IEC 60601-2-28

Edition 3.0 2017-06
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC 60601-2-28:2017-06 RLV(en)

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CONTENTS

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

FOREWORD

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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International Standard IEC 60601-2-28 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2010. This edition constitutes a technical revision.

The third edition of this particular standard has been prepared to fit IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (the amended third edition of IEC 60601-1), which is referred to as the general standard. Apart from the changes related to the amendment of IEC 60601-1, changes related to technical improvements are also included.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/1040/FDIS	62B/1051/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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

In this standard, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-RAY TUBE ASSEMBLIES and to components thereof~~, hereafter referred to as ME EQUIPMENT~~, intended for medical diagnosis and imaging.

Where the general standard IEC 60601-1 and the collateral standard IEC 60601-1-3 refer to ME EQUIPMENT, this is interpreted as X-RAY TUBE ASSEMBLIES in this particular standard. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE This document is also applicable to the X-RAY TUBE ASSEMBLY aspects of X-RAY SOURCE ASSEMBLIES and X-RAY TUBE HEADS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-RAY TUBE ASSEMBLIES for medical diagnosis.

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 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply as modified in Clause 203. IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 101 IEC 60601-1-2 does not apply because RISKS for the X-RAY TUBE ASSEMBLY outside the system may only be indicative of RISKS for the system due to the difference in electromagnetic environment.

NOTE 102 IEC 60601-1-6 and IEC 60601-1-8 do not apply because X-RAY TUBE ASSEMBLIES are not operated as a stand-alone device.

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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*.

NOTE 103 X-RAY TUBE ASSEMBLIES are not in the scope of IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 3.147, additional definitions in this document 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 document" 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.

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 60522, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

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

201.3 Terms and definitions

Clause 3 of the general standard applies, except as follows:

For the purposes of this document, the terms and definitions given in the general standard, applicable collateral standards, IEC 60613:2010, IEC 60522, IEC 60336 and IEC TR 60788:2004 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 24.

201.3.71
NORMAL USE

Addition:

Note 1 to entry: Where used in this document, the defined term NORMAL USE is understood to only apply to the X-RAY TUBE ASSEMBLY as it operates in X-RAY EQUIPMENT.

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

The entity X-RAY TUBE ASSEMBLY itself does not have ESSENTIAL PERFORMANCE. Whether characteristics of an X-RAY TUBE ASSEMBLY ~~must~~ shall be considered ESSENTIAL PERFORMANCE,

depends on the X-ray system and HIGH-VOLTAGE GENERATOR characteristics combined with the X-RAY TUBE ASSEMBLY.

201.4.4 EXPECTED SERVICE LIFE

Addition:

EXPECTED SERVICE LIFE may also be based on metrics related to use.

NOTE 101 Examples of use: number of scans, radiographs, PATIENT exams.

NOTE 102 X-RAY TUBE ASSEMBLIES are consumables, i.e. their use leads ultimately to their replacement. By design, an X-RAY TUBE ASSEMBLY maintains BASIC SAFETY throughout its life and its replacement.

NOTE 103 EXPECTED SERVICE LIFE typifies the estimated replacement times of a population of X-RAY TUBE ASSEMBLIES. EXPECTED SERVICE LIFE is based on a statistical analysis of the survival of e.g. 5 % of the X-RAY TUBE ASSEMBLIES in the population.

201.4.11 Power input

Subclause 4.11 of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.5 Supply voltages, type of current, nature of supply, frequency

Addition to paragraph 5.5 f):

A HIGH-VOLTAGE GENERATOR which is not SPECIFIED in the ACCOMPANYING DOCUMENTS can be used if the characteristics which are essential for a given test are equivalent to the SPECIFIED HIGH-VOLTAGE GENERATOR.

201.5.7 Humidity preconditioning treatment

Addition:

For those X-RAY TUBE ASSEMBLIES that are to be used only in controlled environments, as to be SPECIFIED in the ACCOMPANYING DOCUMENTS, no humidity preconditioning is required.

~~The ACCOMPANYING DOCUMENTS shall include the time period that the room environmental operating conditions must be maintained prior to applying power to the X-RAY TUBE ASSEMBLY.~~

~~*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.*~~

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.2 ACCESSIBLE PARTS

Subclause 5.9.2 of the general standard does not apply.

NOTE Parts accessibility of the X-RAY TUBE ASSEMBLY will necessarily be evaluated as integrated in specific X-RAY EQUIPMENT.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Addition:

X-RAY TUBE ASSEMBLIES shall be classified as CLASS I equipment.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.1 General

201.7.1.1 USABILITY of the identification, marking and documents

Subclause 7.1.1 of the general standard does not apply.

NOTE The user interface is part of the X-RAY EQUIPMENT, but not of the X-RAY TUBE ASSEMBLY.

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

201.7.2.2 Identification

Replacement of the first paragraph by:

The X-RAY TUBE ASSEMBLY shall be marked with:

– the name or trademark and address of the MANUFACTURER;
– a MODEL OR TYPE REFERENCE;
– an individual identification;
– the date of manufacture.

NOTE 101 See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture, and use by date.

NOTE 102 See also 201.7.2.102.

201.7.2.5 ME EQUIPMENT intended to receive power from other equipment

~~*Addition:*~~

~~The marking required in subclause 7.2.5 of the general standard may be replaced by a description of the interface to the power supply in the ACCOMPANYING DOCUMENTS as required in 201.7.9.3.101.~~

Subclause 7.2.5 of the general standard does not apply.

NOTE For applicable requirements, see 201.7.9.3.101.

201.7.2.11 Mode of operation

Subclause 7.2.11 of the general standard does not apply.

NOTE X-RAY TUBE ASSEMBLIES are not operated as a stand alone device.

201.7.2.14 HIGH VOLTAGE TERMINAL DEVICES

Replacement:

HIGH VOLTAGE cable connections between the X-RAY TUBE ASSEMBLY and the HIGH-VOLTAGE GENERATOR accessible in NORMAL USE shall be marked with symbol IEC 60417-5036 (2002-10) (see Table D.1, symbol 24) unless a tool is required for removal of the cable connection.

201.7.2.15 Cooling conditions

Addition:

Marking of cooling conditions is not required if the cooling unit and the X-RAY TUBE ASSEMBLY have been designed for compatibility.

NOTE A cooling unit is a standalone device or integral part of the X-RAY TUBE ASSEMBLY which provides increased cooling capability of the X-RAY TUBE ASSEMBLY.

