IEC 60601-2-63

Edition 1.2 2021-05
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 60601-2-63:2012-09+AMD1:2017-07+AMD1:2021-05 CSV(en)

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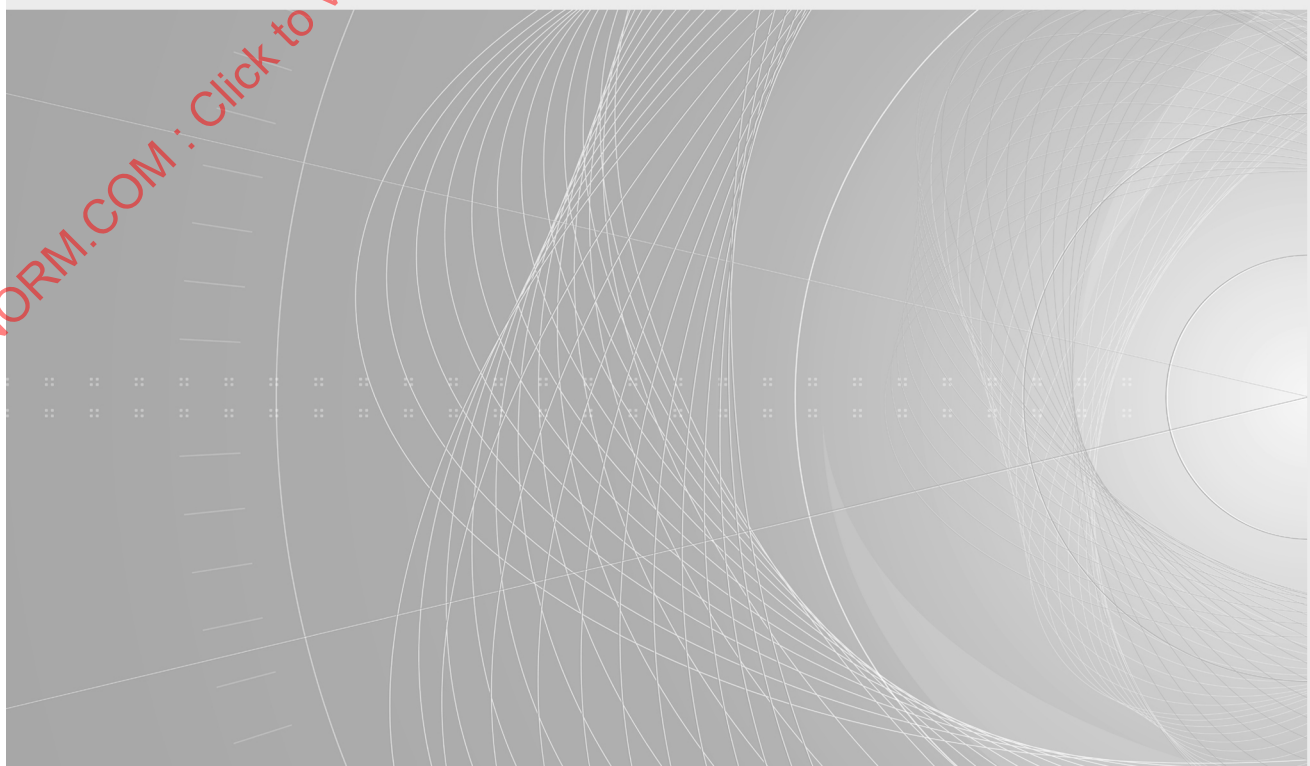

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

IEC 60601-2-63 edition 1.2 contains the first edition (2012-09) [documents 62B/888/FDIS and 62B/898/RVD], its amendment 1 (2017-07) [documents 62B/1049/FDIS and 62B/1058/RVD] and its amendment 2 (2021-05) [documents 62B/1232/FDIS and 62B/1237/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-2-63 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: 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 the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- 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.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-63:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-63:2012 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL EXTRA-ORAL X-RAY EQUIPMENT, hereafter also called ME EQUIPMENT. The scope includes ME SYSTEMS containing such ME EQUIPMENT.

NOTE 1 ~~This includes PANORAMIC equipment, CEPHALOMETRIC equipment, and equipment for dental volumetric reconstruction (hereafter DVR) as defined in 201.3.203 below.~~ An example of such equipment is an equipment designed to perform PANORAMIC, CEPHALOMETRIC and DENTAL VOLUMETRIC RECONSTRUCTION (hereafter DVR) as defined in 201.3.203.

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.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT are X-RAY EQUIPMENT designed for EXTRA-ORAL RADIOGRAPHY in which 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. In such equipment, the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

NOTE 5 DENTAL INTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard.

NOTE 6 FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and FOCAL SPOT to object distance are preset in the design of DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

NOTE 7 For DENTAL X-RAY EQUIPMENT not in the scope of this document because of the restriction above, applicable clauses of IEC 60601-2-54 may be used with this document.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45, IEC 60601-2-65 or IEC 60601-2-43 are excluded from the scope of this particular standard. The scope of this International Standard also excludes RADIOTHERAPY SIMULATORS and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME EQUIPMENT intended to be used for DENTAL RADIOSCOPY.

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 8 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or this particular standard. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the IEC 60601-1 3rd edition scheme for DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to ME EQUIPMENT in the scope of this International Standard with the exception of X-RAY TUBE ASSEMBLIES that are replaceable in the field by entities other than the manufacturer.

NOTE 9 Requirements particular to DENTAL X-RAY-EQUIPMENT which were included in previous editions of the collateral standard IEC 60601-1-3 or the particular standard IEC 60601-2-28 have been extracted and moved into this particular standard.

NOTE 10 For X-RAY EQUIPMENT in the scope of this particular standard X-RAY TUBE ASSEMBLIES are X-RAY MONOBLOCK ASSEMBLIES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT for EXTRA-ORAL DENTAL RADIOGRAPHY.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10[2)], IEC 60601-1-11[3)] and IEC 60601-1-12[4)] 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.

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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*

4) IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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.

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 42.

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
IEC 60601-1-3:2008/AMD1:2013

Addition:

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-29:2008, *Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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

IEC ~~/PAS~~ 61910-1:~~2007~~2014, *Medical electrical equipment – Radiation dose documentation – Part 1: ~~Equipment~~ Radiation dose structured reports for radiography and radioscopy*

201.3 Terminology and definitions

Amendment:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, its applicable collateral standards, IEC/TR 60788:2004 and the following apply:

NOTE An index of defined terms is found beginning on page 45.

Addition:

201.3.201
CEPHALOMETRIC
related to PROJECTION RADIOGRAPHY of the whole dento-maxillo-facial anatomy, whereas the projection geometry is such to minimize geometrical image distortions

Note 1 to entry: This is usually achieved by setting a sufficiently large source-to-object-distance and source-to-detector-distance.

Note 2 to entry: Another term often used for CEPHALOMETRIC RADIOGRAPHY is teleradiography.

201.3.202
DENTAL
related to structures in the dento-maxillo-facial district of the PATIENT, including dentition

201.3.203
***DENTAL VOLUMETRIC RECONSTRUCTION**
DVR
reconstruction of the 3-dimensional attenuation distribution of the whole or part of the irradiated volume from a series of 2-dimensional projections produced by an X-RAY BEAM on an X-RAY IMAGE RECEPTOR moving around the head of the PATIENT

201.3.204
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$).

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

201.3.205
ELECTRONIC X-RAY IMAGE RECEPTOR
X-RAY IMAGE RECEPTOR comprising an electrically-powered conversion method

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

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

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

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

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

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

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

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

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

201.3.211
*** PANORAMIC**
related to DENTAL RADIOGRAPHY, produced by the coordinated motion of a scanning fan-shaped X-RAY BEAM, oriented parallel to the cranio-caudal axis of the PATIENT, and an X-RAY IMAGE RECEPTOR, both rotating around the head of the PATIENT

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

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

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

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

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

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

201.3.214
DENTAL CONE BEAM COMPUTED TOMOGRAPHY
DENTAL CBCT
3-dimensional imaging of DENTAL anatomical structures, performed by reconstruction of a volume from a series of 2-dimensional projections produced by circular or rectangular collimated X-RAY BEAM on an X-RAY IMAGE RECEPTOR rotating around the head of the PATIENT

201.3.215
EXAMINATION PROTOCOL
full set of programmed LOADING FACTORS, control functions and settings, including image processing settings, designed to the image acquisition and DISPLAY

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional potential ESSENTIAL PERFORMANCE requirements

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

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

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

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

~~**201.4.10.1 Source of power for ME EQUIPMENT**~~

~~*Addition:*~~

~~**201.4.10.1.101 Connection to SUPPLY MAINS**~~

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

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

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

For this purpose, the APPARENT RESISTANCE of SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

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 items 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).

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENTS, as identified in the RISK MANAGEMENT PROCESS.

