BS EN 60601-2-65:2013

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-65:2013. It is identical to IEC 60601-2-65:2012. It partially supersedes BS EN 60601-2-7:1998 and BS EN 60601-2-32:1995, which are withdrawn.

BSI as a member of CENELEC is obliged to publish EN 60601-2-65 as a British Standard. However, attention is drawn to the fact that the UK national committee voted against the UK implementation of EN 60601-2-65, as it feels that provisions are not quite fit for purpose for those hand held devices that are new to the market with regards to assessing leakage radiation at the surface of the units.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

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English version

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)

Appareils électromédicaux -
Partie 2-65: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils à rayonnement X dentaires
intra-oraux
(CEI 60601-2-65:2012)

Medizinische elektrische Geräte -
Teil 2-65: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von intraoralen
zahnärztlichen Röntgeneinrichtungen
(IEC 60601-2-65:2012)

CENELEC

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

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Foreword

The text of document 62B/889/FDIS, future edition 1 of IEC 60601-2-65, prepared by IEC/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 60601-2-65:2013.

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)	2013-07-24
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-10-24

This document supersedes EN 60601-2-7:1998 (PART) and EN 60601-2-32:1994 (PART).

EN 60601-2-65:2013 includes the following significant technical changes with respect to EN 60601-2-7:1998 and EN 60601-2-32:1994:

Within its specific scope, the clauses of EN 60601-2-65:2012 supersede and replace those of EN 60601-2-7:1998 and EN 60601-2-32:1994.

This standard is to be read in conjunction with EN 60601-1:2006.

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.

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.

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.

Endorsement notice

The text of the International Standard IEC 60601-2-65:2012 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 [1)] (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 [1)] (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 60601-2-54:2009	NOTE	Harmonised as EN 60601-2-54:2009 (not modified).
IEC 60601-2-63	NOTE	Harmonised as EN 60601-2-63.

[1)] Superseded by EN 60601-2-54:2009 (IEC 60601-2-54:2009, not modified).

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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

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

Publication	Year	Title	EN/HD	Year
In Annex ZA of EN 60601-1:2006 ***replace*** *IEC 60601-1-2 and IEC 60601-1-3 by:*				
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 2010
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
Add *to Annex ZA of EN 60601-1:2006 the following new references:*				
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-
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	EN 62220-1	2004

CONTENTS

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.

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 standard[1] 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.

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1 The general standard is IEC 60601-1:2005, *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 60601-1-10[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 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.

“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.

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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*

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 37.

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

NOTE An index of defined terms is found beginning on page 40.

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 ($Gy \cdot m^2$).

[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 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 203.6.4.3.102.2 (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.

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:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

Except for item a) to c) below, for ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

NOTE These requirements are adapted from IEC 60601-2-7 subclause 6.1j).

Additional subclause:

201.7.2.101 BEAM LIMITING DEVICE

Where detachable in NORMAL USE, BEAM LIMITING DEVICES shall be provided with the following markings:

- those required in subclause 7.2.2 of the general standard;
- serial designation or individual identification;
- the EXIT FIELD SIZE in terms of dimension or graphical means. If the EXIT FIELD SIZE is described by graphical means, such means shall be described in the instructions for use;
- ADDITIONAL FILTRATION, if the additional value is more than the equivalent of 0,2 mm Al.

Compliance is checked by inspection.

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-ray related states shall be excluded from subclause 7.8 in the general standard. 203.6.4.2 and 203.6.4.101 shall apply instead.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

NOTE 101 Annex C, Table 201.C.102 lists the requirements of this particular standard that are additional to those of the general standard for statements in the ACCOMPANYING DOCUMENTS.

The ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the ME EQUIPMENT by the RESPONSIBLE ORGANISATION. These shall include acceptance criteria and the recommended minimum frequency for the tests.

Additionally for ELECTRONIC X-RAY IMAGE RECEPTORS, the ACCOMPANYING DOCUMENTS shall contain

- a description of the performance of means, required to display the images for diagnostic purpose according to the INTENDED USE;

  NOTE For instance, the minimum required number of pixel and number of discernible grey levels of the display screen.

- indication of the nominal IMAGE RECEPTOR AIR KERMA range needed for the INTENDED USE;
- recommendations for typical LOADING FACTORS and FOCAL SPOT TO SKIN DISTANCES to achieve this AIR KERMA.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Additional subclauses:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use of ME EQUIPMENT, the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

a) value(s) of X-RAY TUBE VOLTAGE settings;

b) value(s) of X-RAY TUBE CURRENT settings;

c) values or range of IRRADITION TIME settings;

d) maximum X-RAY TUBE CURRENT at each X-RAY TUBE VOLTAGE setting, if different from b);

e) maximum and minimum IRRADIATION TIME at each X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT setting, if different from c).

Compliance is checked by inspection of the instructions for use.

201.7.9.2.1.102 BEAM LIMITING DEVICES

The EXIT FIELD SIZE(S) provided by the BEAM LIMITING DEVICE shall be stated in the instructions for use and technical description.

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

The technical description of the integrated X-RAY SOURCE ASSEMBLY shall specify the following, in addition to the data required to be marked according to subclause 7.2 of the general standard:

a) specification of the REFERENCE AXIS to which the TARGET ANGLE(s) and the FOCAL SPOT characteristics of the X-RAY SOURCE ASSEMBLY refer;

b) TARGET ANGLE(s) with respect to the specified REFERENCE AXIS;

c) position of the FOCAL SPOT;

d) NOMINAL FOCAL SPOT VALUE(s) determined according to IEC 60336 for the specified REFERENCE AXIS.

e) The EXIT FIELD SIZE(S) provided by the BEAM LIMITING DEVICE.

Compliance is checked by inspection of the technical description.

Additional subclause:

201.7.9.101 Requirements to the SUPPLY MAINS

The information on the RATED electrical input power for DENTAL INTRA-ORAL X-RAY GENERATORS shall also include:

- either the maximum permissible value for the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility; and
- the characteristics of OVER-CURRENT RELEASES eventually required in the SUPPLY MAINS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.5 Separation of parts

201.8.5.1 MEANS OF PROTECTION (MOP)

Additional subclause:

201.8.5.1.101 Additional limitation of voltage, current or energy for DENTAL INTRA-ORAL X-RAY GENERATORS

Provision shall be made to prevent the appearance of an unacceptably HIGH VOLTAGE in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example by

– provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between HIGH VOLTAGE and low-voltage circuits, or

– provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes open-circuited.

Compliance is checked by inspection of design data and construction.

NOTE these requirements are adapted from IEC 60601-2-7:1998, subclause 15bb).

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 * Allowable values

Amendment:

Item c) is amended as follows:

For non-PERMANENTLY INSTALLED X-RAY GENERATORS the allowable value of TOUCH CURRENT in SINGLE FAULT CONDITION is 2 mA.

NOTE This relaxation from the requirement of the general standard does not apply to PATIENT LEAKAGE CURRENT.

Item e) is amended as follows:

For PERMANENTLY INSTALLED X-RAY GENERATORS the allowable value of EARTH LEAKAGE CURRENT is 20 mA r.m.s. in NORMAL CONDITION and SINGLE FAULT CONDITION.

201.8.8.3 * Dielectric strength

Addition:

Instead of subclause 8.8.3 of the general standard, the HIGH VOLTAGE circuit of X-RAY MONOBLOCK ASSEMBLIES shall be tested as follows:

The test for the HIGH VOLTAGE circuit shall be made with a test voltage between 1,1 and 1,15 times the maximum NOMINAL X-RAY TUBE VOLTAGE of the X-RAY MONOBLOCK ASSEMBLY*. If the HIGH VOLTAGE circuit is not accessible, the voltage measurement may be indirect.*

The HIGH VOLTAGE circuit of X-RAY MONOBLOCK ASSEMBLIES *is tested by applying the test voltage for a time equal to two times the maximum permissible IRRADIATION TIME for NORMAL USE, as specified in the ACCOMPANYING DOCUMENTS. The test is repeated three times with a minimum interval of two minutes between each test.*

For ONE-PEAK HIGH-VOLTAGE GENERATORS, the test voltage for the HIGH VOLTAGE circuit shall be referenced to the no-load half cycle if the X-RAY TUBE VOLTAGE for the no-load half cycle is higher than in the on-load half cycle.