Additional subclauses:

201.7.2.101 Marking of X-RAY TUBES

The markings on the X-RAY TUBE shall remain readable when the X-RAY TUBE is dismantled from the X-RAY TUBE HOUSING after a period of NORMAL USE.

The markings shall enable individual products, series or types to be correlated with their ACCOMPANYING DOCUMENTS.

X-RAY TUBES shall be provided with the following markings:

- name or trademark of the MANUFACTURER;
- MODEL OR TYPE REFERENCE;
- individual identification.

The above markings may be given in the form of a combined designation explained in the ACCOMPANYING DOCUMENTS.

201.7.2.102 Marking on the outside of X-RAY TUBE ASSEMBLIES

X-RAY TUBE ASSEMBLIES shall be provided with the following markings:

- ~~name or trademark of the MANUFACTURER;~~
- ~~MODEL OR TYPE REFERENCE;~~
- ~~individual identification;~~
- NOMINAL X-RAY TUBE VOLTAGE for which the X-RAY TUBE ASSEMBLY is designed;
- ~~indication of the polarity of the cable receptacles;~~
- ~~PERMANENT FILTRATION according to IEC 60522;~~
- ~~NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.~~
- if there is more than one HIGH VOLTAGE cable receptacle, indication of the polarity of the HIGH VOLTAGE cable receptacles;

- FOCAL SPOT size(s). If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then mark the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.

NOTE ~~The requirement to mark the position of FOCAL SPOTs on the X-RAY TUBE ASSEMBLY has not been taken over from the first edition (1993) of this particular standard because this method is only indicative versus the drawing as required in 201.7.9.3.101 n).~~ See further 201.7.2.2 and 203.7.3.

201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.3.2 HIGH VOLTAGE parts

Subclause 7.3.2 of the general standard does not apply.

NOTE While the inside of an X-RAY TUBE ASSEMBLY is being worked on, the assembly is normally not energized. Even if the assembly is energized, only trained service personnel are allowed to perform the work, so safe operation is assured.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Replacement:

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTS may be provided with the X-RAY TUBE ASSEMBLY, or they may be integrated into the ACCOMPANYING DOCUMENTS of any ME SYSTEM for which the X-RAY TUBE ASSEMBLY is compatible.

If an X-RAY TUBE ASSEMBLY is intended to receive its power from other equipment in an ME SYSTEM, or otherwise puts special requirements on the supporting ME SYSTEM, the ACCOMPANYING DOCUMENTS shall sufficiently specify such other equipment to ensure compliance with the requirements of this document.

NOTE 101 The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its EXPECTED SERVICE LIFE.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

– name or trade-name of the MANUFACTURER and contact information to which the RESPONSIBLE ORGANIZATION can refer;

– MODEL OR TYPE REFERENCE.

NOTE 102 Contact information can be e.g. a telephone number, email address, address or website, where the MANUFACTURER can be contacted.

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. a file on an electronic medium. If the ACCOMPANYING DOCUMENTS are provided electronically, the RISK MANAGEMENT FILE shall include consideration on which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT.

EXAMPLE Information to cover emergency operation.

NOTE 103 ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

NOTE 104 Instead of the USABILITY ENGINEERING PROCESS (IEC 60601-1-6 is not applicable for an X-RAX TUBE ASSEMBLY), the RISK MANAGEMENT PROCESS (based on ISO 14971) is the carrier of the considerations. ISO

14971:2007, 4.2 (INTENDED USE) and C.2.29 (human factors) cover the USABILITY aspects of X-RAY TUBE ASSEMBLIES sufficiently.

The ACCOMPANYING DOCUMENTS shall specify special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and, when provided electronically, by inspection of the RISK MANAGEMENT FILE.

201.7.9.2 Instructions for use

201.7.9.2.2 Warning and safety notices

Replacement of the second paragraph of this subclause:

For X-RAY TUBE ASSEMBLIES, the ACCOMPANYING DOCUMENTS shall include a warning statement to the effect: "WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth."

NOTE 101 X-RAY TUBE ASSEMBLIES normally do not connect to a SUPPLY MAINS.

201.7.9.2.3 ME EQUIPMENT SPECIFIED for connection to a separate power supply

Subclause 7.9.2.3 of the general standard does not apply.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Subclause 7.9.2.14 of the general standard applies, except as follows:

– the second paragraph;

– the Note.

201.7.9.2.17 ME EQUIPMENT emitting RADIATION

Subclause 7.9.2.17 of the general standard does not apply.

NOTE RADIATION intensity and distribution are governed at system level. Nature and type of the RADIATION are SPECIFIED in 201.7.9.3.101 a).

Additional subclause:

201.7.9.2.101 Instructions for use of X-RAY TUBE ASSEMBLIES

The instructions for use of an X-RAY TUBE ASSEMBLY shall state the following data as appropriate to the INTENDED USE:

a) SINGLE LOAD RATING;

b) SERIAL LOAD RATING;

c) NOMINAL RADIOGRAPHIC ANODE INPUT POWER according to IEC 60613:2010;

d) NOMINAL CT ANODE INPUT POWER according to IEC 60613:2010;

e) NOMINAL CT SCAN POWER INDEX according to IEC 60613:2010.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Technical description of X-RAY TUBE ASSEMBLIES

The technical descriptions of X-RAY TUBE ASSEMBLIES shall specify the following data:

a) the identity of the TARGET material(s) that characterize the RADIATION SPECTRUM;

b) the REFERENCE AXIS;

c) the TARGET ANGLE(S);

d) FOCAL SPOT size(s);

If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then state the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336;

e) PERMANENT FILTRATION according to IEC 60522 or the thickness(es) of the material(s) concerned, together with its/their chemical symbol(s);

f) QUALITY EQUIVALENT FILTRATION of parts which are or could become ADDED FILTERS and method of mounting/dismounting such, if applicable;

NOTE 101 The preceding two FILTRATION requirements cover requirements SPECIFIED in 7.3 of IEC 60601-1-3:2008.

g) NOMINAL X-RAY TUBE VOLTAGE;

h) data concerning the HIGH VOLTAGE required from the HIGH-VOLTAGE GENERATOR or the type designation of suitable supply equipment;

i) type-designation or specification of the HIGH VOLTAGE connectors;

j) requirements for the HIGH-VOLTAGE GENERATOR, for supplying the filament(s), for rotating the ANODE (when appropriate) and for auxiliary equipment (such as for cooling ~~unit, or a fan~~ purposes), appropriate for the safe application of the X-RAY TUBE ASSEMBLY as defined in the RISK MANAGEMENT FILE;

k) CATHODE EMISSION CHARACTERISTIC;

