



**NSAI**  
Standards

Irish Standard  
I.S. EN 60601-2-63:2015

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

**I.S. EN 60601-2-63:2015**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):*

*NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.*

*This document is based on:*

EN 60601-2-63:2015

*Published:*

2015-05-29

*This document was published  
under the authority of the NSAI  
and comes into effect on:*

2015-06-16

ICS number:

11.040.50

NOTE: If blank see CEN/CENELEC cover page

NSAI  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

Sales:  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

**EN 60601-2-63**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2015

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)**

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)

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

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

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 European Standard 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, 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: Avenue Marnix 17, B-1000 Brussels**

**EN 60601-2-63:2015****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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

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.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-7:1998	NOTE	Harmonised as EN 60601-2-7:1998 <sup>1)</sup> (not modified).
IEC 60601-2-28:2010	NOTE	Harmonised as EN 60601-2-28:2010 (not modified).
IEC 60601-2-32:1994	NOTE	Harmonised as EN 60601-2-32:1994 <sup>1)</sup> (not modified).
IEC 60601-2-43:2010	NOTE	Harmonised as EN 60601-2-43:2010 (not modified).
IEC 60601-2-44:2009	NOTE	Harmonised as EN 60601-2-44:2009 (not modified).
IEC 60601-2-45:2011	NOTE	Harmonised as EN 60601-2-45:2011 (not modified).
IEC 60601-2-65:2012	NOTE	Harmonised as EN 60601-2-65:2013 (not modified).

---

<sup>1)</sup> Superseded by EN 60601-2-54:2009 (IEC 60601-2-54:2009) and partially by EN 60601-2-65:2013 (IEC 60601-2-65:2012).

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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](http://www.cenelec.eu)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
--------------------	-------------	--------------	--------------	-------------

#### **Annex ZA of EN 60601-1:2006 applies except as follows:**

##### **Replacement:**

IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 <sup>1)</sup> 2010 <sup>1)</sup>
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	EN 60601-1-3 + corr. March	2008 2010

##### **Addition:**

IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
IEC 60601-2-29	2008	Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	EN 60601-2-29 + A11	2008 2011
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	EN 60601-2-54	2009
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	-	-

<sup>1)</sup> Superseded by EN 60601-1-2:2014 (IEC 60601-1-2:2014): DOW = 2018-12-31.

**EN 60601-2-63:2015**

**Annex ZZ**  
(informative)

**Coverage of Essential Requirements of EU Directives**

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

**WARNING:** Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.



**IEC 60601-2-63**

Edition 1.0 2012-09

# **INTERNATIONAL STANDARD**

## **NORME INTERNATIONALE**



**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**



## **THIS PUBLICATION IS COPYRIGHT PROTECTED**

**Copyright © 2012 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

### **About the IEC**

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

### **About IEC publications**

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

#### **Useful links:**

IEC publications search - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).

It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [csc@iec.ch](mailto:csc@iec.ch).

---

### **A propos de la CEI**

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

### **A propos des publications CEI**

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

#### **Liens utiles:**

Recherche de publications CEI - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

La recherche avancée vous permet de trouver des publications CEI en utilisant différents critères (numéro de référence, texte, comité d'études,...).

Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

Just Published CEI - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Restez informé sur les nouvelles publications de la CEI. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (VEI) en ligne.

Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [csc@iec.ch](mailto:csc@iec.ch).





**IEC 60601-2-63**

Edition 1.0 2012-09

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



---

**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**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

PRICE CODE  
CODE PRIX



ICS 11.040.50

ISBN 978-2-83220-382-8

<p><b>Warning! Make sure that you obtained this publication from an authorized distributor.</b></p> <p><b>Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.</b></p>
--

## CONTENTS

FOREWORD .....	4
INTRODUCTION .....	7
201.1 Scope, object and related standards .....	8
201.2 Normative references .....	10
201.3 Terms and definitions .....	11
201.4 General requirements .....	12
201.5 General requirements for testing of ME EQUIPMENT .....	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS .....	13
201.7 ME EQUIPMENT identification, marking and documents .....	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT .....	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS .....	17
201.10 Protection against unwanted and excessive radiation HAZARDS .....	18
201.11 Protection against excessive temperatures and other HAZARDS .....	18
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	18
201.13 HAZARDOUS SITUATIONS and fault conditions .....	18
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....	18
201.15 Construction of ME EQUIPMENT .....	18
201.16 ME SYSTEMS .....	18
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	19
202 Electromagnetic compatibility – Requirements and tests .....	19
203 Radiation protection in diagnostic X-ray equipment .....	19
Annexes .....	31
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS .....	32
Annex AA (informative) Particular guidance and rationale .....	33
Bibliography .....	39
Index of defined terms used in this particular standard .....	42
Figure 203.101 – Zone of EXTRA-FOCAL RADIATION .....	28
Figure AA.1 – PANORAMIC X-RAY EQUIPMENT .....	33
Figure AA.2 – AIR KERMA during IRRADIATION with direct current X-RAY GENERATOR .....	35
Figure AA.3 – AIR KERMA during IRRADIATION with ONE-PEAK X-RAY GENERATOR .....	36
Figure AA.4 – Example – series of (numerous) pulsed IRRADIATIONS for a CBCT (cone beam computed tomography) IRRADIATION event, with CONSTANT POTENTIAL HIGH- VOLTAGE GENERATOR and time-width modulation .....	37
Figure AA.5 – Example – series of two irradiations for PANORAMIC-like views of right and left TMJ (temporo-mandibular joint) in the same image, with ONE-PEAK HIGH- VOLTAGE GENERATOR .....	37

Table 201.101 – List of potential ESSENTIAL PERFORMANCE to be considered by MANUFACTURER in the RISK MANAGEMENT PROCESS .....	13
Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts .....	32
Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS .....	32

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 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 (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<sup>1</sup> 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 RADIOLOGY.

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*.

<sup>1)</sup> 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 3<sup>rd</sup> 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<sup>2)</sup> and IEC 60601-1-11<sup>3)</sup> 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”

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*

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- Looking for additional Standards? Visit Intertek Inform Infostore
  - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-