If during the dielectric strength test there is a risk of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Additional subclause:

201.9.8.4.101 MECHANICAL PROTECTIVE DEVICE

Ropes, chains or bands running parallel to other ropes, chains or bands may be regarded as a MECHANICAL PROTECTIVE DEVICE if they are not loaded during NORMAL USE.

Ropes, chains or bands used as a MECHANICAL PROTECTIVE DEVICE shall be accessible for inspection and the ACCOMPANYING DOCUMENTS shall give appropriate instructions for inspection.

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

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

NOTE The collateral standard IEC 60601-1-3 is referenced in the general standard and is covered under clause 203 of this document.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

Additional subclause:

201.11.101 *Protection against excessive temperatures of X-RAY MONOBLOCK ASSEMBLIES

The limitations of temperatures do not apply inside the protective housing of the X-RAY MONOBLOCK ASSEMBLY.

The temperature of the painted metal surface of an X-RAY MONOBLOCK ASSEMBLY which can be touched during INTENDED USE by the OPERATOR, and occasionally also by the PATIENT, may exceed the values in Table 23 of the general standard but shall not exceed 65 °C.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies.

NOTE According to subclause 12.4.5.1 of the general standard, the dose-related aspects of this question are addressed under 203.6.4.3 of this document.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies:

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies:

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies:

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows.

Additional subclause:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional ESSENTIAL PERFORMANCE listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER needs to take into account the sensitivity to the EMC environment, probability of EMC condition and severity, and probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Only non-invasive measurements shall be performed.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 applies, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If for ME EQUIPMENT, or a sub-assembly, compliance with this standard is to be stated, the statement shall be made in the following form:

X-RAY EQUIPMENT for DENTAL INTRA-ORAL RADIOGRAPHY ++) IEC 60601-2-65:2012

++) MODEL OR TYPE REFERENCE

Additional subclause:

203.4.101 Qualifying conditions for defined terms

203.4.101.1 * IRRADIATION TIME

IRRADIATION TIME is measured as the time interval between the instant when the AIR KERMA RATE has risen for the first time to a value of 50 % of the peak value, and the instant when it finally drops below the same value.

NOTE 1 see also definition 3.32 of IEC 60601-1-3:2008

203.5 ME EQUIPMENT identification, marking and documents

203.5.2.4.5 Deterministic effects

Addition:

NOTE No deterministic effects are known at this date with DENTAL INTRA-ORAL X-RAY EQUIPMENT in NORMAL USE.

203.6 RADIATION management

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Addition:

It shall not be possible to initiate any IRRADIATION event without releasing the control by which the previous IRRADIATION event was initiated.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.2.1.101 Connections of external INTERLOCKS

ME EQUIPMENT, except MOBILE ME EQUIPMENT and HAND-HELD ME EQUIPMENT, should be provided with connections for external electrical INTERLOCKS separate from the ME EQUIPMENT that either:

- can prevent the ME EQUIPMENT from starting to emit X-RADIATION;
- can cause the ME EQUIPMENT to stop emitting X-RADIATION;
- or both.

If the state of the signals from these external electrical INTERLOCKS is not displayed on the CONTROL PANEL, the ACCOMPANYING DOCUMENTS shall contain information for the RESPONSIBLE ORGANISATION that this state should be indicated by visual means in the installation.

NOTE An example of the use of this means would be to ensure the presence of PROTECTIVE SHIELDING as a condition to initiate an IRRADIATION, which is required in some countries.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Addition:

If the normal termination depends upon a RADIATION measurement

- the safety measure shall comprise means for automatic termination of IRRADIATION in the event of a failure of the normal termination, and
- either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME shall be limited to not more than 3,2 kJ per IRRADIATION, or the CURRENT TIME PRODUCT shall be limited to no more than 32 mAs per IRRADIATION.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.3 *RADIATION dose and RADIATION quality

203.6.3.1 Adjustment of RADIATION dose and RADIATION quality

Replacement:

It shall be possible to restrict the RADIATION dose to the PATIENT in line with the INTENDED USE of the X-RAY EQUIPMENT. This is achieved by the following:

a) Systems for automatic selection of LOADING FACTORS shall provide an adequate range of combinations of preselectable LOADING FACTORS.

b) The increments of scale values of X-RAY TUBE CURRENT or IRRADIATION TIME or CURRENT TIME PRODUCT shall not be greater than the respective steps according to the R'10 series in the IEC 60601-1-3 Annex B.

   NOTE It is recommended to use scale increments according to the R'10 or R'20 series according to IEC 60601-1-3, Annex B.

c) A minimum range of 16:1 for the CURRENT TIME PRODUCT shall be provided for each X-RAY TUBE VOLTAGE available.

d) For IRRADIATION TIMES shorter than 0,08 s in ONE-PEAK HIGH-VOLTAGE GENERATORS and TWO-PEAK HIGH-VOLTAGE GENERATORS where, because of the dependence on the pulsed nature of SUPPLY MAINS, it is not possible to provide all values belonging to the geometrical series within the range, missing values and consequently different geometrical intervals between the values provided shall be recognisable on the scale, and shall be explained in the instructions for use.

e) In ME EQUIPMENT with different MODES OF OPERATION, in order to compensate for the variable sensitivity of the X-RAY IMAGE RECEPTOR,

- the available range of adjustment of the CURRENT TIME PRODUCT shall be at least 4 to 1;
- the step size of the adjustment between adjacent settings of the CURRENT TIME PRODUCT shall not be greater than 1.6.

Compliance is checked by inspection and by the appropriate functional tests.

Additional subclause:

203.6.3.1.101 Linearity of AIR KERMA

The variation of the MEASURED VALUES of AIR KERMA shall linearly follow the change of the selected X-RAY TUBE CURRENT TIME PRODUCT over the whole range of X-RAY TUBE CURRENT TIME PRODUCT selections available, with an accuracy equal or better than 0,2.

Compliance is checked by the following test PROCEDURE:

The linearity test shall be performed at the lowest and highest kV setting available.

For each of these kV settings, pairs of X-RAY TUBE CURRENT TIME PRODUCT shall be selected as follows:

- The lower value of the first pair shall correspond to the lowest available CURRENT TIME PRODUCT setting.
- The ratio of the values of the selected X-RAY TUBE CURRENT TIME PRODUCT settings in each pair shall be as close as possible to 2, but not exceeding 2.
- The higher value of the X-RAY TUBE CURRENT TIME PRODUCT settings in each pair to be measured shall be used as the lower value of the next pair of X-RAY TUBE CURRENT TIME PRODUCT settings.
- The higher value of the last pair shall correspond to the highest available X-RAY TUBE *CURRENT TIME PRODUCT* setting and the lower value shall be half or next to half of the value corresponding to the highest available X-RAY TUBE CURRENT TIME PRODUCT setting.

In case of ONE-PEAK HIGH-VOLTAGE GENERATOR, the test shall be limited to IRRADIATION TIMES not shorter than 80 ms.

The series of measurements required for the test shall be performed in a continuous session. The time between two subsequent measurements shall not violate the duty cycle of the ME EQUIPMENT.

Perform a minimum of three LOADINGS at both of the selected X-RAY TUBE CURRENT TIME PRODUCT settings and measure the AIR KERMA.

Calculate the averages of the MEASURED VALUES of AIR KERMA for both series of three (or more) measurements.

Calculate the linearity according to the following formula for the highest and lowest kV setting

The quotients of the averages divided by the respective selected X-RAY TUBE CURRENT TIME PRODUCTS shall not differ by more than 0,2 times the mean value of these quotients

$$\left| \frac{\overline{K}_1}{Q_1} - \frac{\overline{K}_2}{Q_2} \right| \leq 0{,}2 \frac{\frac{\overline{K}_1}{Q_1} + \frac{\overline{K}_2}{Q_2}}{2}$$

where

$\overline{K}_1$, $\overline{K}_2$ are the averages of the measured values of AIR KERMA;

Q_1 and Q_2 are the indicated X-RAY TUBE CURRENT TIME PRODUCT.

203.6.3.2 Reproducibility of the RADIATION output

Addition:

203.6.3.2.101 Coefficient of variation of the AIR KERMA

The coefficient of variation of MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS over the range for INTENDED USE:

Compliance is checked by the following test PROCEDURE:

Select a set of LOADING FACTOR combinations for the reproducibility tests, including at least the following combinations:

- *highest available X-RAY TUBE VOLTAGE with the lowest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE;*
- *lowest available X-RAY TUBE VOLTAGE with the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE;*
- *a combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT for the highest electrical power;*
- *a combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT for the lowest electrical power.*

The series of measurements required for the test shall be performed in a continuous session. The time between two subsequent measurements shall not violate the duty cycle of the ME EQUIPMENT.