NOTE 102 For the 4 preceding items, (h) to k)), for an X-RAY TUBE ASSEMBLY which comes built in into an X-ray system with HIGH-VOLTAGE GENERATOR, normally no data are required. If the X-RAY TUBE ASSEMBLY is sold to an OEM-system MANUFACTURER, then normally an elaborate interface specification will be included.

l) ENVELOPE VOLTAGE according to IEC 60613:2010, if applicable;

m) ENVELOPE CURRENT according to IEC 60613:2010, if applicable;

n) principal dimensions and interfaces in the form of a drawing; this drawing also shows the REFERENCE AXIS, the position and the accuracy of the position of the FOCAL SPOT(S);

o) mass with and without additional components;

p) CONTINUOUS ANODE INPUT POWER according to IEC 60613:2010 at the highest value of NOMINAL X-RAY TUBE VOLTAGE under any operating condition;

q) classifications according to Clause 6 of the general standard;

r) polarity of HIGH-VOLTAGE connections;

s) limits for the conditions for transport and storage;

t) if applicable, any requirements that shall be fulfilled prior to applying power to the X-RAY TUBE ASSEMBLY, e.g. the time period that the room environmental operating conditions shall be maintained, precautions to be observed before the first LOADING upon completion of the installation of an X-RAY TUBE ASSEMBLY, special procedures for conditioning the X-RAY TUBE~~, if appropriate~~;

u) NOMINAL CONTINUOUS INPUT POWER according to IEC 60613:2010.

NOTE 103 As equipment (example: BEAM LIMITING DEVICE) which is – electrically or mechanically – attached to the X-RAY TUBE ASSEMBLY can affect compliance of the X-RAY TUBE ASSEMBLY with this document, the technical

description of the X-RAY TUBE ASSEMBLY in this clause lists those specifications and interfaces which might affect compliance of the X-RAY TUBE ASSEMBLY. This is not an exhaustive list of technical descriptions, as such equipment attached to the X-RAY TUBE ASSEMBLY might pose additional requirements on interfacing.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.2 Requirements related to power sources

201.8.2.1 Connection to a separate power source

Subclause 8.2.1 of the general standard does not apply.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

Addition:

NOTE Measurements on the X-RAY TUBE ASSEMBLY outside the system are only indicative of measurements on the system, due to the difference in electrical connections.

201.8.8 Insulation

201.8.8.3 Dielectric strength

~~*Addition:*~~

~~For X-RAY TUBE ASSEMBLIES, Subclause 201.8.8.3 from particular standards pertaining to ME EQUIPMENT for which the X-RAY TUBE ASSEMBLY is intended shall be applied.~~

Amendment to Table 6 of the general standard:

For PEAK WORKING VOLTAGES U_N >14 140 V, the HIGH VOLTAGE circuits of the X-RAY TUBE ASSEMBLY are tested at 110 % of the NOMINAL X-RAY TUBE VOLTAGE of the X-RAY TUBE ASSEMBLY, where the voltage is raised over a period of 10 s or less, and is then maintained for 3 min.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

201.8.9.3 Spaces filled by insulating compound

Addition:

Subclause 8.9.3 is not applicable for testing HIGH VOLTAGE circuits of X-RAY TUBE ASSEMBLIES.

NOTE 201.8.8.3 describes HIGH VOLTAGE testing of X-RAY TUBE ASSEMBLIES.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.5 Expelled parts HAZARD

~~**201.9.5.1 Protective means**~~

Addition:

~~**201.9.5.1.101 Protective housing**~~

~~The kinetic energy stored in the rotating system of the ANODE, and the high temperatures occurring during operation, are potential causes of expelled parts.~~

RISK ANALYSIS in the RISK MANAGEMENT FILE shall include the criteria for expelled parts or liquid spilled that would result in an unacceptable RISK.

NOTE The kinetic and thermal energy stored in the rotating system of the ANODE, coupled with a malfunction, are potential sources of disintegration of the X-RAY TUBE, and in consequence, RISKS of parts being expelled. X-RAY TUBE ASSEMBLY MANUFACTURERS can test for such RISKS, but, as protective means can also be provided by the ME SYSTEM, and as the application of the X-RAY TUBE ASSEMBLY is system-dependent, these test results are only indicative of the RISKS at the system level. Considerations regarding the tests which can be applied for RISK MANAGEMENT purposes are given in Annex AA.

201.9.5.2 CATHODE ray tubes

Subclause 9.5.2 of the general standard does not apply.

NOTE An X-RAY TUBE is not a CATHODE ray tube.

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

201.9.7.1 General

Addition:

An X-RAY TUBE ASSEMBLY is not a pressure vessel. However, 9.7.5 regarding pressure vessels may be applied.

RISK ANALYSIS in the RISK MANAGEMENT FILE shall include the criteria for liquid spilled or other consequences that would result in an unacceptable RISK.

NOTE Pressure can be caused by excessive energy inputs and certain malfunctions, including those resulting in disintegration of the X-RAY TUBE. The thermal energy stored in the rotating system of the ANODE, and high temperatures occurring during operation coupled with a malfunction, are potential sources of ~~excessive~~ pressure and in consequence of leakage of the insulating medium. X-RAY TUBE ASSEMBLY MANUFACTURERS ~~may~~ can test for pressure-related RISKS, but, as protective means ~~may~~ can also be provided by the ME SYSTEM, and as the application of the X-RAY TUBE ASSEMBLY is system-dependent, these test results are only indicative of the RISKS at the system level. Considerations regarding the tests which ~~may~~ can be applied for RISK MANAGEMENT purposes are given in Annex AA.

~~**201.9.7.5 Pressure vessels**~~

~~*Addition:*~~

~~NOTE Pressure in the X-RAY TUBE ASSEMBLY should not result in an unacceptable RISK, when incorporated in the system.~~

201.9.7.7 Pressure-relief device

Addition:

X-RAY TUBE ASSEMBLIES shall either comply with items a) to g) of subclause 9.7.7 of the general standard, or be provided with other means to respond to one or more critical levels of thermal energy or pressure, for example by sensing predetermined levels of temperature, volume or pressure of the insulating medium inside the X-RAY TUBE HOUSING.