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

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;
– 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 frequency for the tests.

Additionally for ME EQUIPMENT provided with one or more integrated ELECTRONIC X-RAY IMAGE RECEPTORS, the ACCOMPANYING DOCUMENTS shall contain a description of the minimum performance required of the means, used to display the images for diagnostic purpose according to the INTENDED USE for each ELECTRONIC X-RAY IMAGE RECEPTOR used.

If a test or a QUALITY CONTROL PROCEDURE recommended by the MANUFACTURER requires a device-specific arrangement (including a TOOL, a PHANTOM, a special software or a software setting); that is only available from the MANUFACTURER, the MANUFACTURER shall provide this arrangement for the RESPONSIBLE ORGANIZATION.

NOTE 103 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the ACCOMPANYING DOCUMENTS.

NOTE 102 For instance, the minimum required number of pixels and number of discernible grey levels at the DISPLAY.

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

NOTE 104 The MANUFACTURER can provide PHANTOM with the equipment, if specified in the local regulations.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Additional subclause:

201.7.9.2.1.101 LOADING FACTORS

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

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

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

c) values or range of IRRADIATION 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);

f) for ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT;

g) if the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence;

h) the NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT;

i) if the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid;

j) the maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATION, controlled with the AUTOMATIC CONTROL SYSTEM

NOTE these requirements are adapted from IEC 60601-2-7 subclause 6.8.2 a).

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 Technical description for DENTAL EXTRA-ORAL X-RAY EQUIPMENT

In addition to the data required to be marked according to subclause 7.2 of the general standard, the technical description shall specify a description of the geometric relationship of the FOCAL SPOT, X-RAY BEAM dimensions, PATIENT position and IMAGE RECEPTION AREA, as well as a method used to estimate the DOSE AREA PRODUCT.

Additional subclause:

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

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 EXTRA-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

Provisions 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).

201.8.5.4 Working voltage

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE These requirements are adapted from IEC 60601-2-7:1998, subclause 20.4 l).

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 * Allowable values

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 ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 20 mA 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 referred 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 HAZARDS associated with support systems

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 rope, 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.

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 clause 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.

Addition:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements 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.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

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

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 appli~~es~~y, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

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

ME EQUIPMENT for DENTAL EXTRA-ORAL RADIOGRAPHY ++) IEC 60601-2-63:2012

++) 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 See also definition 3.32 of IEC 60601-1-3:2008

203.4.101.2 X-RAY FIELD

The boundary of the X-RAY FIELD is determined by the points where the AIR KERMA drops to 25 % of the AIR KERMA at the center of the X-RAY FIELD. The reduction of local AIR KERMA by non-removable FILTERS with non-uniform FILTRATION shall be compensated by calculation

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELDS the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.

203.5 ME EQUIPMENT identification, marking and documents

203.5.2.4.5 Deterministic effects

Addition:

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the INSTRUCTIONS FOR USE shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the user.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE.

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

203.6 Radiation management

Addition:

203.6.1.102 *Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For DVR (DENTAL CBCT, DVT) if EXAMINATION PROTOCOLS are preloaded and multiple EXAMINATION PROTOCOLS are intended for both the same clinical task and, if applicable, the same PATIENT size, then those EXAMINATION PROTOCOLS will be differentiated by qualitative indication of their effect on image resolution and dose.

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

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 series of IRRADIATION without releasing the control by which the previous IRRADIATION series was initiated.

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

Additional subclauses:

203.6.2.1.101 Connections of external INTERLOCKS

ME EQUIPMENT except MOBILE ME EQUIPMENT, should be provided with connections for external electrical devices 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 devices 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.

203.6.2.1.102 Charging mode INTERLOCK

Every MOBILE ME EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorized persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present but battery charging is also possible in the absence of the key.

Compliance is checked by inspection.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Addition:

If the normal termination depends upon a RADIATION measurement

a) the safety measure shall comprise means for automatic termination of IRRADIATION in the event of a failure of the normal termination, and

b) either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME shall be limited to not more than 64 kJ per IRRADIATION-EVENT, or the CURRENT TIME PRODUCT shall be limited to no more than 640 mAs per IRRADIATION-EVENT.

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.

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) In ME EQUIPMENT with MODES OF OPERATION, not using an integrated ELECTRONIC X-RAY IMAGE RECEPTOR, the following requirement applies to adjustments provided to compensate for the variable sensitivity of the X-RAY IMAGE RECEPTOR by controlling the CURRENT TIME PRODUCT:
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.*

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 CURRENT TIME PRODUCT settings and measure the AIR KERMA close to the IMAGE RECEPTION PLANE.

NOTE The dose meter must not move relative to the X-RAY BEAM and must be continuously irradiated. If the ME EQUIPMENT is equipped with a measurement mode allowing LOADING without movement such mode may be used. Otherwise the dose meter must be attached to the entrance of X-RAY IMAGE RECEPTOR.

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 PRODUCTS*.*

203.6.3.2 Reproducibility of the RADIATION output

Additional subclauses:

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 FACTORS *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
- *highest available* X-RAY TUBE VOLTAGE *with the highest available* X-RAY TUBE CURRENT *for that* X-RAY TUBE VOLTAGE
- *lowest 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

Perform at least five LOADINGS *at each of the combinations of* LOADING FACTORS *selected and measure the* AIR KERMA *close to the* X-RAY IMAGE RECEPTION PLANE*.*

NOTE 101 The dose meter must not move relative to the X-RAY BEAM and must be continuously irradiated. If the ME EQUIPMENT is equipped with a measurement mode allowing LOADING without movement such mode may be used. Otherwise the dose meter must be attached to the entrance of X-RAY IMAGE RECEPTOR.

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 CONTROLS

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.

203.6.4 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, kilovolts;
- for X-RAY TUBE CURRENT, milliamperes;
- 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 %.

The increment or decrement of the X-RAY TUBE VOLTAGE between any two indicated settings shall be within 50 % and 150 % of the indicated change.

For ME EQUIPMENT in which the X-RAY TUBE VOLTAGE is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement

Compliance is checked by the following test PROCEDURE and by inspection of the instructions for use.

a) One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the lowest X-RAY TUBE CURRENT available for that X-RAY TUBE VOLTAGE and the shortest indicated value of duration of IRRADIATION-EVENT but not less than 0,1 S.

b) 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 the highest indicated value of duration of IRRADIATION-EVENT.

c) 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 the highest indicated value of duration of IRRADIATION-EVENT.

d) 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 the shortest indicated value of duration of IRRADIATION-EVENT but not less than 0,1 S.

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 %.

For ME EQUIPMENT in which the X-RAY TUBE CURRENT is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement

Compliance is checked based on data acquired by the test according to 203.6.4.3.102.2:

203.6.4.3.102.4 *Accuracy of IRRADIATION TIME

The error of the value of the X-RAY TUBE IRRADIATION TIME, in any combination of LOADING FACTORS, shall be not greater than ± (5 % + 50 ms).

For ME EQUIPMENT in which the IRRADIATION TIME is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement.

For ME EQUIPMENT in which the RADIATION dose is using time-width modulation during the IRRADIATION EVENT, the MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS a description of the modulation pattern, including the NOMINAL duration(s) of single pulses, which are generated during the IRRADIATION EVENT.

NOTE These pulses are synchronized with the RADIATION cycle used for a single projection image within the DVT or DENTAL CBCT image acquisition sequence and are generated from CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR.

Compliance is checked based on calculation of the IRRADIATION TIME using the examination of typical pulse pattern according to the description provided in the ACCOMPANYING DOCUMENTS on data acquired by the test according to 203.6.4.3.102.2.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

The error of the value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

NOTE This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation(eg X-RAY TUBE CURRENT and X-RAY TUBE IRRADIATION TIME).

For ME EQUIPMENT in which the CURRENT TIME PRODUCT is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement.

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.103 Indication of ADDED FILTERS

If an ME EQUIPMENT has provisions to select ADDED FILTERS by remote control or automatic systems, the selected ADDED FILTER shall be indicated on the CONTROL PANEL. Where the filter change is automatic it may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For ME EQUIPMENT operating in RADIOGRAPHY in which AUTOMATIC EXPOSURE CONTROL is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

Compliance is checked by inspection of the instructions for use and by the appropriate functional tests.

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 the entrance of the X-RAY IMAGE RECEPTOR for any combination of selected LOADING FACTORS.

ME EQUIPMENT shall be provided with an indication of the DOSE AREA PRODUCT.

Information of the overall uncertainty of the indicated values of the AIR KERMA and DOSE AREA PRODUCT shall be provided in the ACCOMPANYING DOCUMENT and shall not exceed 50 %.

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 of that indicator shall be green.

Means shall be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for MOBILE ME EQUIPMENT

Compliance is checked by inspection.