The IRRADIATION TIME for these measurements should be selected to the RADIATION dose defined for imaging the upper molar region of an adult PATIENT in the ACCOMPANYING DOCUMENTS.

Perform at least five LOADINGS at each of the combinations of LOADING FACTORS selected and measure the AIR KERMA.

Calculate the coefficient of variation for each of the series of measured values of AIR KERMA.

$$cv = \frac{s}{\overline{K}} = \frac{1}{\overline{K}}\sqrt{\sum_{i=1}^{n}\frac{(K_i - \overline{K})^2}{n-1}}$$

where

K_i are the MEASURED VALUES of AIR KERMA;

n is the number of measurements;

s is the estimated standard deviation of the population;

$\overline{K} = \frac{K_1 + K_2 + ... + K_n}{n}$ is the mean value over n measurements.

203.6.3.2.102 *AUTOMATIC EXPOSURE CONTROL

For ME EQUIPMENT which is equipped with means of AUTOMATIC EXPOSURE CONTROL, the RISK MANAGEMENT PROCESS shall determine the reproducibility of the AIR KERMA relative to the range of LOADING FACTORS adjusted by such AUTOMATIC EXPOSURE CONTROL as required for the INTENDED USE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203.6.3.2.103 INTERNALLY POWERED ME EQUIPMENT

INTERNALLY POWERED ME EQUIPMENT shall comply with the requirements for reproducibility of the radiation output according to 203.6.3.2 over the range of usable charging stages of the internal supply.

Compliance is checked by functional tests.

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

The LOADING STATE shall be indicated by a yellow indicator on the CONTROL PANEL.

NOTE An audible signal emitted during the LOADING STATE is an adequate indication of termination.

Compliance is checked by inspection.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Additional subclauses:

203.6.4.3.101 General requirements for the indication of LOADING FACTORS

The units of indication shall be as follows:

- for X-RAY TUBE VOLTAGE, kilovolt;
- for X-RAY TUBE CURRENT, milliampere;
- for IRRADIATION TIME, seconds and/or milliseconds;
- for CURRENT TIME PRODUCT, milliampereseconds.

For ME EQUIPMENT operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE.

In this case, the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the INSTRUCTIONS FOR USE.

In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the CONTROL PANEL.

For ME EQUIPMENT operating with fixed combinations of semi-permanently preselectable LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination.

In this case, provisions shall be made to enable

– the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the instructions for use, and in addition to enable
– the values to be listed in a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.

Compliance is checked by inspection.

NOTE MODE OF OPERATION and OBJECT PROGRAMMED CONTROL are synonymous (see IEC glossary).

203.6.4.3.102 Accuracy of LOADING FACTORS

203.6.4.3.102.1 General aspects for the accuracy of LOADING FACTORS

In HIGH-VOLTAGE GENERATORS the requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is checked by inspection and tests.

203.6.4.3.102.2 Accuracy of X-RAY TUBE VOLTAGE

The error of the value of the X-RAY TUBE VOLTAGE, in any combination of LOADING FACTORS, shall be not greater than 10 %.

Compliance is checked by the following test procedure:

a) One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest X-RAY TUBE CURRENT available for that X-RAY TUBE VOLTAGE, and an IRRADIATION TIME of approximately 0,1 s.
b) One measurement shall be made at the highest indicated value of X-RAY TUBE VOLTAGE, the lowest X-RAY TUBE CURRENT available for that X-RAY TUBE VOLTAGE and an IRRADIATION TIME of approximately 0,1 s.
c) One measurement shall be made at the highest indicated value of X-RAY TUBE VOLTAGE and the highest X-RAY TUBE CURRENT available for that X-RAY TUBE VOLTAGE, and an IRRADIATION TIME of approximately 0,5 s (or the longest selectable IRRADIATION TIME if 0,5 s is not available).

The X-RAY TUBE VOLTAGE shall be measured 5 ms after its onset or after the X-RAY TUBE CURRENT has exceeded 75 % of its final value, whichever occurs later.

203.6.4.3.102.3 Accuracy of X-RAY TUBE CURRENT

The error of the value of the X-RAY TUBE CURRENT, in any combination of LOADING FACTORS, shall be not greater than 20 %.

Compliance is checked by the following test procedure:

One measurement shall be made at the highest indicated value of X-RAY TUBE CURRENT, the lowest indicated value of X-RAY TUBE VOLTAGE for that and X-RAY TUBE CURRENT, and an IRRADIATION TIME of approximately 0,1 s.

One measurement shall be made at the lowest indicated value of X-RAY TUBE CURRENT, the highest indicated value of X-RAY TUBE VOLTAGE for that X-RAY TUBE CURRENT, and an IRRADIATION TIME of approximately 0,1 s.

One measurement shall be made at the highest indicated value of X-RAY TUBE CURRENT, the highest available X-RAY TUBE VOLTAGE for that X-RAY TUBE CURRENT, and an IRRADIATION TIME of approximately 0,5 s (or the longest selectable IRRADIATION TIME if 0,5 s is not available).

203.6.4.3.102.4 Accuracy of IRRADIATION TIME

The error of the value of the IRRADIATION TIME, in any combination of LOADING FACTORS, shall not be greater than ± 5 % or ± 20 ms, whichever is larger.

In ONE-PEAK HIGH-VOLTAGE GENERATORS, this requirement does not apply for IRRADIATION TIME shorter than 0,1 s

NOTE See Annex AA.

Compliance is checked by the following test procedure:

One pair of measurements shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the highest indicated value of X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE, at the shortest and the longest indicated value of IRRADIATION TIME.

One pair of measurements shall be made at the highest indicated value of X-RAY TUBE VOLTAGE, the lowest indicated value of X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE, at the shortest and the longest indicated value of IRRADIATION TIME.

203.6.4.5 Dosimetric indications

Replacement:

ME EQUIPMENT shall be provided with information in the ACCOMPANYING DOCUMENTS or displayed indication of the estimated AIR KERMA at a given distance from the FOCAL SPOT for any combination of selected LOADING FACTORS.

The overall deviation of the AIR KERMA from the estimated AIR KERMA shall be provided in the ACCOMPANYING DOCUMENTS and shall not exceed 50 %.

The ACCOMPANYING DOCUMENTS shall also provide a method to calculate the DOSE AREA PRODUCT based on the estimated AIR KERMA and the EXIT FIELD SIZE.

Compliance is checked by inspection and by the appropriate functional tests.

Additional subclause:

203.6.4.101 READY STATE

Visible indication shall be provided to the OPERATOR indicating the state when one further actuation of a control will initiate the LOADING of the X-RAY TUBE.

If this state is indicated by means of a single function visual indicator, the colour green shall be used.

Compliance is checked by inspection.

203.6.5 *AUTOMATIC CONTROL SYSTEM

Subclause 6.5 of 60601-1-3 does not apply.

203.6.6 * SCATTERED RADIATION reduction

Subclause 6.6 of 60601-1-3 does not apply.

203.6.7 Imaging performance

203.6.7.4 RADIATION DETECTOR or X-RAY IMAGE RECEPTOR

Addition:

The contribution of ELECTRONIC X-RAY IMAGE RECEPTORS to the metrics of imaging performance shall be specified. This contribution should ensure the efficient use of X-RAY.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.7 RADIATION QUALITY

203.7.1 * HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Addition:

For ME EQUIPMENT operating at a NOMINAL X-RAY TUBE VOLTAGE not exceeding 70 kV, alternative to the requirements for HALF VALUE LAYER in table 3 of IEC 60601-1-3, a TOTAL FILTRATION of at least 1,5 mm Al EQUIVALENT FILTRATION is permitted.

Additional subclause:

203.7.101 *Limitation of X-RAY TUBE VOLTAGE

The indicated setting of X-RAY TUBE VOLTAGE shall not be lower than 60 kV.

Compliance is checked by inspections.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Replacement:

ME EQUIPMENT shall have a BEAM LIMITING DEVICE, whose EXIT FIELD SIZE shall not exceed a circle of 6 cm diameter.