If other means than a pressure-relief device are used, then the following shall be provided:

– a SPECIFIED signal for the ME EQUIPMENT for which the X-RAY TUBE ASSEMBLY is intended, when a critical level has been reached;

– a statement in the ACCOMPANYING DOCUMENTS addressing the RISK associated with this critical level.

Replacement of item h) and of the compliance statement:

h) if a pressure-relief device is used, the number of cycles to be tested is as follows:

1) for a single-event pressure-relief device (e.g., bursting disk): this undergoes a single test by definition;
2) for a pressure-relief device that resets, but that signals the tube as having failed and requiring replacement (either tube or system SW or HW prohibits further exposures): the number of test cycles is 5;
3) for a pressure-relief device that resets and the tube can continue to be used: the number of test cycles is 1 000.

NOTE The modified requirement in item h) (1 000 instead of 100 000 cycles) is reasonable because in ~~practicable use~~ practice even a few actuations of the pressure-relief device would result in subsequent replacement of the X-RAY TUBE ASSEMBLY.

Compliance is checked by inspection, and where necessary, by functional test.

201.10 Protection against unwanted and excessive RADIATION HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1 Excessive temperatures in ME EQUIPMENT

Addition:

NOTE According to 4.6 of the general standard, the RISK MANAGEMENT process can determine that the X-RAY TUBE ASSEMBLY is subject to the requirements for TYPE B APPLIED PARTS.

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

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

The temperature of the painted surface of an X-RAY TUBE ASSEMBLY which can unintentionally be touched during INTENDED USE may exceed the values in Table 23 of the general standard but shall not exceed 85 °C.

NOTE 101 Table 23 of the general standard does not cover painted metal surfaces. However, reference [38] in the general standard: EN 563, indicates a maximum temperature of 85 °C for a painted metal surface and for a typical maximum contact period of 1 second. EN 563 has been withdrawn; It has been replaced by ISO 13732-1. For the temperature considerations above, the same conclusion holds.

In NORMAL USE Table 23 does not apply for X-RAY TUBE ASSEMBLIES protected by GUARDS.

NOTE 102 Service personnel are aware of the RISKS involved when a GUARD is removed.

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

In NORMAL CONDITION 201.11.1.1 applies. In SINGLE FAULT CONDITION 201.13.1.2 applies.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Subclause 11.8 of the general standard does not apply.

NOTE In case of interruption of the power to the X-RAY TUBE ASSEMBLY, it is up to the ME SYSTEM to maintain BASIC SAFETY, ESSENTIAL PERFORMANCE and to prevent HAZARDOUS SITUATIONS; an X-RAY TUBE ASSEMBLY cannot maintain these aspects in this case.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.2 USABILITY of ME EQUIPMENT

Subclause 12.2 of the general standard does not apply.

201.12.3 ALARM SYSTEMS

Subclause 12.3 of the general standard does not apply.

201.12.4 Protection against hazardous output

201.12.4.5 Diagnostic or therapeutic RADIATION

201.12.4.5.2 Diagnostic X-RAY EQUIPMENT

Replacement:

X-RAY TUBE ASSEMBLIES shall comply with IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.

Compliance is checked as *SPECIFIED* in IEC 60601-1-3:2008 and *IEC 60601-1-3:2008*/AMD1:2013.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

201.13.1.2 Emission, deformation of ENCLOSURE or exceeding maximum temperature

Addition:

The requirement per the fourth dash of the first paragraph is considered fulfilled, if the temperature of the painted surface of an X-RAY TUBE ASSEMBLY which can unintentionally be

touched during INTENDED USE may exceed the values in Table 23 of the general standard but shall not exceed 105 °C.

NOTE 101 The value of 105 °C is based on IEC 61010-1:2010.

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, except as follows:

201.15.1 Arrangement of controls and indicators of ME EQUIPMENT

Subclause 15.1 of the general standard does not apply.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.2 Temperature and overload control devices

201.15.4.2.1 Application

Subclause 15.4.2.1, item d) does not apply.

NOTE In case of the loss of function indicated in item d) it is up to the ME SYSTEM to maintain ESSENTIAL PERFORMANCE and to prevent the HAZARDOUS SITUATIONS described in 13.1 of the general standard; an X-RAY TUBE ASSEMBLY cannot maintain these aspects in case of such loss of function.

201.16 ME SYSTEMS

Clause 16 of the general standard ~~applies~~ does not apply.

NOTE While subclause 16.3 is applicable in principle, this requirement is covered in 201.7.9.3.101 instead.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard ~~applies except as follows~~ does not apply.

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with:

– the electromagnetic phenomena ~~existing at the locations where~~ the X-RAY TUBE ASSEMBLY is exposed to during INTENDED USE ~~to be used as indicated in the ACCOMPANYING DOCUMENTS~~; and

– the introduction by the X-RAY TUBE ASSEMBLY of electromagnetic phenomena ~~into the environment~~ that might degrade the performance of other devices, electrical equipment and systems.

The MANUFACTURER of the X-RAY TUBE ASSEMBLY is not required to assess electromagnetic capability according to IEC 60601-1-2 on the stand-alone X-RAY TUBE ASSEMBLY.

NOTE RISKS for the X-RAY TUBE ASSEMBLY outside the system ~~may~~ can only be indicative of RISKS for the system due to the difference in electromagnetic environment.

Compliance is checked by 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 X-RAY TUBE ASSEMBLIES, compliance with this document is to be stated, the statement shall be made in the following form:

X-RAY TUBE ASSEMBLY ..... *), IEC 60601-2-28:~~2010~~ 2017

* MODEL OR TYPE REFERENCE

If means other than those described in this document have been used to achieve equivalent safety, the variations shall be mentioned in the ACCOMPANYING DOCUMENTS when stating compliance with this document.

203.7 RADIATION QUALITY

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

Addition:

NOTE The requirements for HALF-VALUE LAYERS in 7.1 pertain to X-RAY EQUIPMENT and not to X-RAY TUBE ASSEMBLIES alone.

203.7.3 Indication of FILTER properties

Replacement:

The text in the second paragraph, first dash, is replaced by:

X-RAY TUBE ASSEMBLIES shall be marked with their PERMANENT FILTRATION according to IEC 60522 or with the thickness(es) of the material(s) concerned, together with its/their chemical symbol(s).