203.6.4.5.101 RADIATION DOSE STRUCTURED REPORTS

ME EQUIPMENT intended for DENTAL CBCT applications shall be capable of creating RADIATION DOSE STRUCTURED REPORTS (RDSR) and have the ability to perform an RDSR END OF PROCEDURE TRANSMISSION. The relevant elements for the specified type of X-RAY EQUIPMENT and for which data are available shall be populated with relevant data.

Compliance is checked by functional tests.

203.6.5 AUTOMATIC CONTROL SYSTEM

Replacement:

If the ME EQUIPMENT is equipped with AUTOMATIC EXPOSURE CONTROLS then the constancy of AUTOMATIC EXPOSURE CONTROLS required for the INTENDED USE shall be determined in the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS shall state the accuracy of AUTOMATIC CONTROL SYSTEMS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the appropriate functional tests.

203.6.6 * SCATTERED RADIATION reduction

Addition:

NOTE 201 SCATTERED RADIATION is not known to have significant influence on the image quality with EXTRA-ORAL ME EQUIPMENT based upon scanning. In most cases the reduction of SCATTERED RADIATION is usually achieved by secondary collimation before the IMAGE RECEPTOR. In case of DVR, no scatter reduction methods are established in the art.

203.7 RADIATION QUALITY

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

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Addition:

X-RAY SOURCE ASSEMBLIES employing rotating anode X-RAY TUBES shall be so constructed that the zone of intersection of all straight lines that pass through all RADIATION APERTURES of the X-RAY SOURCE ASSEMBLY, with a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT shall not extend more than 15 cm outside the boundary of the largest selectable X-RAY FIELD.

Compliance is checked by geometrical/graphical examination of the design documentation. In Figure 201, w_1 represents the width of the largest selectable X-RAY FIELD in a plane P, which is perpendicular to the REFERENCE AXIS at 1 m from the FOCAL SPOT. The zone of intersection with plane P of all straight lines passing through all RADIATION APERTURES extends beyond w_1 by the distance w_2. The shaded portion of this zone is a region where EXTRA-FOCAL RADIATION can extend beyond the largest X-RAY FIELD. Compliance is achieved if w_2 does not exceed 15 cm.

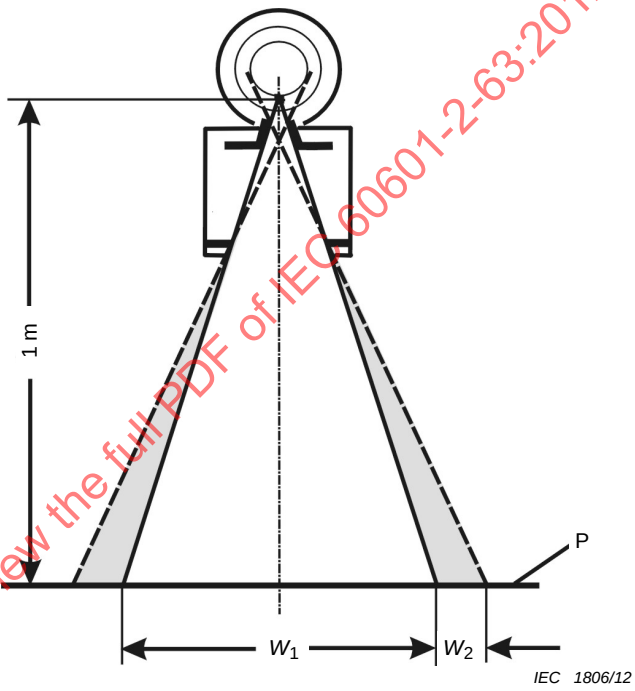


Figure 203.101 – Zone of EXTRA-FOCAL RADIATION

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Replacement:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the region of interest and, where applicable, the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL or AUTOMATIC INTENSITY CONTROL.

In DVR:

~~– If the IMAGE RECEPTION AREA is circular, then the X-RAY FIELD shall coincide with the EFFECTIVE IMAGE RECEPTION AREA as required in a) and b):~~

~~a) the X-RAY FIELD measured along a diameter in the direction of greatest discrepancy with the EFFECTIVE IMAGE RECEPTION AREA shall not extend beyond the boundary of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm; and~~

~~b) at least 90 % of the area of the X-RAY FIELD shall overlap the EFFECTIVE IMAGE RECEPTION AREA.~~

~~– If the IMAGE RECEPTION AREA is rectangular, then the X-RAY FIELD shall coincide with the EFFECTIVE IMAGE RECEPTION AREA as required in c) and d):~~

~~c) along each of the two axes of the IMAGE RECEPTION AREA, the edges of the X-RAY FIELD shall not exceed the corresponding edges of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm or 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTION PLANE is normal to the X-RAY BEAM AXIS, whichever the larger;~~

~~d) the sum of the discrepancies on both axes shall not exceed 3 cm or 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, whichever the larger.~~

The X-RAY FIELD shall not extend beyond the EFFECTIVE IMAGE RECEPTION AREA at the surface of the X-RAY IMAGE RECEPTOR more than 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 3 % in both directions. In the case of the X-RAY IMAGE RECEPTOR having an active surface side length below 8 cm, the over-RADIATION shall not be larger than 1 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 2 % in two directions.

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELD, the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.

In PROJECTION RADIOGRAPHY the X-RAY FIELD shall not exceed the EFFECTIVE IMAGE RECEPTION AREA.

NOTE 1 The most common case of PROJECTION RADIOGRAPHY used in DENTAL EXTRA-ORAL X-RAY EQUIPMENT is CEPHALOMETRIC exposures using film-screen systems, CR or large area ELECTRONIC X-RAY IMAGE RECEPTORS.

In narrow beam scanning RADIOGRAPHY the X-RAY FIELD shall coincide with the EFFECTIVE IMAGE RECEPTION AREA as required in e) and f):

e) along the axis of the IMAGE RECEPTION AREA that is parallel to the direction of the scanning, the X-RAY FIELD shall not exceed the EFFECTIVE IMAGE RECEPTION AREA by more than 1 mm on each side.

f) along the axis of the IMAGE RECEPTION AREA that is perpendicular to the direction of the scanning the X-RAY FIELD shall not exceed the EFFECTIVE IMAGE RECEPTION AREA.

NOTE The most common case of narrow beam scanning RADIOGRAPHY with DENTAL EXTRA-ORAL X-RAY EQUIPMENT is PANORAMIC RADIOGRAPHY. Narrow beam scanning RADIOGRAPHY is also used for CEPHALOMETRIC purposes.

Compliance is checked with the relevant requirements above, by inspection of the ME EQUIPMENT, by examination of the instructions for use and by measurement of the X-RAY FIELDS, where appropriate. When automatic adjustment of the RADIATION APERTURE is provided, allow a period of at least 5 s before measurements are made, for the automatic mechanism to complete any adjustment occurring during the tests.

When determining compliance with the requirements at c) and d), make the measurements with the REFERENCE AXIS normal to the IMAGE RECEPTION PLANE within three degrees.

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Replacement:

ME EQUIPMENT shall be provided with adequate means ensuring proper positioning of the PATIENT with respect to the geometry and to stabilise the PATIENTS during the IRRADIATION-EVENT.

ME EQUIPMENT for DVR and PANORAMIC may provide means to assess the positioning of the region, subject to examination, prior to the IRRADIATION-EVENT.

NOTE Examples for such means are scout views for DVR and laser pointers for DVR or PANORAMIC.

Compliance is checked by inspection of the ME EQUIPMENT.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replacement:

~~The BEAM LIMITING SYSTEM shall ensure a minimum FOCAL SPOT TO SKIN DISTANCE of 15 cm.~~

THE FOCAL SPOT TO SKIN DISTANCE shall be nominally 15 cm or greater.

NOTE the value of 15 cm for the minimum FOCAL SPOT TO SKIN DISTANCE has been established in IEC 60601-1-3:1993 and is preserved for DENTAL application here.

Compliance is checked by inspection and measurement.

203.10 Attenuation of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Replacement:

The ATTENUATION EQUIVALENT of the items forming part of ME EQUIPMENT and located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, shall not exceed 1,2 mm Al.

Compliance is checked by inspection of the ME EQUIPMENT or by the following test.

Using the X-RAY GENERATOR of the ME EQUIPMENT under test, operated at the highest X-RAY TUBE VOLTAGE, determine the ATTENUATION EQUIVALENT as the thickness of aluminum that gives the same degree of ATTENUATION as the material under consideration, from measurements of AIR KERMA under NARROW BEAM CONDITIONS.

NOTE 1 Devices such as RADIATION DETECTORS are not included in the item listed in this table.

NOTE 2 Requirements concerning the ATTENUATION properties of RADIOGRAPHIC CASSETTES and of INTENSIFYING SCREENS are given in ISO 4090, for ANTI-SCATTER GRIDS in IEC 60627.

