and its amendments will remain unchanged 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
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INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 and its collaterals, a complete set of BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for DENTAL INTRA-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 INTRA-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 INTRA-ORAL X-RAY EQUIPMENT.

The minimum safety requirements for DENTAL EXTRA-ORAL X-RAY EQUIPMENT are specified in a separate particular standard IEC 60601-2-63 to simplify and improve the readability

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereinafter referred to as the general standard.

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*. 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, 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. Therefore IEC 60601-2-28 does not apply to equipment in the scope of this International Standard.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-65:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-65:2012 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 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL INTRA-ORAL X-RAY EQUIPMENT and its main components, hereafter also called ME EQUIPMENT.

The scope of this standard is restricted to X-RAY EQUIPMENT where the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard

NOTE 1 The X-RAY GENERATOR in DENTAL INTRA-ORAL X-RAY EQUIPMENT always comprises an X-RAY MONOBLOCK ASSEMBLY. Therefore in this particular standard the concept of X-RAY TUBE ASSEMBLY is replaced by that of X-RAY MONOBLOCK ASSEMBLY.

NOTE 2 Main components may be for instance the X-RAY MONOBLOCK ASSEMBLY and an ELECTRONIC X-RAY IMAGE RECEPTOR.

NOTE 3 Photostimulated phosphor plates and their readers (hardware and software) are excluded from the scope of this particular standard, since they have no electrical APPLIED PARTS in the PATIENT ENVIRONMENT, and are not ME EQUIPMENT.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-63, IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45 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*.

NOTE 4 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 in 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 INTRA-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.

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*

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 DENTAL INTRA-ORAL 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 Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10², IEC 60601-1-11³ and IEC 60601-1-12⁴ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE OPERATORS of DENTAL INTRA-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” 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.

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*

“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 40.

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

Replacement:

~~<https://standards.iteh.ai/catalog/standards/sist/4f6aea8f71f0-4317-9816-cd9fa4dd05eb/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

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

IEC 62220-1:2003, Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1: Determination of the detective quantum efficiency

201.3 Terms 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 43.

Addition:

201.3.201

DENTAL

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

[SOURCE: IEC 60601-2-63:2012, 201.3.202]

201.3.202

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 meter (Gy·m²).

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

201.3.203

ELECTRONIC X-RAY IMAGE RECEPTOR

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

[SOURCE: IEC 60601-2-63:2012, 201.3.205]

201.3.204

EXIT FIELD SIZE

dimensions of the RADIATION FIELD at the distal end of the dental cone as determined by the BEAM LIMITING DEVICE

Note 1 to entry: The dental cone ensures the minimum focus to skin distance. Usually the BEAM LIMITING DEVICE is part of the dental cone.

201.3.205

EXTRA-ORAL

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

[SOURCE: IEC 60601-2-63:2012, 201.3.206]

201.3.206

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]

201.3.207

INTRA-ORAL

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

[SOURCE: IEC 60601-2-63: 2012, 201.3.208]

201.3.208

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

201.3.209

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

201.3.210

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.

[SOURCE: IEC 60601-2-63:2012, 201.3.213]

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 potential 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.

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NOTE Subclause 203.6.4.3.102 (Accuracy of LOADING FACTORS) specifies a limitation in applying subclause 203.6.4.3.102.2 (Accuracy of X-RAY TUBE VOLTAGE) and 203.6.4.3.102.3 (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

201.4.10.2 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.