203.12 Protection against LEAKAGE RADIATION

203.12.5 LEAKAGE RADIATION when not in the LOADING STATE

Addition:

Subclause 12.5 is not applicable for X-RAY TUBE ASSEMBLIES where X-RAY production is not possible in the non-loading state, e.g. for X-RAY TUBE ASSEMBLIES designed for primary HIGH VOLTAGE switching operation.

Annexes

The annexes of the general standard apply.

Additional annex:

Annex AA
(informative)

Test of X-RAY TUBE ASSEMBLIES for ~~pressure-related RISKS~~ expelled parts-related and/or tube implosion-related RISKS

AA.1 Overview

The kinetic and thermal energy stored in the rotating system of the ANODE, coupled with a malfunction, are potential sources of pressure and of disintegration of the X-RAY TUBE, and in consequence of parts being expelled or liquids being spilled. The evaluation of ~~pressure related~~ the concomitant RISKS determines whether or not testing is required. If this evaluation concludes that testing is required, this particular standard does not prescribe a mandatory, generally-valid test for expelled parts pressure, X-RAY TUBE implosion or explosion, because there are too many different types of X-RAY TUBES, X-RAY TUBE ASSEMBLIES, X-RAY SOURCE ASSEMBLY and X-RAY EQUIPMENT configurations, with – consequently – different test setups. Instead, the tests ~~mentioned~~ and conditions indicated in this annex are for information only. As the tests are based on long-standing practice and experience, they may nevertheless often be considered representative ~~for the situation to be analysed~~.

MANUFACTURERs can choose to perform the test mentioned in this annex, as long as the RISK MANAGEMENT FILE states and reasons, that the test so performed is appropriate.

AA.2 General considerations

Whether a test is appropriate depends on many conditions. These conditions ~~must be~~ are mentioned with the test performed, ~~with~~ based on a reasoning (calculations, experience, …) as to the appropriateness of the conditions.

All known weak spots of the X-RAY TUBE HOUSING ~~shall be~~ are subject to testing~~, i.e. they may not be modified for the test~~. More than one test set-up may be necessary to fulfil this requirement.

~~These conditions are (attention: not an exhaustive list)~~ Regarding the conditions for a test, at least the following aspects should be considered:

a) temperature of the ANODE;

B) ANODE SPEED;

c) type of medium enveloping the X-RAY TUBE (oil, water, …);

d) temperature of medium enveloping the X-RAY TUBE;

e) electrical condition of the X-RAY TUBE:

- HIGH VOLTAGE (on or off, value of voltage, …);
- filament supply (on or off, value of current, …);
- rotor-unit energized or not;

f) weak spots of the X-RAY TUBE HOUSING (weakest spot can be the RADIATION APERTURE, or mechanical joints, …);

g) parts to be contained (fractured ANODE, medium enveloping the X-RAY TUBE, …);

h) X-RAY EQUIPMENT configuration (BEAM LIMITING DEVICE, protective covers, location of the X-RAY TUBE ASSEMBLY i.e. under table, overhead, in a CT-gantry, etc.).

AA.3 ~~General start conditions for the typical tests~~ Test procedure

Out of the list of start conditions for the test below, it will be clear that certain safety devices (e.g. temperature-cut-out) ~~must~~ would be made in-active for ~~certain~~ some test conditions or combinations of test conditions. The following conditions simulate the result of demanding applications:

a) the X-RAY TUBE has been loaded such that the maximum permitted temperature for the medium enveloping the X-RAY TUBE ~~is~~ has been attained and has been maintained for at least 10 min;

b) the ANODE of the ROTATING ANODE X-RAY TUBE rotates at the maximum SPECIFIED ANODE SPEED;

c) HIGH VOLTAGE is on;

d) filament is energized;

e) rotor unit is energized;

f) the X-RAY TUBE shall then be further loaded for 2 min at the corresponding highest SPECIFIED ANODE INPUT POWER.

~~g) Disintegration of the X-RAY TUBE is then induced.~~

The implosion of the X-RAY TUBE is then induced by disintegration of the ENVELOPE of the X-RAY TUBE, e.g. by mechanical impact on the ENVELOPE. The evaporation of the cooling liquid while hitting the hot ANODE will lead to pressure which may force deformation of the housing and cooling liquid spilled or (ENVELOPE-) fragments being expelled. There is also a chance on disintegration of the ANODE – in that case this test would also determine whether ANODE-fragments are expelled. However, for a well-designed X-RAY TUBE, disintegration of the ANODE is very unlikely. So, disintegration of the ANODE is induced by applying conditions beyond the SPECIFIED ANODE ratings, e.g. higher than SPECIFIED ANODE SPEED, or by defects that may weaken the ANODE (notches, etc.).

~~AA.4 Disintegration inducement of X-RAY TUBES~~

~~Preferably the disintegration of the ENVELOPE of the X-RAY TUBE is induced by disintegration of the ANODE (e.g. by a higher than maximum SPECIFIED ANODE SPEED), as this situation presents often the highest RISK on expelled parts. Alternatively the ENVELOPE of the X-RAY TUBE is disintegrated by, for example, mechanical impact on a part forming part of the ENVELOPE of the X-RAY TUBE.~~

AA.4 Pass/fail criteria

Pass/fail criteria are based on the results of the RISK MANAGEMENT process. Whether expelled parts or fragments, or the escape of insulating/cooling medium poses a RISK, depends on ~~the system configuration~~ the X-RAY TUBE ASSEMBLY ~~makes part of~~ and system-configuration.

Bibliography

IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

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*

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

ISO 13732-1, *Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Part 1: Hot surfaces*

Index of defined terms used in this particular standard

NOTE The definitions used in this particular standard ~~may~~ can be viewed at <http://std.iec.ch/glossary>.

IEC 60601-2-28

Edition 3.0 2017-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

Appareils électromédicaux –
Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical

IEC 60601-2-28:2017-06(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

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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International Standard IEC 60601-2-28 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2010. This edition constitutes a technical revision.

The third edition of this particular standard has been prepared to fit IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 (the amended third edition of IEC 60601-1), which is referred to as the general standard. Apart from the changes related to the amendment of IEC 60601-1, changes related to technical improvements are also included.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/1040/FDIS	62B/1051/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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

In this standard, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-RAY TUBE ASSEMBLIES and to components thereof, intended for medical diagnosis and imaging.