NOTE 3 Patient positioning tools and ACCESSORIES are intentionally not listed above, because they are not homogeneous layers and are visible in the radiographic image.

203.11 Protection against residual radiation

Replacement:

ME EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING.

The PRIMARY PROTECTIVE SHIELDING shall completely overlap the X-RAY FIELD. The minimum attenuation equivalent shall be 0,5 mm Pb up to a NOMINAL X-RAY TUBE VOLTAGE of 90 kV, and 2 mm Pb above.

Compliance is checked by inspection of the ME EQUIPMENT or by measurement of the ATTENUATION EQUIVALENT.

203.13 Protection against STRAY RADIATION

203.13.2 Control of X-RAY EQUIPMENT from a PROTECTED AREA

Replacement:

ME EQUIPMENT specified exclusively for examinations that do not need the OPERATOR or staff to be close to the PATIENT during NORMAL USE shall be provided with means to enable the operation of the following control functions from a PROTECTED AREA after installation:

- actuation of the IRRADIATION SWITCH;
- other necessary controls for OPERATOR the during LOADING.

Relevant instructions shall be given in the ACCOMPANYING DOCUMENTS.

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

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

Annexes

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

Annex C
(informative)

Guide to marking and labelling 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 ME EQUIPMENT	201.7.2.101

201.C.4 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 and ME SYSTEMS	201.4.10.2
Electrical input power from the SUPPLY MAINS	201.7.2.7
Cooling conditions	201.7.2.15
ACCOMPANYING DOCUMENTS	201.7.9
LOADING FACTORS	201.7.9.2.1.101
X-RAY SOURCE ASSEMBLY	201.7.9.3.101
Requirements to the SUPPLY MAINS	201.7.9.101
MECHANICAL PROTECTIVE DEVICE	201.9.8.4.101
Management of EXAMINATION PROTOCOLS	203.6.1.102
Connections of external INTERLOCKS	203.6.2.1.101
Accuracy of X-RAY TUBE VOLTAGE	203.6.4.3.102.2
Indication of automatic modes	203.6.4.4
Dosimetric indications	203.6.4.5
AUTOMATIC CONTROL SYSTEM	203.6.5
Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA	203.8.5.3
Control of X-RAY EQUIPMENT from a PROTECTED AREA	203.13.2

Annex AA
(informative)

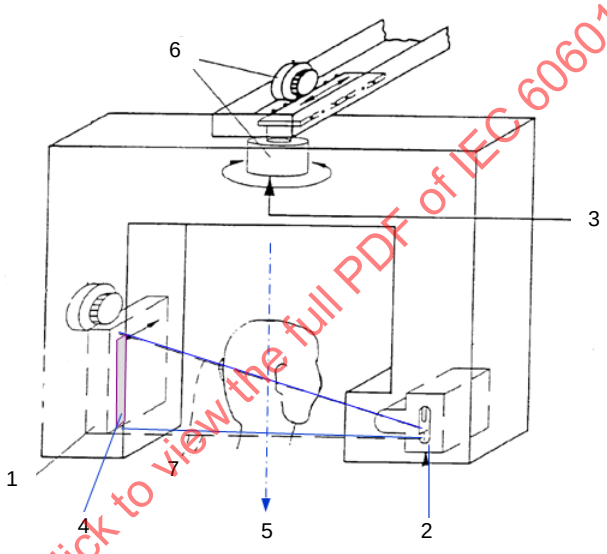
Particular guidance and rationale

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.

Definition 201.3.203 – DENTAL VOLUMETRIC RECONSTRUCTION (DVR)

As indicated in Note 102 of the scope, DVR comprises different technologies including DENTAL CBCT and DENTAL tomosynthesis. DENTAL CBCT is generally regarded as a technique where the source detector system rotates at least 180°. DENTAL tomosynthesis is generally regarded as technique where reconstruction is achieved from a small number of projections at different angles. In any case the quality of the volumetric image reconstruction depends on the amount of input data for inherent physical and mathematical reasons.

Definition 201.3.211 – PANORAMIC



IEC 1807/12

1 X-ray image receptor
2 X-ray source focal spot
3 Plane of rotation
4 Image reception area
5 Cranio-caudal axis
6 Actuators to provide correlated movement of the x-ray image receptor and the x-ray source around the head of the PATIENT
7 Fan shaped x-ray beam

Figure AA.1 – PANORAMIC X-RAY EQUIPMENT

The definition for PANORAMIC in this International Standard is derived from the involved movements using a narrow beam x-ray geometry and a fixed mechanical alignment of the x-ray source and the x-ray receiving area, which are moved / rotated around the PATIENTS head.

Formation of the tomographic like layer(s) is achieved by the integration of the x-ray signal subject to correlated movements:

a) The x-ray source and x-ray image reception area system is moved during the acquisition (that movement is typically a rotation combined with simultaneous translation of the rotation centre)).

b) The movement of the x-ray image receptor behind the x-ray reception area.

According to this definition, PANORAMIC acquisition modes can always been implemented with classical film-screen systems and are not limited to electronic x-ray receptors.

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 the X-RAY GENERATOR 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 EXTRA-ORAL X-RAY EQUIPMENT where the design is always based upon 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 noted that, in a 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.

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 as to maintain its linear relationship with the quantity 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 instantaneously, 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, results in 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.

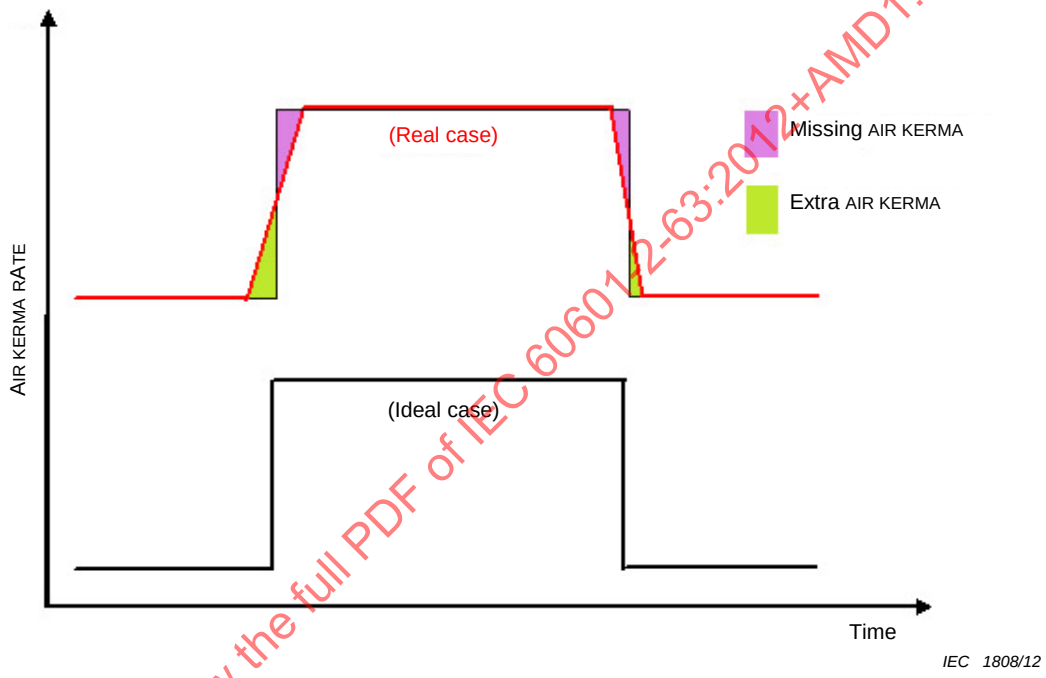


Figure AA.2 – AIR KERMA during IRRADIATION with direct current X-RAY GENERATOR

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 short with respect to the rise time, due to the fact that the termination of the exposure occurs when the tube anode becomes negative with respect to the cathode i.e. when simultaneously both X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT fall to zero. The profile of envelope of the pulses’ peak value at the leading edge normally follows a gradual concave-convex profile, with the midpoint 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, results in that the amount of extra AIR KERMA produced before the defined start point approximately balances the amount of AIR KERMA missing from that point to reaching the maximum and steady state value, retaining with good approximation the linear proportionality between the thus-defined IRRADIATION TIME and the total AIR KERMA.