The BEAM LIMITING DEVICE should include further means for optionally limiting the EXIT FIELD SIZE to a rectangular shape inside the circular area of 6 cm diameter.

In case of ME EQUIPMENT with integrated ELECTRONIC X-RAY IMAGE RECEPTOR, the BEAM LIMITING DEVICE shall include means to limit the EXIT FIELD SIZE to a rectangular shape not exceeding the EFFECTIVE IMAGE RECEPTION AREA of the integrated ELECTRONIC X-RAY IMAGE RECEPTOR by more than 1 cm in the diagonal.

With rectangular EXIT FIELD SIZE, it shall be possible to rotate the exit field with respect to the X-RAY BEAM AXIS.

NOTE As the X-RAY FIELD needs to be aligned to the X-RAY IMAGE RECEPTOR located inside the oral cavity, it must be possible to rotate the BEAM LIMITING DEVICE for alignment with the EFFECTIVE IMAGE RECEPTION AREA indicated by the positioning system used for the X-RAY IMAGE RECEPTOR.

The boundary of an X-RAY FIELD is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

Compliance is checked by inspection and functional test according to the conditions above and by examination of the instructions for use.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replacement:

The design of the ME EQUIPMENT shall ensure a FOCAL SPOT TO SKIN DISTANCE of at least 20 cm.

Compliance is checked by inspection and measurement.

203.10 ATTENUATION OF THE X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Clause 10 of the collateral standard does not apply.

203.11 *Protection against RESIDUAL RADIATION

Replacement:

The instructions for use shall inform the OPERATOR about the presence of RESIDUAL RADIATION and shall provide guidance to avoid unnecessary exposure.

Compliance is checked by inspection of the instructions for use.

203.12 Protection against LEAKAGE RADIATION

203.12.2 Mounting OF X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS

Replacement:

The INTRA-ORAL X-RAY IMAGE RECEPTOR may be HAND-HELD during LOADING in NORMAL USE.

DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES may be HAND-HELD during LOADING in NORMAL USE, if the following information is provided with the ACCOMPANYING DOCUMENTS:

- values for the LEAKAGE RADIATION and STRAY RADIATION to the OPERATOR,
- guidance to avoid image degradation due to motion of the X-RAY SOURCE ASSEMBLY during LOADING,
- an illustrational drawing and dimensions of the designated SIGNIFICANT ZONE OF OCCUPANCY and
- the methods specified by the MANUFACTURER to assess the LEAKAGE RADIATION and STRAY RADIATION to the OPERATOR, and the image degradation due to motion.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.12.4 LEAKAGE RADIATION in the LOADING STATE

Replacement:

In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, at 1 m from the FOCAL SPOT, averaged over any area of 100 cm^2 of which no principal linear dimension exceeds 20 cm, when operated at the NOMINAL X-RAY TUBE VOLTAGE under conditions of LOADING corresponding to the reference LOADING conditions, shall not exceed 0,25 mGy in one hour.

NOTE 101 The protection of the OPERATOR of HAND-HELD ME EQUIPMENT against LEAKAGE RADIATION is subject to the MANUFACTURERS RISK MANAGEMENT PROCESS.

Compliance is checked by the following test procedure:

a) block the RADIATION APERTURE sufficiently to ensure that measurements of LEAKAGE RADIATION are not affected by RADIATION passing through it. Make and fit any cover used for this purpose to be as close as practicable to the RADIATION APERTURE and not to overlap it to an extent greater than is required for effective blocking;

b) for LOADING during the test

1) use the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY SOURCE ASSEMBLY under test;

2) use a convenient value of CURRENT TIME PRODUCT;

3) do not use LOADINGS so as to cause any specified ratings to be exceeded during the test;

c) determine, if necessary by making measurements, how the determination of LEAKAGE RADIATION will be affected by the settings and configurations specified for the NORMAL USE of the assembly under test. For the test itself, adopt the combination appearing to be the least favourable with regard to compliance;

d) with the appropriate LOADING FACTORS applied, make a sufficient number of measurements to determine the maximum AIR KERMA at 1 m from the FOCAL SPOT over the entire spherical surface;

e) normalize the MEASURED VALUES at the LOADING FACTORS actually used, to values of AIR KERMA in one hour corresponding to the reference conditions of LOADING stated in the ACCOMPANYING DOCUMENTS, in accordance with 12.3 of the collateral standard;

f) make any necessary adjustments to the values to take into account the permitted averaging over areas, as described in this subclause;

g) compliance is achieved if no MEASURED VALUE obtained by the test procedure exceeds the required limit.

203.12.5 LEAKAGE RADIATION when not in the LOADING STATE

Subclause 12.5 of 60601-1-3 does not apply.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Replacement:

ME EQUIPMENT shall be provided with means to optionally allow actuation of the IRRADIATION SWITCH from a PROTECTED AREA after installation.

Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

The ACCOMPANYING DOCUMENTS shall include a statement drawing the attention of the RESPONSIBLE ORGANISATION to the need for providing means for audio and visual communication between the OPERATOR and the PATIENT.

This requirement does not apply to HAND-HELD ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

203.13.3 Protection by distance

Addition:

Protection against STRAY RADIATION can be achieved, without provision for control from a PROTECTED AREA, by enabling the OPERATOR to control IRRADIATION from a distance not less than 2 m from the FOCAL SPOT and out of the path of the X-RAY BEAM.

This requirement does not apply to HAND-HELD ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.

Additional subclause:

203.13.101 Protection against stray radiation for HAND-HELD ME EQUIPMENT

NOTE The protection of the OPERATOR of HAND-HELD ME EQUIPMENT against stray radiation is subject to the MANUFACTURERS RISK MANAGEMENT PROCESS.

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labeling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies with the following exceptions:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of ME EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of ME EQUIPMENT or its parts

Description of marking	Subclause
Indication on the EQUIPMENT	201.7.2.101

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Addition:

Additional requirements for statements in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Table 201.C.102

Table 201.C.102 – Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Title	Subclause
SUPPLY MAINS for ME EQUIPMENT	201.4.10.2.
ACCOMPANYING DOCUMENTS	201.7.9
MECHANICAL PROTECTIVE DEVICE	201.9.8.4.101
Connections of external INTERLOCKS	203.6.2.1.101
Adjustment of RADIATION dose and RADIATION quality	203.6.3.1
Coefficient of variation of the AIR KERMA	203.6.3.2.101
Dosimetric indications	203.6.4.5
Protection by distance	203.13.3

Annex AA
(informative)

Particular guidance and rationale

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.8.7.3 – Allowable values

These requirements have been retained from IEC 60601-2-7:1998, subclause 19.3 because mandatory EMI filtering in combination with the surge in electrical power required for the LOADING of ME EQUIPMENT makes it a challenge to achieve the leakage current required in the general standard.

Subclause 201.8.8.3 – Dielectric strength

The general prescription for dielectric strength test of the HIGH VOLTAGE circuit in the now-superseded particular standard IEC 60601-2-7:1995 (2nd edition) was a test voltage 1,2 times the NOMINAL X-RAY TUBE VOLTAGE.

However, the particular standard prescribed a reduction of the test voltage to 1,1 times the NOMINAL X-RAY TUBE VOLTAGE under certain conditions: (quote) "If the HIGH-VOLTAGE GENERATOR can be tested only with the X-RAY TUBE connected and if the X-RAY TUBE does not allow the HIGH-VOLTAGE GENERATOR to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage shall be lower but not less than 1,1 times that voltage." (unquote).

The above is always the case for DENTAL INTRA-ORAL X-RAY EQUIPMENT where the design is always based upon X-RAY MONOBLOCK ASSEMBLIES.

Therefore, in this particular standard the dielectric strength test requirement has been simplified to address the only applicable condition, keeping into account the restriction in the scope.

It should be remarked that, in a X-RAY MONOBLOCK ASSEMBLY design, it is unlikely that HIGH VOLTAGE can be generated and maintained which significantly exceeds the NOMINAL X-RAY TUBE VOLTAGE, except for short transient spikes.

Subclause 201.11.101 – Protection against excessive temperatures of X-RAY MONOBLOCK ASSEMBLIES

The internal components of a DENTAL X-RAY MONOBLOCK ASSEMBLY are sealed and protected from air. If insulation materials are overheated, the HIGH-VOLTAGE GENERATOR fails and further LOADING is impossible.

Table 23 of IEC 60601-1:2005 does not cover painted metal surfaces. In addition the handling of the X-RAY MONOBLOCK ASSEMBLY by the OPERATOR during an exam is in the range of a few seconds.