Where the general standard IEC 60601-1 and the collateral standard IEC 60601-1-3 refer to ME EQUIPMENT, this is interpreted as X-RAY TUBE ASSEMBLIES in this particular standard. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE This document is also applicable to the X-RAY TUBE ASSEMBLY aspects of X-RAY SOURCE ASSEMBLIES and X-RAY TUBE HEADS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-RAY TUBE ASSEMBLIES for medical diagnosis.

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 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 applies as modified in Clause 203. IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 101 IEC 60601-1-2 does not apply because RISKS for the X-RAY TUBE ASSEMBLY outside the system may only be indicative of RISKS for the system due to the difference in electromagnetic environment.

NOTE 102 IEC 60601-1-6 and IEC 60601-1-8 do not apply because X-RAY TUBE ASSEMBLIES are not operated as a stand-alone device.

NOTE 103 X-RAY TUBE ASSEMBLIES are not in the scope of IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12.

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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*.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 document 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 3.147, additional definitions in this document 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 document" 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.

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 60522, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

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

201.3 Terms and definitions

Clause 3 of the general standard applies, except as follows:

For the purposes of this document, the terms and definitions given in the general standard, applicable collateral standards, IEC 60613:2010, IEC 60522, IEC 60336, and IEC TR 60788:2004 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 24.

201.3.71
NORMAL USE

Addition:

Note 1 to entry: Where used in this document, the defined term NORMAL USE is understood to only apply to the X-RAY TUBE ASSEMBLY as it operates in X-RAY EQUIPMENT.

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

The entity X-RAY TUBE ASSEMBLY itself does not have ESSENTIAL PERFORMANCE. Whether characteristics of an X-RAY TUBE ASSEMBLY shall be considered ESSENTIAL PERFORMANCE, depends on the X-ray system and HIGH-VOLTAGE GENERATOR characteristics combined with the X-RAY TUBE ASSEMBLY.

201.4.4 EXPECTED SERVICE LIFE

Addition:

EXPECTED SERVICE LIFE may also be based on metrics related to use.

NOTE 101 Examples of use: number of scans, radiographs, PATIENT exams.

NOTE 102 X-RAY TUBE ASSEMBLIES are consumables, i.e. their use leads ultimately to their replacement. By design, an X-RAY TUBE ASSEMBLY maintains BASIC SAFETY throughout its life and its replacement.

NOTE 103 EXPECTED SERVICE LIFE typifies the estimated replacement times of a population of X-RAY TUBE ASSEMBLIES. EXPECTED SERVICE LIFE is based on a statistical analysis of the survival of e.g. 5 % of the X-RAY TUBE ASSEMBLIES in the population.

201.4.11 Power input

Subclause 4.11 of the general standard does not apply.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.5 Supply voltages, type of current, nature of supply, frequency

Addition to paragraph 5.5 f):

A HIGH-VOLTAGE GENERATOR which is not SPECIFIED in the ACCOMPANYING DOCUMENTS can be used if the characteristics which are essential for a given test are equivalent to the SPECIFIED HIGH-VOLTAGE GENERATOR.

201.5.7 Humidity preconditioning treatment

Addition:

For those X-RAY TUBE ASSEMBLIES that are to be used only in controlled environments, as to be SPECIFIED in the ACCOMPANYING DOCUMENTS, no humidity preconditioning is required.

201.5.9 Determination of APPLIED PARTS and ACCESSIBLE PARTS

201.5.9.2 ACCESSIBLE PARTS

Subclause 5.9.2 of the general standard does not apply.

NOTE Parts accessibility of the X-RAY TUBE ASSEMBLY will necessarily be evaluated as integrated in specific X-RAY EQUIPMENT.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Addition:

X-RAY TUBE ASSEMBLIES shall be classified as CLASS I equipment.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.1 General

201.7.1.1 USABILITY of the identification, marking and documents

Subclause 7.1.1 of the general standard does not apply.

NOTE The user interface is part of the X-RAY EQUIPMENT, but not of the X-RAY TUBE ASSEMBLY.

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

201.7.2.2 Identification

Replacement of the first paragraph by:

The X-RAY TUBE ASSEMBLY shall be marked with:

– the name or trademark and address of the MANUFACTURER;
– a MODEL OR TYPE REFERENCE;
– an individual identification;
– the date of manufacture.

NOTE 101 See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture, and use by date.

NOTE 102 See also 201.7.2.102.

201.7.2.5 ME EQUIPMENT intended to receive power from other equipment

Subclause 7.2.5 of the general standard does not apply.

NOTE For applicable requirements, see 201.7.9.3.101.

201.7.2.11 Mode of operation

Subclause 7.2.11 of the general standard does not apply.

NOTE X-RAY TUBE ASSEMBLIES are not operated as a stand alone device.

201.7.2.14 HIGH VOLTAGE TERMINAL DEVICES

Replacement:

HIGH VOLTAGE cable connections between the X-RAY TUBE ASSEMBLY and the HIGH-VOLTAGE GENERATOR accessible in NORMAL USE shall be marked with symbol IEC 60417-5036 (2002-10) (see Table D.1, symbol 24) unless a tool is required for removal of the cable connection.

201.7.2.15 Cooling conditions

Addition:

Marking of cooling conditions is not required if the cooling unit and the X-RAY TUBE ASSEMBLY have been designed for compatibility.

NOTE A cooling unit is a standalone device or integral part of the X-RAY TUBE ASSEMBLY which provides increased cooling capability of the X-RAY TUBE ASSEMBLY.

Additional subclauses:

201.7.2.101 Marking of X-RAY TUBES

The markings on the X-RAY TUBE shall remain readable when the X-RAY TUBE is dismantled from the X-RAY TUBE HOUSING after a period of NORMAL USE.

The markings shall enable individual products, series or types to be correlated with their ACCOMPANYING DOCUMENTS.

X-RAY TUBES shall be provided with the following markings:

- name or trademark of the MANUFACTURER;
- MODEL OR TYPE REFERENCE;
- individual identification.

The above markings may be given in the form of a combined designation explained in the ACCOMPANYING DOCUMENTS.

201.7.2.102 Marking on the outside of X-RAY TUBE ASSEMBLIES

X-RAY TUBE ASSEMBLIES shall be provided with the following markings:

- NOMINAL X-RAY TUBE VOLTAGE for which the X-RAY TUBE ASSEMBLY is designed;
- if there is more than one HIGH VOLTAGE cable receptacle, indication of the polarity of the HIGH VOLTAGE cable receptacles;
- FOCAL SPOT size(s). If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then mark the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.