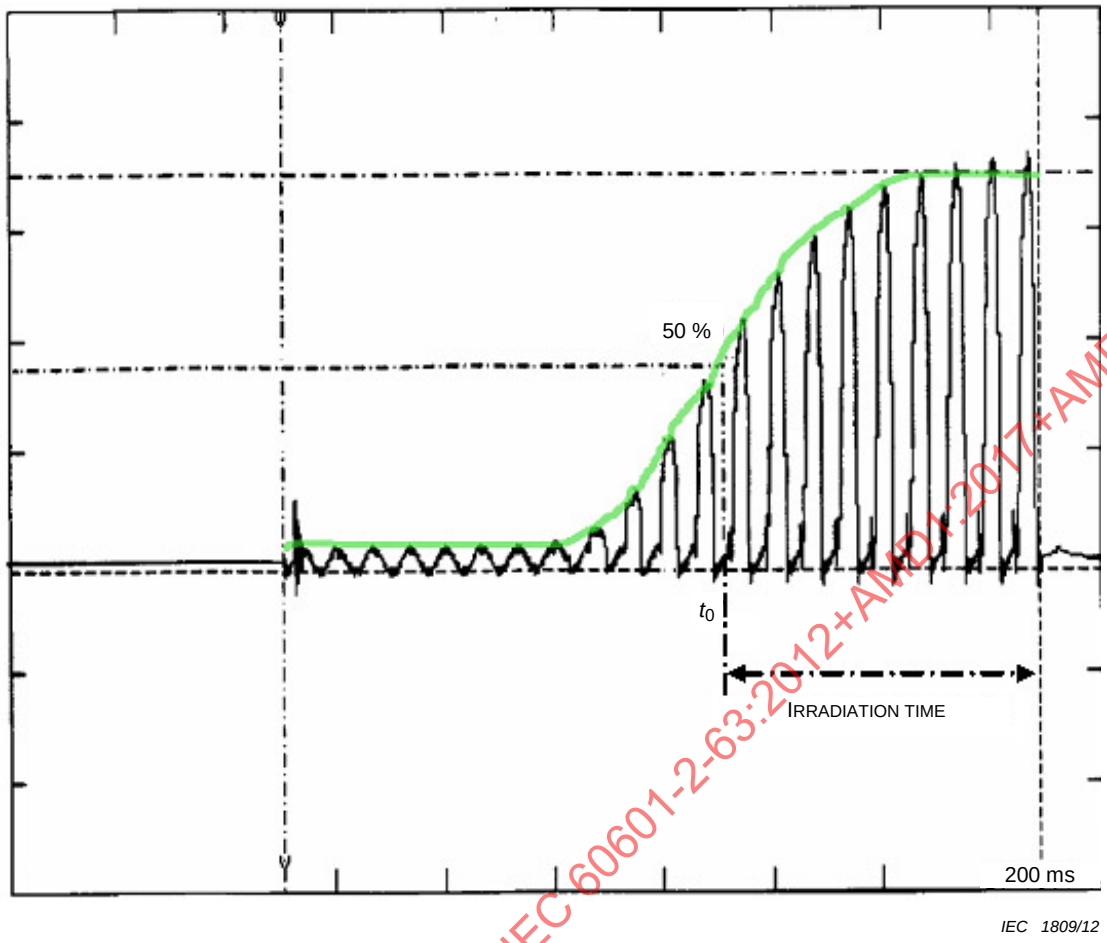


Figure AA.3 – AIR KERMA during IRRADIATION with ONE-PEAK X-RAY GENERATOR

Subclause 203.6.1.102 – Management of EXAMINATION PROTOCOLS

This subclause defines the PATIENT size to allow the OPERATOR the selection of EXAMINATION PROTOCOLS with low RADIATION DOSES to protect the PATIENT while achieving the clinical image quality needed for the diagnostic task.

This radiation dose selection is a function of size and weight of the PATIENT. Hence, there is a clear overlap between (for example) small female adults and an adolescent patient with obesity. This overlapping between age groups is relevant for the design and designation of EXAMINATION PROTOCOLS.

Likewise, the increased likelihood of image artefacts due to paediatric PATIENT movements during the exposure, as well as the small size and weight of a paediatric PATIENT is relevant for the OPERATOR. Hence the OPERATOR needs access to information allowing to choose an EXAMINATION PROTOCOL for a paediatric patient.

Subclause 203.6.4.3.102.2 – Accuracy of X-RAY TUBE VOLTAGE

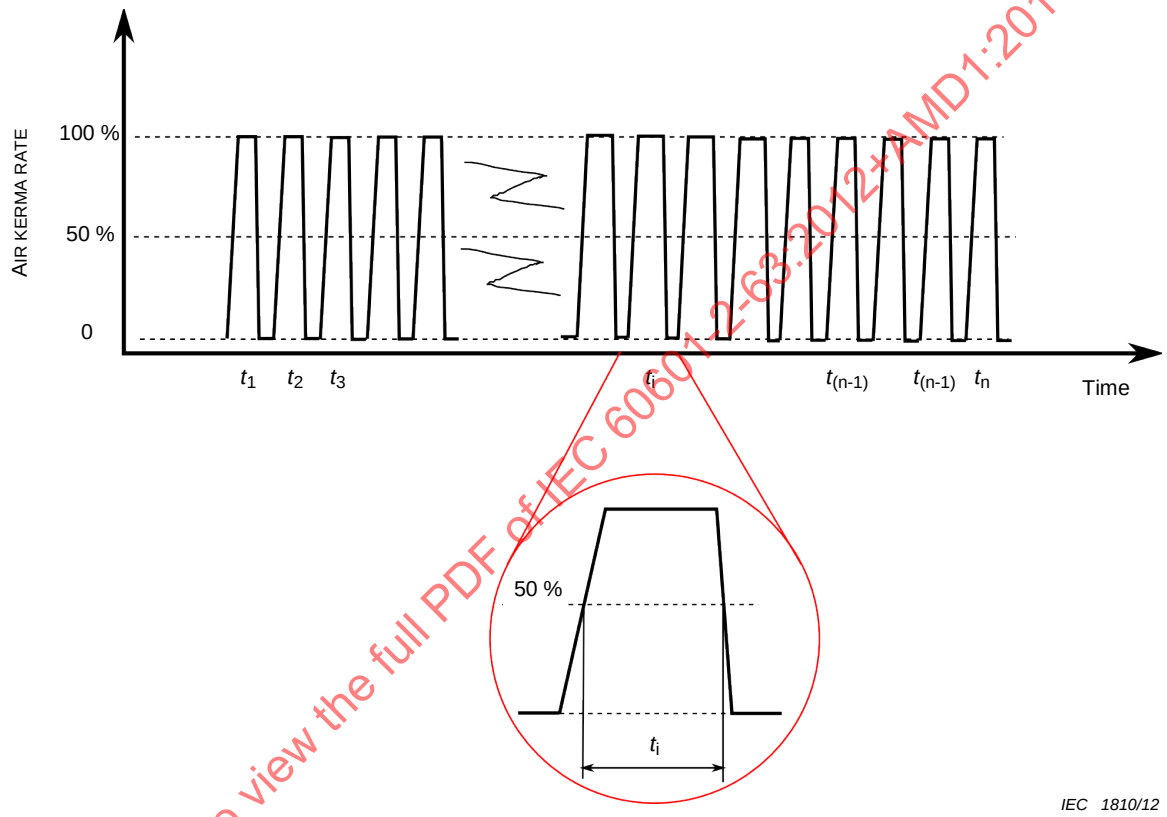
This clause defines the accuracy of the X-RAY TUBE VOLTAGE that contributes to the image. Especially for the pulsed x-ray, the overshoot during initial rising part(s) and the ripple shall be accurately defined. Therefore, the MANUFACTURER should provide the information about the X-RAY TUBE VOLTAGE as follows:

Graphical presentation of the evaluating point (such as delay time or evaluation period) with a typical wave form.

Subclause 203.6.4.3.102.4 – Accuracy of IRRADIATION TIME

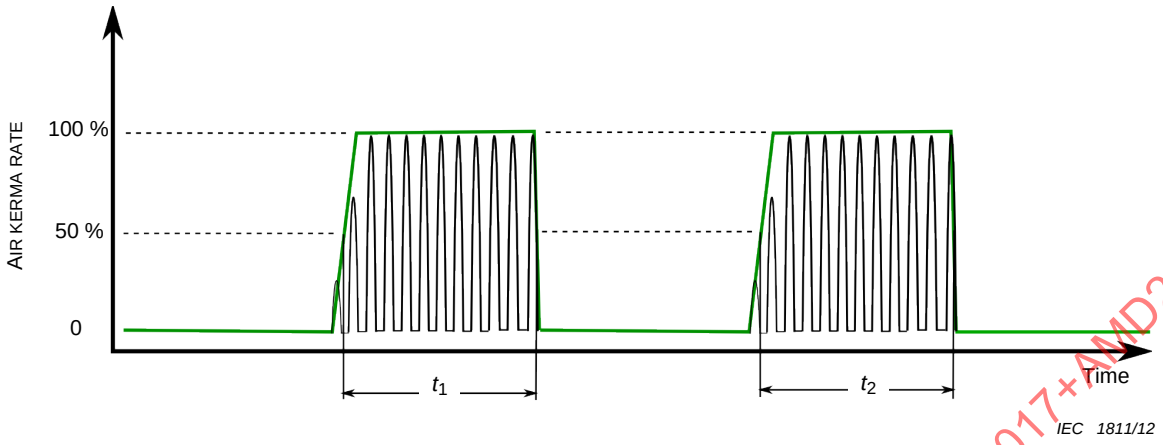
~~In some case~~ The IRRADIATION-EVENT may consist~~s~~ of a series of IRRADIATIONS. Typical examples of that are pulsed DENTAL CBCT, where the IRRADIATION is performed with series of several hundred pulses ~~(potentially of variable and modulated duration)~~ synchronized with the acquisition of the image frames; series of scanning projections for tomosynthesis; and certain special PANORAMIC-like projections consisting of a series of multiple images, such as separate views of both TMJs (temporo-mandibular joints), transversal quasi-tomographic views or sections of the jaw (typically 3 or 4 views); etc.