Subclause 203.4.101.1 – IRRADIATION TIME

Some fundamental tenets of radiology are that:

- The RADIATION dose rate, i.e. amount of radiation produced (and absorbed by the RADIOLOGICAL object) per time unit (AIR KERMA RATE) is directly and linearly proportional to the instantaneous X-RAY TUBE CURRENT.

- Given a constant X-RAY TUBE CURRENT, the RADIATION dose, i.e. the total amount of radiation produced (and absorbed by the RADIOLOGICAL object) per IRRADIATION event (AIR KERMA) is directly and linearly proportional to the IRRADIATION TIME.
- Consequently, the RADIATION dose (AIR KERMA) is directly and linearly proportional to the product between the average X-RAY TUBE CURRENT and the IRRADIATION TIME, i.e. the CURRENT TIME PRODUCT (expressed in mAs).

Therefore the precise definition (i.e. "qualifying conditions for defined term") of IRRADIATION TIME should be such as to maintain its linear proportionality with the amount of radiation (radiation dose) as accurately as possible, even in non-ideal emission conditions.

The ideal condition occurs, evidently, when the IRRADIATION starts and stops abruptly, i.e. with instantaneous rise and fall time. In this condition the definition of IRRADIATION TIME is obvious and unnecessary, and its linearity with the radiation dose is implicit. In a real case, however, there is a finite rise and drop time for the X-RAY TUBE CURRENT and for the AIR KERMA RATE. Given the current technology, in X-RAY GENERATORS based upon d.c. (direct current) electronic converter, such rise and fall time is usually a linear ramp. In such a circumstance, setting the threshold of AIR KERMA RATE, for defining the start and stop of IRRADIATION TIME, at 50 % of the steady state and maximum value, achieves that the amount of extra AIR KERMA produced before the defined start instant balances exactly the amount of AIR KERMA missing from that instant to reaching the maximum and steady state value, thus retaining the linear proportionality between the IRRADIATION TIME and the total AIR KERMA.

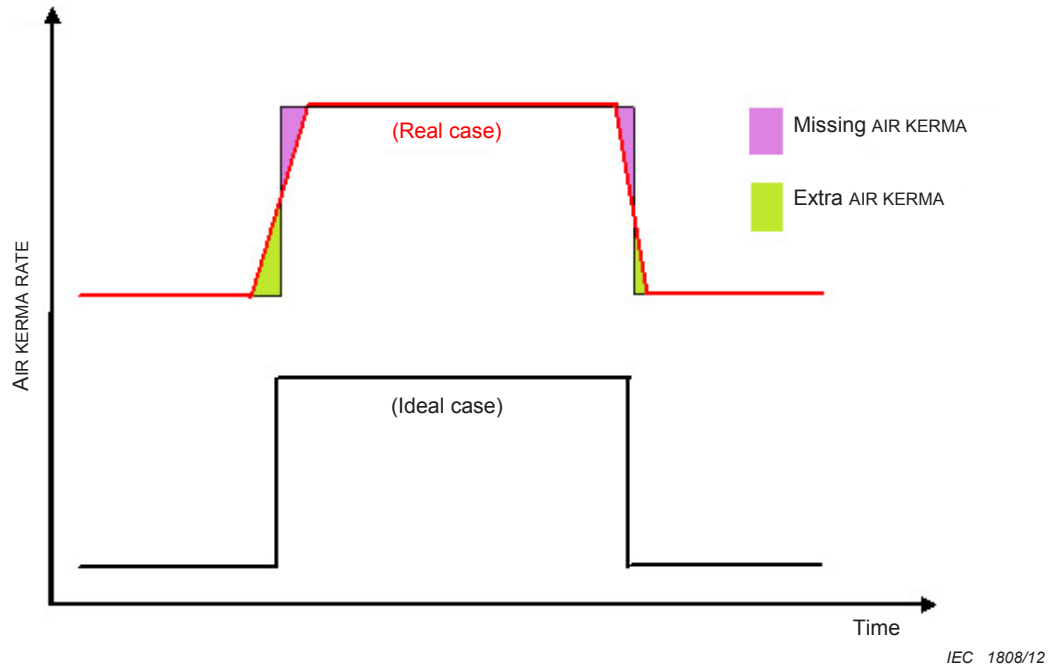


Figure AA.1 – AIR KERMA during IRRADIATION with direct current X-RAY GENERATOR

In ONE-PEAK and TWO-PEAK X-RAY GENERATORS, the situation is more complex, since the radiation is produced in pulses, and the rise of the envelope of the pulses' peak value (i.e. the leading edge) does not follow a linear ramp. The fall time at the trailing edge is normally negligibly short respect to the rise time, due to the fact that the termination of irradiation is achieved by turning-off the power i.e. simultaneously both X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT. The profile of the envelope of the pulses' peak value at the leading edge normally follows a gradual concave-convex profile, with the flex point at approximately 50 % of the steady state and maximum value.

Therefore, also in this circumstance setting the threshold of AIR KERMA RATE, referenced to the envelope of the pulses' peak value, at 50 % of the steady state and maximum value, means that the amount of extra AIR KERMA produced before the defined start instant approximately

balances the amount of AIR KERMA missing from that point-in-time to reaching the maximum and steady state value, thus retaining a good approximation of the linear proportionality between the thus-defined IRRADIATION TIME and the total AIR KERMA.

Subclause 203.6.3 – RADIATION dose and RADIATION quality

DENTAL INTRA-ORAL X-RAY EQUIPMENT with ONE-PEAK X-RAY GENERATOR

Practical DENTAL INTRA-ORAL X-RAY EQUIPMENT are always based upon an X-RAY MONOBLOCK ASSEMBLY, whose design encapsulates, inside a sealed X-RAY TUBE HOUSING, all the HIGH VOLTAGE parts of the X-ray-generating circuitry, these including (among else) the X-RAY TUBE and a HIGH-VOLTAGE TRANSFORMER ASSEMBLY. This design is necessary in order to keep the size and weight of the X-RAY SOURCE ASSEMBLY as low as possible consistent with both PATIENT and OPERATOR's ergonomics, and with the need to handle it – manually positioning and orienting – in the typically confined environment of the dental office.

Conversely, in a typical X-RAY EQUIPMENT for conventional medical radiography, the X-RAY TUBE is enclosed in a X-RAY TUBE HOUSING and is powered via HIGH VOLTAGE cables (and related HIGH VOLTAGE cable connections) carrying the power from a separate source of HIGH VOLTAGE. This makes possible to separate the HIGH VOLTAGE supply of the anodic circuit (for controlling the X-RAY TUBE VOLTAGE – the "kV") and that of the filament circuit (for controlling the X-RAY TUBE CURRENT – the "mA").

Many models of DENTAL INTRA ORAL X-RAY EQUIPMENT are based upon ONE-PEAK HIGH-VOLTAGE GENERATOR, a design which makes possible inexpensive and compact products albeit with some limitations in performance. With ONE-PEAK HIGH-VOLTAGE GENERATORS, the HIGH VOLTAGE across the X-RAY TUBE (the X-RAY TUBE VOLTAGE) is obtained by directly stepping-up the SUPPLY MAINS voltage (e.g. 100V, 115V, or 230V) by means of one HIGH-VOLTAGE TRANSFORMER ASSEMBLY. Such a transformer has a single primary coil and a multi-tapped secondary coil to power the anodic circuit and the filament circuit.

NOTE 101 Although using two separate transformers to power the anode circuit and the filament circuit separately is possible, most ONE-PEAK HIGH VOLTAGE GENERATORS of DENTAL INTRA-ORAL X-RAY EQUIPMENT commercially produced at the time of writing and many years before, use a single high-voltage transformer with an additional filament winding. The additional HIGH VOLTAGE insulation requirements would result in substantial increase in size and weight, thus defying the design purpose of this kind of equipment.

It is obvious that, in a ONE-PEAK design with single HIGH-VOLTAGE TRANSFORMER ASSEMBLY, the anodic circuit and the filament circuit can only be powered simultaneously, and that they cannot be controlled independently, i.e. only one nominal value of X-RAY TUBE VOLTAGE and of X-RAY TUBE CURRENT can be set.