NOTE See further 201.7.2.2 and 203.7.3.

201.7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.3.2 HIGH VOLTAGE parts

Subclause 7.3.2 of the general standard does not apply.

NOTE While the inside of an X-RAY TUBE ASSEMBLY is being worked on, the assembly is normally not energized. Even if the assembly is energized, only trained service personnel are allowed to perform the work, so safe operation is assured.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Replacement:

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTS may be provided with the X-RAY TUBE ASSEMBLY, or they may be integrated into the ACCOMPANYING DOCUMENTS of any ME SYSTEM for which the X-RAY TUBE ASSEMBLY is compatible.

If an X-RAY TUBE ASSEMBLY is intended to receive its power from other equipment in an ME SYSTEM, or otherwise puts special requirements on the supporting ME SYSTEM, the ACCOMPANYING DOCUMENTS shall sufficiently specify such other equipment to ensure compliance with the requirements of this document.

NOTE 101 The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its EXPECTED SERVICE LIFE.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

– name or trade-name of the MANUFACTURER and contact information to which the RESPONSIBLE ORGANIZATION can refer;

– MODEL OR TYPE REFERENCE.

NOTE 102 Contact information can be e.g. a telephone number, email address, address or website, where the MANUFACTURER can be contacted.

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. a file on an electronic medium. If the ACCOMPANYING DOCUMENTS are provided electronically, the RISK MANAGEMENT FILE shall include consideration on which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT.

EXAMPLE Information to cover emergency operation.

NOTE 103 ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

NOTE 104 Instead of the USABILITY ENGINEERING PROCESS (IEC 60601-1-6 is not applicable for an X-RAX TUBE ASSEMBLY), the RISK MANAGEMENT PROCESS (based on ISO 14971) is the carrier of the considerations. ISO 14971:2007, 4.2 (INTENDED USE) and C.2.29 (human factors) cover the USABILITY aspects of X-RAY TUBE ASSEMBLIES sufficiently.

The ACCOMPANYING DOCUMENTS shall specify special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and, when provided electronically, by inspection of the RISK MANAGEMENT FILE.

201.7.9.2 Instructions for use

201.7.9.2.2 Warning and safety notices

Replacement of the second paragraph of this subclause:

For X-RAY TUBE ASSEMBLIES, the ACCOMPANYING DOCUMENTS shall include a warning statement to the effect: “WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth.”

NOTE 101 X-RAY TUBE ASSEMBLIES normally do not connect to a SUPPLY MAINS.

201.7.9.2.3 ME EQUIPMENT SPECIFIED for connection to a separate power supply

Subclause 7.9.2.3 of the general standard does not apply.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Subclause 7.9.2.14 of the general standard applies, except as follows:

– the second paragraph;

– the Note.

201.7.9.2.17 ME EQUIPMENT emitting RADIATION

Subclause 7.9.2.17 of the general standard does not apply.

NOTE RADIATION intensity and distribution are governed at system level. Nature and type of the RADIATION are SPECIFIED in 201.7.9.3.101 a).

Additional subclause:

201.7.9.2.101 Instructions for use of X-RAY TUBE ASSEMBLIES

The instructions for use of an X-RAY TUBE ASSEMBLY shall state the following data as appropriate to the INTENDED USE:

a) SINGLE LOAD RATING;

b) SERIAL LOAD RATING;

c) NOMINAL RADIOGRAPHIC ANODE INPUT POWER according to IEC 60613:2010;

d) NOMINAL CT ANODE INPUT POWER according to IEC 60613:2010;

e) NOMINAL CT SCAN POWER INDEX according to IEC 60613:2010.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Technical description of X-RAY TUBE ASSEMBLIES

The technical descriptions of X-RAY TUBE ASSEMBLIES shall specify the following data:

a) the identity of the TARGET material(s) that characterize the RADIATION SPECTRUM;

b) the REFERENCE AXIS;

c) the TARGET ANGLE(S);

d) FOCAL SPOT size(s);

If the FOCAL SPOT size(s) are in the range of NOMINAL FOCAL SPOT VALUES in IEC 60336, then state the FOCAL SPOT size(s) as NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336.

e) PERMANENT FILTRATION according to IEC 60522 or the thickness(es) of the material(s) concerned, together with its/their chemical symbol(s);

f) QUALITY EQUIVALENT FILTRATION of parts which are or could become ADDED FILTERS and method of mounting/dismounting such, if applicable;

NOTE 101 The preceding two FILTRATION requirements cover requirements SPECIFIED in 7.3 of IEC 60601-1-3:2008.

g) NOMINAL X-RAY TUBE VOLTAGE;

h) data concerning the HIGH VOLTAGE required from the HIGH-VOLTAGE GENERATOR or the type designation of suitable supply equipment;

i) type-designation or specification of the HIGH VOLTAGE connectors;

j) requirements for the HIGH-VOLTAGE GENERATOR, for supplying the filament(s), for rotating the ANODE (when appropriate) and for auxiliary equipment (such as for cooling purposes),

appropriate for the safe application of the X-RAY TUBE ASSEMBLY as defined in the RISK MANAGEMENT FILE;

k) CATHODE EMISSION CHARACTERISTIC;

NOTE 102 For the 4 preceding items,(h) to k)), for an X-RAY TUBE ASSEMBLY which comes built in into an X-ray system with HIGH-VOLTAGE GENERATOR, normally no data are required. If the X-RAY TUBE ASSEMBLY is sold to an OEM-system MANUFACTURER, then normally an elaborate interface specification will be included.

l) ENVELOPE VOLTAGE according to IEC 60613:2010, if applicable;

m) ENVELOPE CURRENT according to IEC 60613:2010, if applicable;

n) principal dimensions and interfaces in the form of a drawing; this drawing also shows the REFERENCE AXIS, the position and the accuracy of the position of the FOCAL SPOT(s);

o) mass with and without additional components;

p) CONTINUOUS ANODE INPUT POWER according to IEC 60613:2010 at the highest value of NOMINAL X-RAY TUBE VOLTAGE under any operating condition;

q) classifications according to Clause 6 of the general standard;

r) polarity of HIGH-VOLTAGE connections;

s) limits for the conditions for transport and storage;

t) if applicable, any requirements that shall be fulfilled prior to applying power to the X-RAY TUBE ASSEMBLY, e.g. the time period that the room environmental operating conditions shall be maintained, precautions to be observed before the first LOADING upon completion of the installation of an X-RAY TUBE ASSEMBLY, special procedures for conditioning the X-RAY TUBE;

u) NOMINAL CONTINUOUS INPUT POWER according to IEC 60613:2010.