In those circumstances, the IRRADIATION TIME that matters, and that must be indicated, is the total IRRADIATION TIME of the series, which is obtained by adding up all the duration of all IRRADIATIONS in the series. Some examples are provided hereunder:



Total IRRADIATION TIME of the IRRADIATION event = $\sum_{1}^{n} t_i$

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



Total IRRADIATION TIME of the IRRADIATION event = $t_1 + t_2$

Figure AA.5 – Example – series of two irradiations for PANORAMIC-like views of right and left TMJ (temporo-mandibolar joint) in the same image, with ONE-PEAK HIGH-VOLTAGE GENERATOR

Subclause 203.6.6 – * SCATTERED RADIATION reduction

Outside DENTAL X-RAY application the means to address SCATTERED RADIATION are x-ray ANTI-SCATTER GRIDS. In case of DENTAL EXTRA-ORAL X-RAY EQUIPMENT, such grids do typically have an impact to the imaging performance as they create artefacts.

Subclause 203.7.101 – Limitation of X-RAY TUBE VOLTAGE

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

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[35] 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*

[36] 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*

[37] IEC 60601-2-65:2012, *Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment*

[38] 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*

[39] 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*

[40] IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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 standards, in IEC 60788:2004, IEC 60601-2-29:2008 and IEC 60601-1:2005/AMD1:2012, IEC 60601-2-54:2010, IEC/~~PAS~~ 61910-1:~~2007~~2014 or in Clause 201.3 of this particular standard were used. The definitions used in this particular standard may be looked up at http://std.iec.ch/glossary.

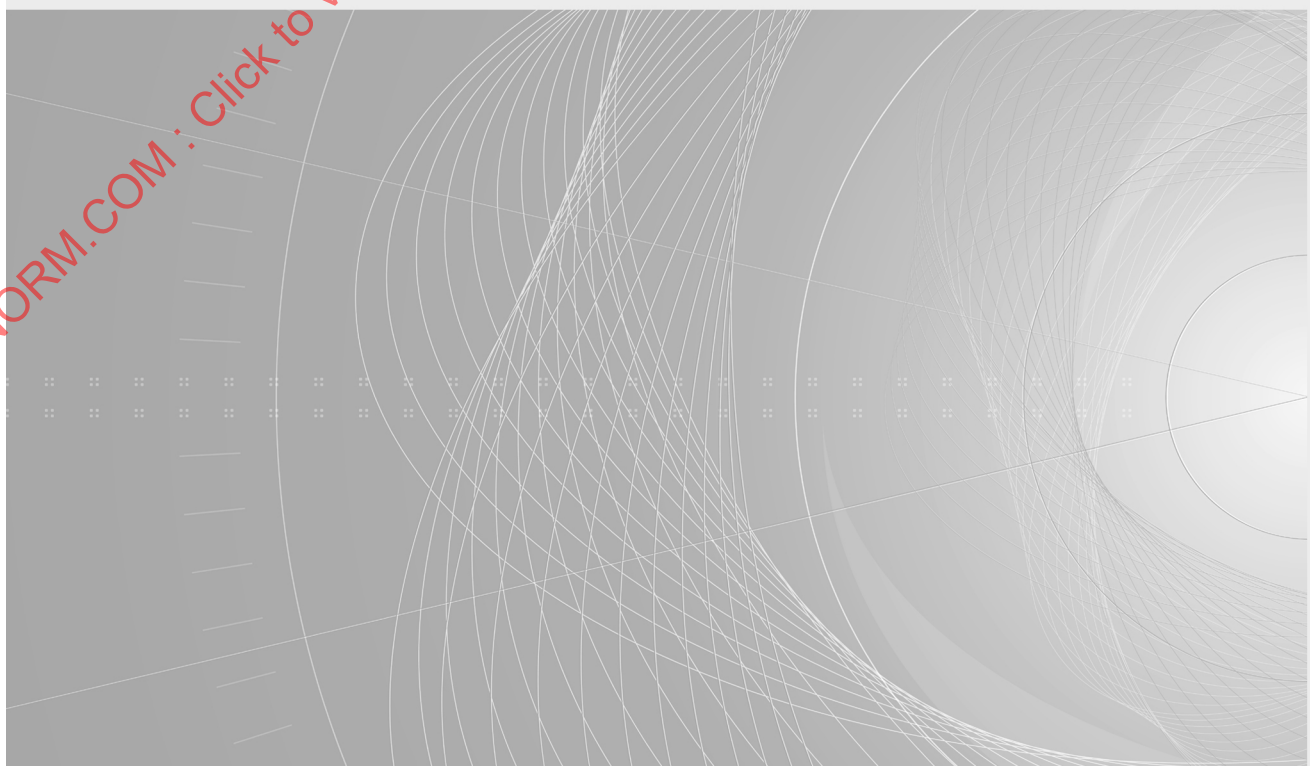
IEC 60601-2-63

Edition 1.2 2021-05
CONSOLIDATED VERSION

FINAL VERSION

colour inside

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



IEC 60601-2-63:2012-09+AMD1:2017-07+AMD1:2021-05 CSV(en)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-63 edition 1.2 contains the first edition (2012-09) [documents 62B/888/FDIS and 62B/898/RVD], its amendment 1 (2017-07) [documents 62B/1049/FDIS and 62B/1058/RVD] and its amendment 2 (2021-05) [documents 62B/1232/FDIS and 62B/1237/RVD].

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

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.

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 the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- 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.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-63:2012 is to introduce changes to reference the Amendment 1 (2012) to IEC 60601-1:2005. As neither IEC 60601-2-63:2012 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of DENTAL EXTRA-ORAL X-RAY EQUIPMENT, hereafter also called ME EQUIPMENT. The scope includes ME SYSTEMS containing such ME EQUIPMENT.

NOTE 1 An example of such equipment is an equipment designed to perform PANORAMIC, CEPHALOMETRIC and DENTAL VOLUMETRIC RECONSTRUCTION (hereafter DVR) as defined in 201.3.203.

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.

DENTAL EXTRA-ORAL X-RAY EQUIPMENT are X-RAY EQUIPMENT designed for EXTRA-ORAL RADIOGRAPHY in which 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. In such equipment, the X-RAY TUBE ASSEMBLY contains the HIGH-VOLTAGE TRANSFORMER ASSEMBLY.

NOTE 5 DENTAL INTRA-ORAL X-RAY EQUIPMENT is excluded from the scope of this standard.

NOTE 6 FOCAL SPOT TO IMAGE RECEPTOR DISTANCE and FOCAL SPOT to object distance are preset in the design of DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

NOTE 7 For DENTAL X-RAY EQUIPMENT not in the scope of this document because of the restriction above, applicable clauses of IEC 60601-2-54 may be used with this document.

ME EQUIPMENT and ME SYSTEMS in the scope of IEC 60601-2-44, IEC 60601-2-54, IEC 60601-2-45, IEC 60601-2-65 or IEC 60601-2-43 are excluded from the scope of this particular standard. The scope of this International Standard also excludes RADIOTHERAPY SIMULATORS and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME EQUIPMENT intended to be used for DENTAL RADIOSCOPY.

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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 8 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or this particular standard. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the IEC 60601-1 3rd edition scheme for DENTAL EXTRA-ORAL X-RAY EQUIPMENT.

All requirements addressing integrated X-RAY TUBE ASSEMBLIES are covered by this particular standard. Therefore IEC 60601-2-28 does not apply to ME EQUIPMENT in the scope of this International Standard with the exception of X-RAY TUBE ASSEMBLIES that are replaceable in the field by entities other than the manufacturer.

NOTE 9 Requirements particular to DENTAL X-RAY-EQUIPMENT which were included in previous editions of the collateral standard IEC 60601-1-3 or the particular standard IEC 60601-2-28 have been extracted and moved into this particular standard.

NOTE 10 For X-RAY EQUIPMENT in the scope of this particular standard X-RAY TUBE ASSEMBLIES are X-RAY MONOBLOCK ASSEMBLIES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT for EXTRA-ORAL DENTAL RADIOGRAPHY.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10[2)], IEC 60601-1-11[3)] and IEC 60601-1-12[4)] 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.