When the X-RAY TUBE VOLTAGE is applied (i.e. the anode becomes positive with respect to the cathode), the X-RAY TUBE is immediately ready to emit X-RAY (with energy spectrum characteristic of that X-RAY TUBE VOLTAGE). However, application of power to the filament circuit does not result into the immediate flow of electrons through the X-RAY TUBE and the consequent emission of X-ray (at a flow rate proportional to the X-RAY TUBE CURRENT). Instead, the immediate effect is to gradually raise the temperature of the filament, up to the temperature at which electrons are released by thermionic effect. The time needed for the filament to reach the thermal steady state, and the steady state in the electrons flow and the emission of X-ray, may be in the order of the hundreds of millisecond. Therefore, in DENTAL INTRA-ORAL X-RAY EQUIPMENT with ONE-PEAK HIGH-VOLTAGE GENERATOR, there is a significant difference between LOADING TIME and IRRADIATION TIME.

The diagrams AA.2 and AA.3 below show the waveform of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT with a ONE-PEAK HIGH-VOLTAGE GENERATOR (with single HIGH VOLTAGE transformer). The rate of X-ray photons is substantially proportional to the X-RAY TUBE CURRENT, and consequently the AIR KERMA RATE also substantially conforms to the same waveform.

The time period between subsequent pulses is the inverse of the mains frequency, i.e. 20 ms in 50 Hz mains power systems, and about 16,7 ms in 60 Hz mains power systems.

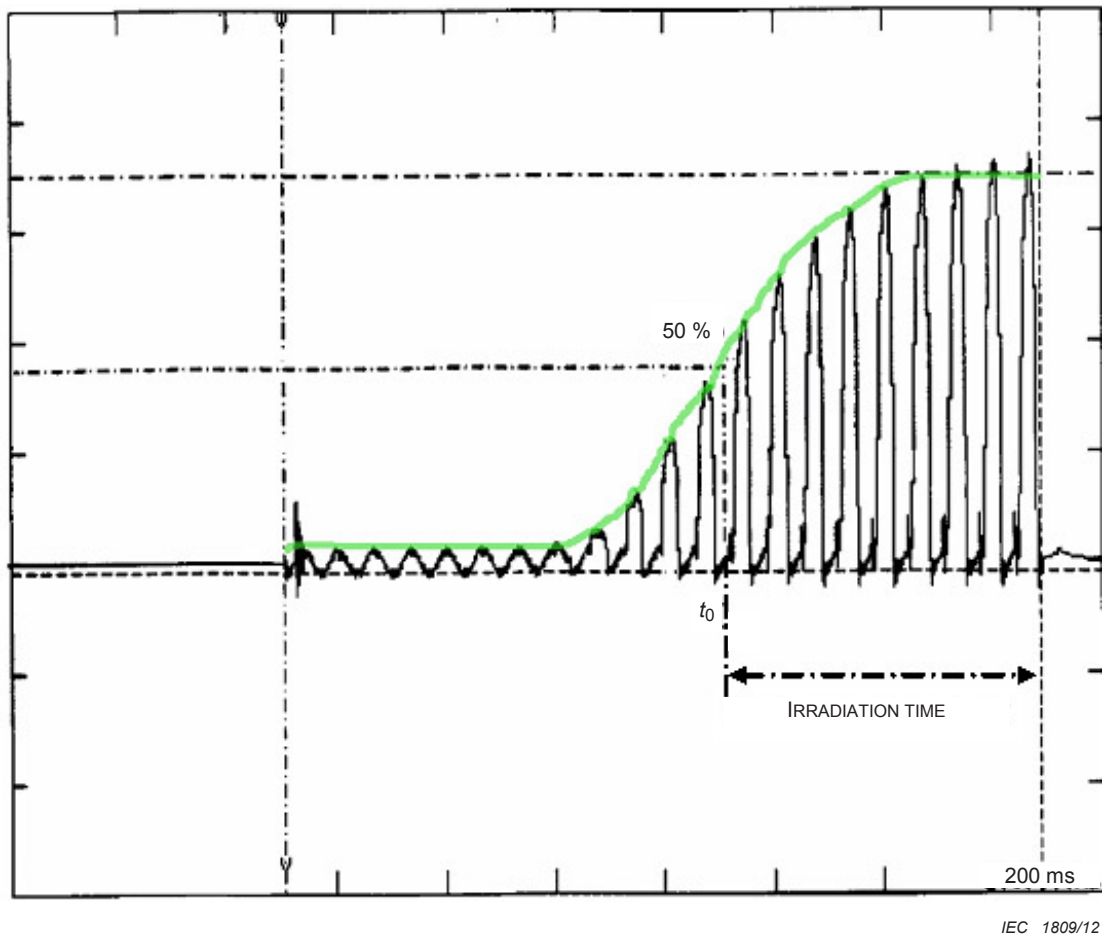


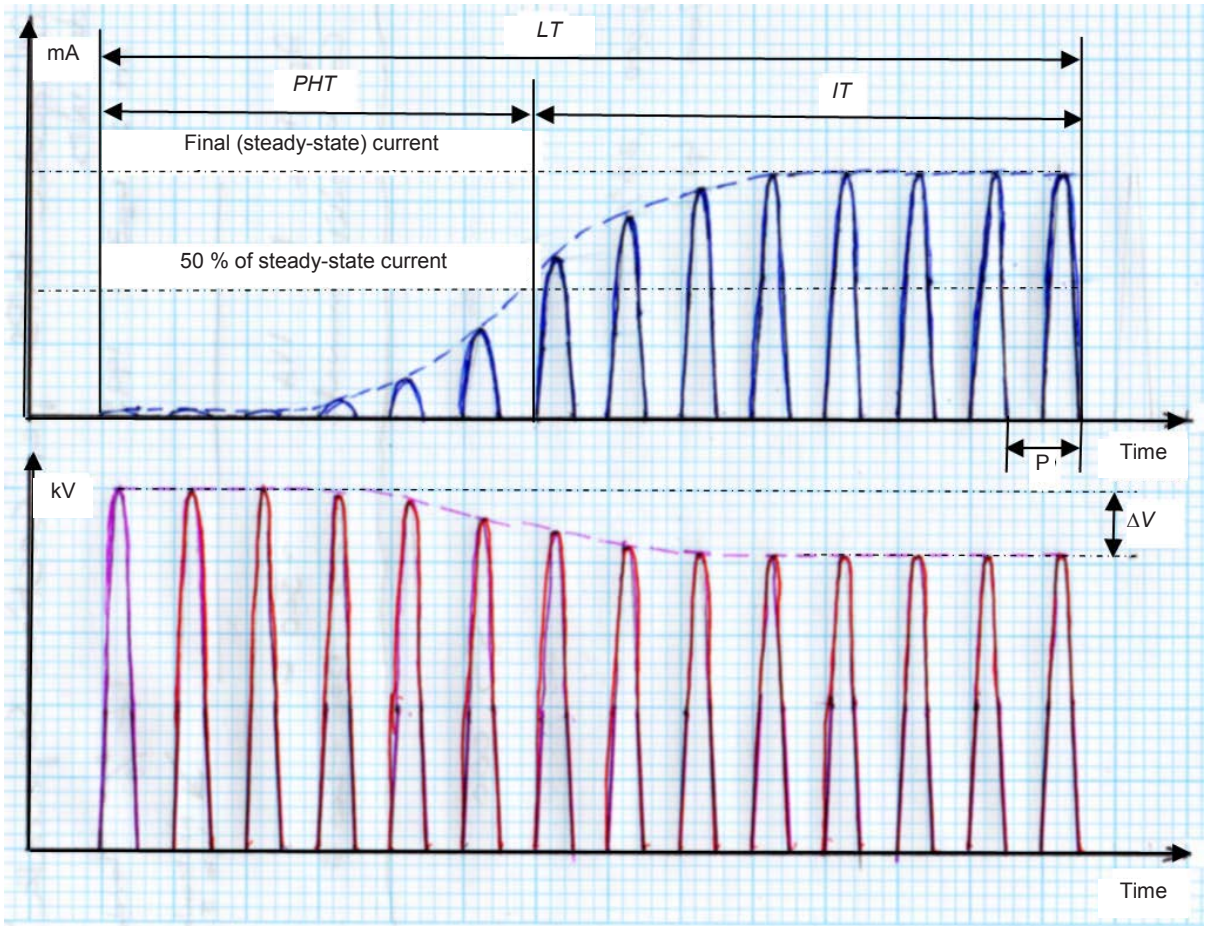
Figure AA.2 – AIR KERMA during IRRADIATION with ONE-PEAK X-RAY GENERATOR

In Figure AA.2, the LOADING TIME is relatively large with respect to both the mains period and the filament heating-up time. It can be seen that there is a significant difference (= lag) between the LOADING TIME (the time during which the X-RAY MONOBLOCK ASSEMBLY is powered) and the IRRADIATION TIME (the time during which the AIR KERMA RATE exceeds a given percentage of the maximum and steady-state value - or in other words the time during which there is significant emission of X-ray), due to the delay in the filament heating up and the start of the release of electrons. Conversely, the IRRADIATION is immediately and abruptly stopped on the trailing edge, because no further X-RAY TUBE CURRENT and X-ray emission are possible as the X-RAY TUBE VOLTAGE drops to zero.

