

FINAL VERSION

VERSION FINALE



Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-65: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X dentaires intra-oraux

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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 IEC 60601-2-65 bears the edition number 1.1. It consists of the first edition (2012-09) [documents 62B/889/FDIS and 62B/897/RVD] and its amendment 1 (2017-05) [documents 62B/1006/CDV and 62B/1039/RVC]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted 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, 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.

The committee has decided that the contents of the base publication and its amendment 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
- 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 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 (2017) 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*