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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*

4) IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

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.

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 41.

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

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

Addition:

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-29:2008, *Medical electrical equipment – Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators*

IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

201.3 Terminology and definitions

Amendment:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, its applicable collateral standards, IEC/TR 60788:2004 and the following apply:

NOTE An index of defined terms is found beginning on page 44.

Addition:

201.3.201
CEPHALOMETRIC
related to PROJECTION RADIOGRAPHY of the whole dento-maxillo-facial anatomy, whereas the projection geometry is such to minimize geometrical image distortions

Note 1 to entry: This is usually achieved by setting a sufficiently large source-to-object-distance and source-to-detector-distance.

Note 2 to entry: Another term often used for CEPHALOMETRIC RADIOGRAPHY is teleradiography.

201.3.202
DENTAL
related to structures in the dento-maxillo-facial district of the PATIENT, including dentition

201.3.203
***DENTAL VOLUMETRIC RECONSTRUCTION**
DVR
reconstruction of the 3-dimensional attenuation distribution of the whole or part of the irradiated volume from a series of 2-dimensional projections produced by an X-RAY BEAM on an X-RAY IMAGE RECEPTOR moving around the head of the PATIENT

201.3.204
DOSE AREA PRODUCT
product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($Gy \cdot m^2$).

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

201.3.205
ELECTRONIC X-RAY IMAGE RECEPTOR
X-RAY IMAGE RECEPTOR comprising an electrically-powered conversion method

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

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

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

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

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

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

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

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

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

201.3.211
*** PANORAMIC**
related to DENTAL RADIOGRAPHY, produced by the coordinated motion of a scanning fan-shaped X-RAY BEAM, oriented parallel to the cranio-caudal axis of the PATIENT, and an X-RAY IMAGE RECEPTOR, both rotating around the head of the PATIENT

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

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

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

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

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

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

201.3.214
DENTAL CONE BEAM COMPUTED TOMOGRAPHY
DENTAL CBCT
3-dimensional imaging of DENTAL anatomical structures, performed by reconstruction of a volume from a series of 2-dimensional projections produced by circular or rectangular collimated X-RAY BEAM on an X-RAY IMAGE RECEPTOR rotating around the head of the PATIENT

201.3.215
EXAMINATION PROTOCOL
full set of programmed LOADING FACTORS, control functions and settings, including image processing settings, designed to the image acquisition and DISPLAY

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional potential ESSENTIAL PERFORMANCE requirements

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

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

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

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

201.4.10.2 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.

For this purpose, the APPARENT RESISTANCE of SUPPLY MAINS R is determined according to the formula:

$$R = \frac{U_0 - U_1}{I_1}$$

where

U_0 is the no-load MAINS VOLTAGE;

U_1 is the MAINS VOLTAGE under load;

I_1 is the mains current under load.

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 items 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).

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENTS, as identified in the RISK MANAGEMENT PROCESS.

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

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;

– 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 frequency for the tests.

Additionally for ME EQUIPMENT provided with one or more integrated ELECTRONIC X-RAY IMAGE RECEPTORS, the ACCOMPANYING DOCUMENTS shall contain a description of the minimum performance required of the means, used to display the images for diagnostic purpose according to the INTENDED USE for each ELECTRONIC X-RAY IMAGE RECEPTOR used.

If a test or a QUALITY CONTROL PROCEDURE recommended by the MANUFACTURER requires a device-specific arrangement (including a TOOL, a PHANTOM, a special software or a software setting); that is only available from the MANUFACTURER, the MANUFACTURER shall provide this arrangement for the RESPONSIBLE ORGANIZATION.

NOTE 103 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the ACCOMPANYING DOCUMENTS.

NOTE 102 For instance, the minimum required number of pixels and number of discernible grey levels at the DISPLAY.

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

NOTE 104 The MANUFACTURER can provide PHANTOM with the equipment, if specified in the local regulations.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Additional subclause:

201.7.9.2.1.101 LOADING FACTORS

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

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

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

c) values or range of IRRADIATION 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);

f) for ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT;

g) if the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence;

h) the NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT;

i) if the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid;

j) the maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATION, controlled with the AUTOMATIC CONTROL SYSTEM

NOTE these requirements are adapted from IEC 60601-2-7 subclause 6.8.2 a).

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

Additional subclauses:

201.7.9.3.101 Technical description for DENTAL EXTRA-ORAL X-RAY EQUIPMENT

In addition to the data required to be marked according to subclause 7.2 of the general standard, the technical description shall specify a description of the geometric relationship of the FOCAL SPOT, X-RAY BEAM dimensions, PATIENT position and IMAGE RECEPTION AREA, as well as a method used to estimate the DOSE AREA PRODUCT.

Additional subclause:

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

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 EXTRA-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

Provisions 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).

201.8.5.4 Working voltage

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE These requirements are adapted from IEC 60601-2-7:1998, subclause 20.4 l).

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 * Allowable values

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 ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 20 mA 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 referred 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 HAZARDS associated with support systems

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 rope, 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.

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 clause 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 applies, except as follows.

Addition:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional potential ESSENTIAL PERFORMANCE requirements 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.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

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

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply, except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

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

ME EQUIPMENT for DENTAL EXTRA-ORAL RADIOGRAPHY ++) IEC 60601-2-63:2012

++) 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 See also definition 3.32 of IEC 60601-1-3:2008

203.4.101.2 X-RAY FIELD

The boundary of the X-RAY FIELD is determined by the points where the AIR KERMA drops to 25 % of the AIR KERMA at the center of the X-RAY FIELD. The reduction of local AIR KERMA by non-removable FILTERS with non-uniform FILTRATION shall be compensated by calculation

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELDS the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.

203.5 ME EQUIPMENT identification, marking and documents

203.5.2.4.5 Deterministic effects

Addition:

203.5.2.4.101 EXAMINATION PROTOCOLS

When EXAMINATION PROTOCOLS are proposed by the MANUFACTURER, and preloaded on the EQUIPMENT, the INSTRUCTIONS FOR USE shall state if they constitute recommendations to be applied directly so as to allow optimized operation or if they are only examples/starting points, to be replaced by more specific protocols developed by the user.

Compliance is checked by inspection of the INSTRUCTIONS FOR USE.

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

203.6 Radiation management

Addition:

203.6.1.102 *Management of EXAMINATION PROTOCOLS

If EXAMINATION PROTOCOLS are preloaded and the INTENDED USE of the X-RAY EQUIPMENT covers both adult and paediatric applications, the designation of these protocols shall clearly distinguish between adult and paediatric applications.

For DVR (DENTAL CBCT, DVT) if EXAMINATION PROTOCOLS are preloaded and multiple EXAMINATION PROTOCOLS are intended for both the same clinical task and, if applicable, the same PATIENT size, then those EXAMINATION PROTOCOLS will be differentiated by qualitative indication of their effect on image resolution and dose.

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

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 series of IRRADIATION without releasing the control by which the previous IRRADIATION series was initiated.

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

Additional subclauses:

203.6.2.1.101 Connections of external INTERLOCKS

ME EQUIPMENT except MOBILE ME EQUIPMENT, should be provided with connections for external electrical devices 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 devices 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.

203.6.2.1.102 Charging mode INTERLOCK

Every MOBILE ME EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorized persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present but battery charging is also possible in the absence of the key.

Compliance is checked by inspection.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Addition:

If the normal termination depends upon a RADIATION measurement

a) the safety measure shall comprise means for automatic termination of IRRADIATION in the event of a failure of the normal termination, and

b) either the product of X-RAY TUBE VOLTAGE, X-RAY TUBE CURRENT and IRRADIATION TIME shall be limited to not more than 64 kJ per IRRADIATION-EVENT, or the CURRENT TIME PRODUCT shall be limited to no more than 640 mAs per IRRADIATION-EVENT.

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.

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) In ME EQUIPMENT with MODES OF OPERATION, not using an integrated ELECTRONIC X-RAY IMAGE RECEPTOR, the following requirement applies to adjustments provided to compensate for the variable sensitivity of the X-RAY IMAGE RECEPTOR by controlling the CURRENT TIME PRODUCT:
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.*

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 CURRENT TIME PRODUCT settings and measure the AIR KERMA close to the IMAGE RECEPTION PLANE.

NOTE The dose meter must not move relative to the X-RAY BEAM and must be continuously irradiated. If the ME EQUIPMENT is equipped with a measurement mode allowing LOADING without movement such mode may be used. Otherwise the dose meter must be attached to the entrance of X-RAY IMAGE RECEPTOR.

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 PRODUCTS.*

203.6.3.2 Reproducibility of the RADIATION output

Additional subclauses:

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 FACTORS 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*
- *highest available X-RAY TUBE VOLTAGE with the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE*
- *lowest 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

Perform at least five LOADINGS at each of the combinations of LOADING FACTORS selected and measure the AIR KERMA close to the X-RAY IMAGE RECEPTION PLANE.