Therefore, the definition of IRRADIATION TIME is subordinate to the a priori knowledge of the filament heating-up time (also known as pre-heating time), which is determined by the manufacturer through type testing of the X-RAY GENERATOR.

Such heating-up time cannot be predicted a priori with absolute certainty. In fact, small variations and fluctuations of the actual value of the RATED SUPPLY MAINS voltage have a great impact on the X-RAY TUBE CURRENT due to the very steep thermionic emission/X-RAY TUBE CURRENT curve. Therefore measurements of IRRADIATION TIME should only be performed with SUPPLY MAINS power stabilized at its RATED value, and even in this case the IRRADIATION TIME may show significant differences in value (due to variations in the filament heating-up time), even if the CONTROL ASSEMBLY regulates the LOADING TIME to a very high degree of accuracy.

NOTE 2 A relatively gradual ramping-up of the pulses peak value is not very detrimental to the linearity of the AIR KERMA versus IRRADIATION TIME relationship, if the threshold for defining the start of IRRADIATION TIME is set to 50 %, because the extra AIR KERMA emitted prior to that time point substantially makes up for the one missing after that time point.



mA: X-RAY TUBE CURRENT

kV: X-RAY TUBE VOLTAGE (emitting half-cycle only)

LT: LOADING TIME

IT: IRRADIATION TIME

PHT: pre-heating time

P: period of one mains pulse (20 ms at 50 Hz, 16,7 ms at 60 Hz)

ΔV: drop of the peak value of X-RAY TUBE VOLTAGE from the initial no-load value to the final (steady-state) load value

Figure AA.3 – Waveform of long IRRADIATION TIME X-RADIATION from a ONE-PEAK X-RAY GENERATOR

In Figure AA.3, the IRRADIATION TIME is a few times larger than, but comparable to the mains period. In this case various issues must be taken into account.

Due to the fact that IRRADIATION occurs by discrete pulses at regular time interval, also the meaningful values of IRRADIATION TIME are discrete, i.e. it makes no conceptual sense to define IRRADIATION TIME (and LOADING TIME) with precision better than one mains period (20 ms or 16,7 ms at 50 Hz and 60 Hz respectively). Consequently the R10 scale can be approximated well enough by the discrete sequence of impulses only from 80 ms up

In the case of this example, the IRRADIATION TIME would be 8 mains pulses, i.e. 160 ms at 50 Hz, and 133 ms at 60 Hz, whose closest approximation in the R10 scale is 125 ms.

NOTE 3 It is conceptually possible to stop or start loading during an active pulse (instead of at zero-crossing as usually done in good technical practice), however, besides presenting a considerable technical challenge, this would impair the inherent linearity relationship between IRRADIATION TIME and AIR KERMA (= radiation dose), which is a basic pillar of radiology.

Even minor fluctuation of the pre-heating time – for example caused by variations in the MAINS VOLTAGE, but not limited to that – may result into variations of one (or more) time period(s) which effects large percent changes to the defined and measured IRRADIATION TIME.

As a consequence of the considerations above, in X-RAY EQUIPMENT with X-RAY MONOBLOCK ASSEMBLY and ONE-PEAK HIGH-VOLTAGE GENERATOR:

- IRRADIATION TIME must always be defined as a discrete multiple of time periods of the SUPPLY MAINS. The implementation of the R10 or R20 scale can only be achieved as a best approximation.
- Measurement of IRRADIATION TIME must be performed at stable value of the mains supply voltage, because in case of short times any variation from the RATED value results into significant percent changes.

NOTE 4 the considerations above substantially apply also in case of a TWO-PEAK HIGH-VOLTAGE GENERATOR. However, this kind of design is not considered advantageous for DENTAL INTRA-ORAL X-RAY EQUIPMENT and is not implemented in actual commercial products, and is, therefore, not considered here.

The time-versus-supply voltage compensation mechanism

In many models of DENTAL INTRA-ORAL X-RAY EQUIPMENT with ONE-PEAK HIGH-VOLTAGE GENERATOR, the CONTROL ASSEMBLY incorporates a special manner of operation directed to mitigate the consequences of MAINS VOLTAGE fluctuations onto the AIR KERMA, that is on the linearity of radiation dose versus the selected IRRADIATION TIME, by altering the LOADING TIME as the MAINS VOLTAGE fluctuates so that the AIR KERMA remains constant at given nominal technique factors. Such alteration has the purpose of compensating the resulting fluctuations (with respect to nominal) of both the X-RAY TUBE VOLTAGE and the IRRADIATION TIME (the latter caused by the resulting fluctuations of the pre-heating time).

The pre-defined relationship between the actual loading time and the actual MAINS VOLTAGE, at any nominal values of IRRADIATION TIME, is determined by the MANUFACTURER basing upon type testing.

In this kind of equipment, any measurement of accuracy and linearity of the technique factors (kV, mA, s) must be performed with mains supply highly-stabilized at nominal value, or, alternatively, the MEASURED VALUES of IRRADIATION TIME must be corrected for the known time-versus-supply voltage compensation relationship declared by the MANUFACTURER,

Subclause 203.6.3.2.102 – Automatic exposure control

This subclause applies only for ME EQUIPMENT with an AUTOMATIC EXPOSURE CONTROL, which is not mandatory. See subclause 203.6.5 below.

Subclause 203.6.5– Automatic control system

Film based DENTAL INTRA-ORAL RADIOGRAPHY practically cannot be equipped with AUTOMATIC EXPOSURE CONTROl.

DENTAL INTRA-ORAL X-RAY EQUIPMENT can be equipped with a sensor to measure the actual dose after the object in case that an integrated ELECTRONIC X-RAY RECEPTOR is used.

For DENTAL INTRA-ORAL X-RAY EQUIPMENT the variation of exposure conditions and consecutively the RISK of erroneous exposure is low. Therefore an AUTOMATIC CONTROL SYSTEM is not mandatory.

Subclause 203.6.6 – Scattered radiation reduction

The anatomy of the oral cavity does not allow for the introduction of means reducing the effects of scattered radiation.

Subclause 203.7.1 – HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

There is a world-wide common exposure practice for INTRA-ORAL DENTAL X-RAY EQUIPMENT to achieve the desired image contrast based on certain X-RAY TUBE CURRENT TIME PRODUCTS at fixed X-RAY TUBE VOLTAGES. This practice has been established using the FILTRATION limits of IEC 60601-1-3:1994.

Keeping the existing limits is beneficial for the patient dose and the image quality as it does not change the established practice in the dental community.

Subclause 203.7.101 – Limitation of X-RAY TUBE VOLTAGE

For DENTAL RADIOGRAPHY a certain penetration is needed because of the presence of bones.

Subclause 203.11 – Protection against RESIDUAL RADIATION

DENTAL RADIOGRAPHIC FILMS do provide means to reduce RESIDUAL RADIATION. The delta between X-ray field and X-ray image receiving area cannot be addressed by ATTENUATION means as these cannot be placed in the oral cavity.

Annex BB
(informative)

Identification of parts of dental X-RAY INTRA-ORAL SYSTEMS in relation to defined terms in this standard

Figure BB.1 demonstrates the hierarchical relationship between the applicable defined terms, per IEC 60601-1-3 and further defined and modified in this particular standard.

Figure BB.2 is an illustrative example of typical DENTAL INTRA-ORAL X-RAY EQUIPMENT with graphical correlation of parts with the defined terms.

NOTE The composition of a given defined term is not constituted exclusively of other defined terms, but may also include parts that are not formally defined in this standard (and that, consequently, do not appear in the diagram hereunder). For instance, an X-RAY GENERATOR, in addition of comprising a CONTROL ASSEMBLY and an X-RAY SOURCE ASSEMBLY, may (and normally does) include also mechanical supporting parts, which are not a formally defined term.