NOTE 101 The dose meter must not move relative to the X-RAY BEAM and must be continuously irradiated. If the ME EQUIPMENT is equipped with a measurement mode allowing LOADING without movement such mode may be used. Otherwise the dose meter must be attached to the entrance of X-RAY IMAGE RECEPTOR.

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 CONTROLS

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.

203.6.4 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, kilovolts;
- for X-RAY TUBE CURRENT, milliamperes;
- 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 %.

The increment or decrement of the X-RAY TUBE VOLTAGE between any two indicated settings shall be within 50 % and 150 % of the indicated change.

For ME EQUIPMENT in which the X-RAY TUBE VOLTAGE is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement

Compliance is checked by the following test PROCEDURE and by inspection of the instructions for use.

a) One measurement shall be made at the lowest indicated value of X-RAY TUBE VOLTAGE, the lowest X-RAY TUBE CURRENT available for that X-RAY TUBE VOLTAGE and the shortest indicated value of duration of IRRADIATION-EVENT but not less than 0,1 S.

b) 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 the highest indicated value of duration of IRRADIATION-EVENT.

c) 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 the highest indicated value of duration of IRRADIATION-EVENT.

d) 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 the shortest indicated value of duration of IRRADIATION-EVENT but not less than 0,1 S.

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 %.

For ME EQUIPMENT in which the X-RAY TUBE CURRENT is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement

Compliance is checked based on data acquired by the test according to 203.6.4.3.102.2:

203.6.4.3.102.4 *Accuracy of IRRADIATION TIME

The error of the value of the X-RAY TUBE IRRADIATION TIME, in any combination of LOADING FACTORS, shall be not greater than ± (5 % + 50 ms).

For ME EQUIPMENT in which the IRRADIATION TIME is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement.

For ME EQUIPMENT in which the RADIATION dose is using time-width modulation during the IRRADIATION EVENT, the MANUFACTURER shall provide in the ACCOMPANYING DOCUMENTS a description of the modulation pattern, including the NOMINAL duration(s) of single pulses, which are generated during the IRRADIATION EVENT.

NOTE These pulses are synchronized with the RADIATION cycle used for a single projection image within the DVT or DENTAL CBCT image acquisition sequence and are generated from CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR.

Compliance is checked based on calculation of the IRRADIATION TIME using the examination of typical pulse pattern according to the description provided in the ACCOMPANYING DOCUMENTS on data acquired by the test according to 203.6.4.3.102.2.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

The error of the value of the X-RAY TUBE CURRENT TIME PRODUCT, in any combination, shall be not greater than ± (10 % + 0,2 mAs).

NOTE This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation(eg X-RAY TUBE CURRENT and X-RAY TUBE IRRADIATION TIME).

For ME EQUIPMENT in which the CURRENT TIME PRODUCT is varying during an IRRADIATION-EVENT, the MANUFACTURER shall provide instruction on how to perform this measurement.

Compliance is checked by the following test PROCEDURE:

One measurement shall be made at the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made at the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.103 Indication of ADDED FILTERS

If an ME EQUIPMENT has provisions to select ADDED FILTERS by remote control or automatic systems, the selected ADDED FILTER shall be indicated on the CONTROL PANEL. Where the filter change is automatic it may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For ME EQUIPMENT operating in RADIOGRAPHY in which AUTOMATIC EXPOSURE CONTROL is achieved by varying one or more LOADING FACTORS, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

Compliance is checked by inspection of the instructions for use and by the appropriate functional tests.

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 the entrance of the X-RAY IMAGE RECEPTOR for any combination of selected LOADING FACTORS.

ME EQUIPMENT shall be provided with an indication of the DOSE AREA PRODUCT.

Information of the overall uncertainty of the indicated values of the AIR KERMA and DOSE AREA PRODUCT shall be provided in the ACCOMPANYING DOCUMENT and shall not exceed 50 %.

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 of that indicator shall be green.

Means shall be provided for a connection to enable this state to be indicated remotely from the CONTROL PANEL. This requirement does not apply for MOBILE ME EQUIPMENT

Compliance is checked by inspection.

203.6.4.5.101 RADIATION DOSE STRUCTURED REPORTS

ME EQUIPMENT intended for DENTAL CBCT applications shall be capable of creating RADIATION DOSE STRUCTURED REPORTS (RDSR) and have the ability to perform an RDSR END OF PROCEDURE TRANSMISSION. The relevant elements for the specified type of X-RAY EQUIPMENT and for which data are available shall be populated with relevant data.

Compliance is checked by functional tests.

203.6.5 AUTOMATIC CONTROL SYSTEM

Replacement:

If the ME EQUIPMENT is equipped with AUTOMATIC EXPOSURE CONTROLS then the constancy of AUTOMATIC EXPOSURE CONTROLS required for the INTENDED USE shall be determined in the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS shall state the accuracy of AUTOMATIC CONTROL SYSTEMS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the appropriate functional tests.

203.6.6 * SCATTERED RADIATION reduction

Addition:

NOTE 201 SCATTERED RADIATION is not known to have significant influence on the image quality with EXTRA-ORAL ME EQUIPMENT based upon scanning. In most cases the reduction of SCATTERED RADIATION is usually achieved by secondary collimation before the IMAGE RECEPTOR. In case of DVR, no scatter reduction methods are established in the art.

203.7 RADIATION QUALITY

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

203.8.4 Confinement of EXTRA-FOCAL RADIATION

Addition:

X-RAY SOURCE ASSEMBLIES employing rotating anode X-RAY TUBES shall be so constructed that the zone of intersection of all straight lines that pass through all RADIATION APERTURES of the X-RAY SOURCE ASSEMBLY, with a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT shall not extend more than 15 cm outside the boundary of the largest selectable X-RAY FIELD.

Compliance is checked by geometrical/graphical examination of the design documentation. In Figure 201, w_1 represents the width of the largest selectable X-RAY FIELD in a plane P, which is perpendicular to the REFERENCE AXIS at 1 m from the FOCAL SPOT. The zone of intersection with plane P of all straight lines passing through all RADIATION APERTURES extends beyond w_1 by the distance w_2. The shaded portion of this zone is a region where EXTRA-FOCAL RADIATION can extend beyond the largest X-RAY FIELD. Compliance is achieved if w_2 does not exceed 15 cm.

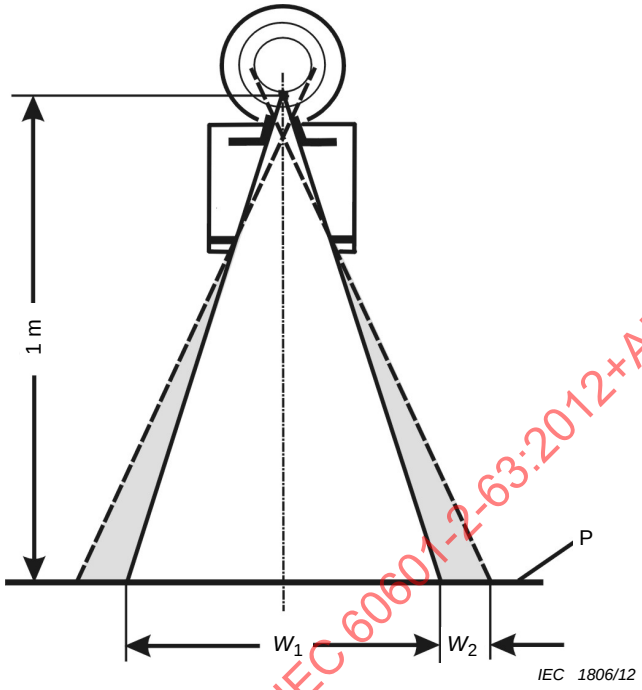

Figure 203.101 – Zone of EXTRA-FOCAL RADIATION

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Replacement:

Means shall be provided to enable the X-RAY FIELD to be positioned to cover the region of interest and, where applicable, the SENSITIVE VOLUMES of the AUTOMATIC EXPOSURE CONTROL or AUTOMATIC INTENSITY CONTROL.

In DVR:

The X-RAY FIELD shall not extend beyond the EFFECTIVE IMAGE RECEPTION AREA at the surface of the X-RAY IMAGE RECEPTOR more than 2 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 3 % in both directions. In the case of the X-RAY IMAGE RECEPTOR having an active surface side length below 8 cm, the over-RADIATION shall not be larger than 1 % of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in one direction or at most 2 % in two directions.

The dimensions of a rectangular X-RAY FIELD are described in terms of the length of its intercepts on each of two orthogonal major axes in the plane of interest.

For circular X-RAY FIELD, the dimensions are described accordingly, replacing the lengths of the intercepts with the diameter.