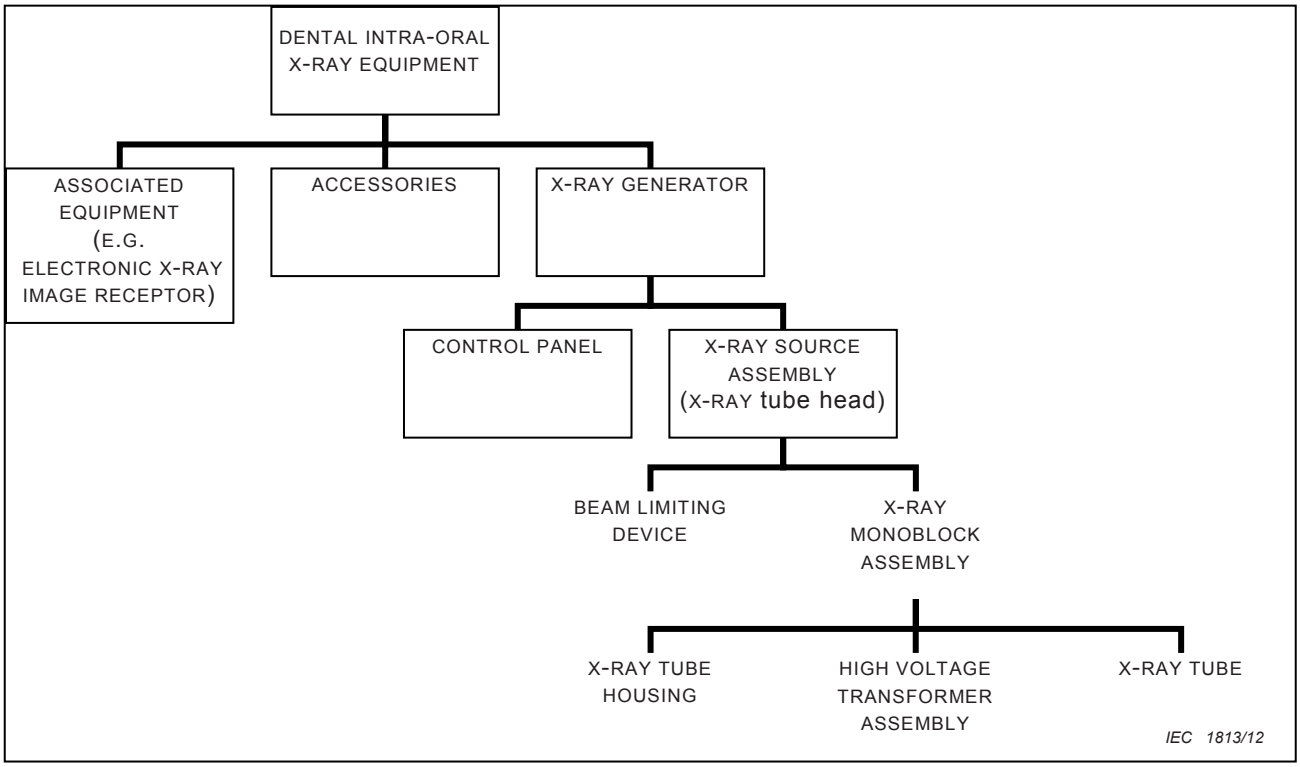
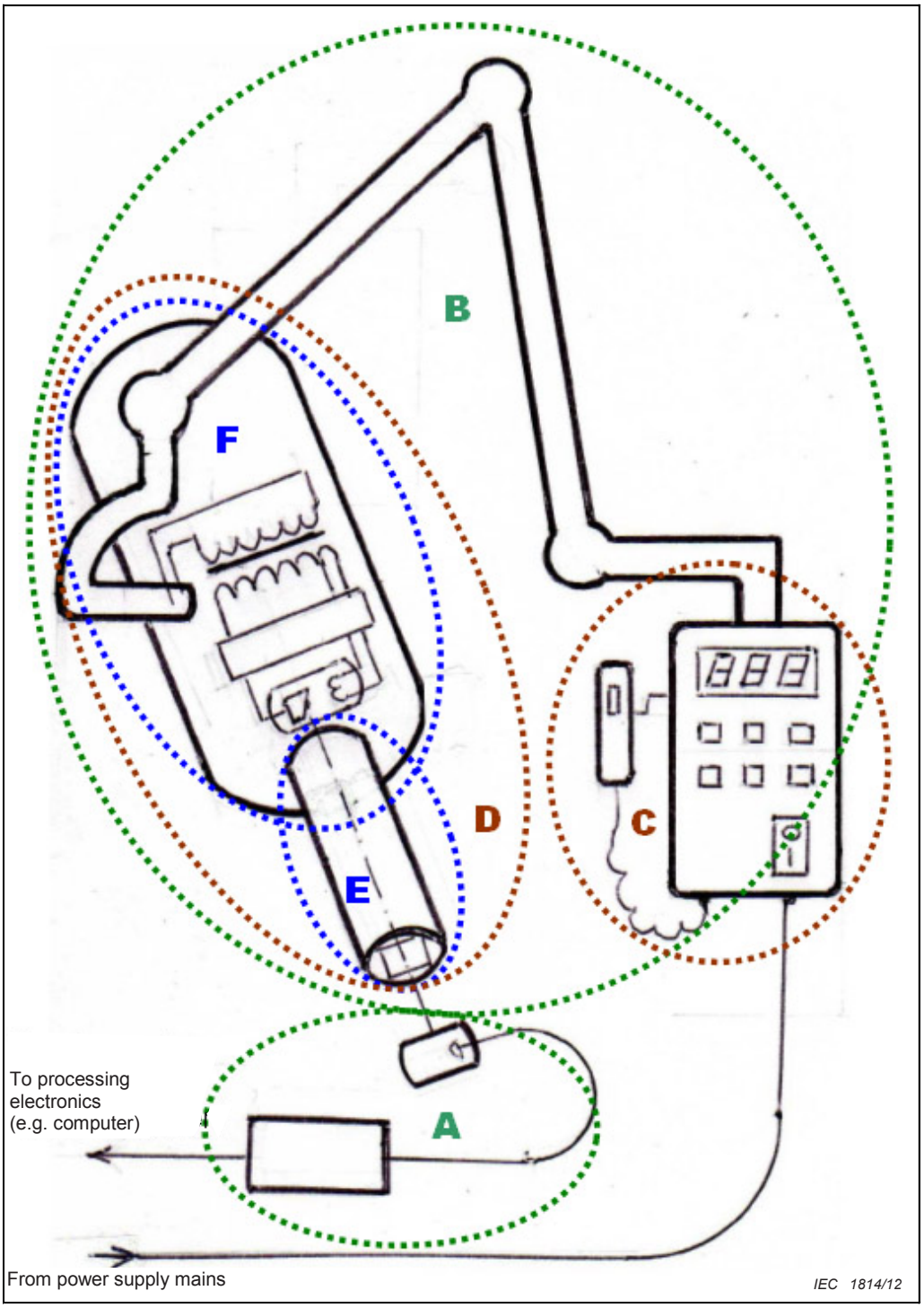


Figure BB.1 – Structure of DENTAL INTRA-ORAL X-RAY EQUIPMENT



A associated equipment (e.g. ELECTRONIC X-RAY IMAGE RECEPTOR)

B X-RAY GENERATOR

C CONTROL PANEL

D X-RAY SOURCE ASSEMBLY

E cone, including the BEAM LIMITING DEVICE

F X-RAY MONOBLOCK ASSEMBLY

Figure BB.2 – Parts of DENTAL INTRA-ORAL X-RAY EQUIPMENT

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[38] IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

[39] IEC 60601-2-44:2009, *Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography*

[40] IEC 60601-2-45:2011, *Medical electrical equipment – Part 2-45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammomagraphic stereotactic devices*

[41] 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*

[42] IEC 60601-2-63, *Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment*

Index of defined terms used in this particular standard

NOTE In the present document only terms defined either in IEC 60601-1:2005, its collateral or particular standards, in IEC 60788:2004, IEC 62220-1:2003 or in Clause 201.3 of this particular standard were used as referenced below. The definitions may be looked up at http://std.iec.ch/glossary.

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