NOTE 103 As equipment (example: BEAM LIMITING DEVICE) which is – electrically or mechanically – attached to the X-RAY TUBE ASSEMBLY can affect compliance of the X-RAY TUBE ASSEMBLY with this document, the technical description of the X-RAY TUBE ASSEMBLY in this clause lists those specifications and interfaces which might affect compliance of the X-RAY TUBE ASSEMBLY. This is not an exhaustive list of technical descriptions, as such equipment attached to the X-RAY TUBE ASSEMBLY might pose additional requirements on interfacing.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.2 Requirements related to power sources

201.8.2.1 Connection to a separate power source

Subclause 8.2.1 of the general standard does not apply.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

Addition:

NOTE Measurements on the X-RAY TUBE ASSEMBLY outside the system are only indicative of measurements on the system, due to the difference in electrical connections.

201.8.8 Insulation

201.8.8.3 Dielectric strength

Amendment to Table 6 of the general standard:

For PEAK WORKING VOLTAGES U >14 140 V, the HIGH VOLTAGE circuits of the X-RAY TUBE ASSEMBLY are tested at 110 % of the NOMINAL X-RAY TUBE VOLTAGE of the X-RAY TUBE ASSEMBLY, where the voltage is raised over a period of 10 s or less, and is then maintained for 3 min.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

201.8.9.3 Spaces filled by insulating compound

Addition:

Subclause 8.9.3 is not applicable for testing HIGH VOLTAGE circuits of X-RAY TUBE ASSEMBLIES.

NOTE 201.8.8.3 describes HIGH VOLTAGE testing of X-RAY TUBE ASSEMBLIES.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.5 Expelled parts HAZARD

Addition:

RISK ANALYSIS in the RISK MANAGEMENT FILE shall include the criteria for expelled parts or liquid spilled that would result in an unacceptable RISK.

NOTE The kinetic and thermal energy stored in the rotating system of the ANODE, coupled with a malfunction, are potential sources of disintegration of the X-RAY TUBE, and in consequence, RISKS of parts being expelled. X-RAY TUBE ASSEMBLY MANUFACTURERS can test for such RISKS, but, as protective means can also be provided by the ME SYSTEM, and as the application of the X-RAY TUBE ASSEMBLY is system-dependent, these test results are only indicative of the RISKS at the system level. Considerations regarding the tests which can be applied for RISK MANAGEMENT purposes are given in Annex AA.

201.9.5.2 CATHODE ray tubes

Subclause 9.5.2 of the general standard does not apply.

NOTE An X-RAY TUBE is not a CATHODE ray tube.

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

201.9.7.1 General

Addition:

An X-RAY TUBE ASSEMBLY is not a pressure vessel. However, 9.7.5 regarding pressure vessels may be applied.

RISK ANALYSIS in the RISK MANAGEMENT FILE shall include the criteria for liquid spilled or other consequences that would result in an unacceptable RISK.

NOTE Pressure can be caused by excessive energy inputs and certain malfunctions, including those resulting in disintegration of the X-RAY TUBE. The thermal energy stored in the rotating system of the ANODE, and high temperatures occurring during operation coupled with a malfunction, are potential sources of pressure and in consequence of leakage of the insulating medium. X-RAY TUBE ASSEMBLY MANUFACTURERS can test for pressure-related RISKS, but, as protective means can also be provided by the ME SYSTEM, and as the application of the X-RAY TUBE ASSEMBLY is system-dependent, these test results are only indicative of the RISKS at the system level. Considerations regarding the tests which can be applied for RISK MANAGEMENT purposes are given in Annex AA.

201.9.7.7 Pressure-relief device

Addition:

X-RAY TUBE ASSEMBLIES shall either comply with items a) to g) of subclause 9.7.7 of the general standard, or be provided with other means to respond to one or more critical levels of thermal energy or pressure, for example by sensing predetermined levels of temperature, volume or pressure of the insulating medium inside the X-RAY TUBE HOUSING.

If other means than a pressure-relief device are used, then the following shall be provided:

– a SPECIFIED signal for the ME EQUIPMENT for which the X-RAY TUBE ASSEMBLY is intended, when a critical level has been reached;
– a statement in the ACCOMPANYING DOCUMENTS addressing the RISK associated with this critical level.

Replacement of item h) and of the compliance statement:

h) if a pressure-relief device is used, the number of cycles to be tested is as follows:

1) for a single-event pressure-relief device (e.g., bursting disk): this undergoes a single test by definition;
2) for a pressure-relief device that resets, but that signals the tube as having failed and requiring replacement (either tube or system SW or HW prohibits further exposures): the number of test cycles is 5;
3) for a pressure-relief device that resets and the tube can continue to be used: the number of test cycles is 1 000.

NOTE The modified requirement in item h) (1 000 instead of 100 000 cycles) is reasonable because in practice even a few actuations of the pressure-relief device would result in subsequent replacement of the X-RAY TUBE ASSEMBLY.

Compliance is checked by inspection, and where necessary, by functional test.

201.10 Protection against unwanted and excessive RADIATION HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.1 Excessive temperatures in ME EQUIPMENT

Addition:

NOTE According to 4.6 of the general standard, the RISK MANAGEMENT process can determine that the X-RAY TUBE ASSEMBLY is subject to the requirements for TYPE B APPLIED PARTS.

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

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

The temperature of the painted surface of an X-RAY TUBE ASSEMBLY which can unintentionally be touched during INTENDED USE may exceed the values in Table 23 of the general standard but shall not exceed 85 °C.

NOTE 101 Table 23 of the general standard does not cover painted metal surfaces. However, reference [38] in the general standard: EN 563, indicates a maximum temperature of 85 °C for a painted metal surface and for a

typical maximum contact period of 1 second. EN 563 has been withdrawn; It has been replaced by ISO 13732-1. For the temperature considerations above, the same conclusion holds.

In NORMAL USE Table 23 does not apply for X-RAY TUBE ASSEMBLIES protected by GUARDS.

NOTE 102 Service personnel are aware of the RISKS involved when a GUARD is removed.

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

In NORMAL CONDITION 201.11.1.1 applies. In SINGLE FAULT CONDITION 201.13.1.2 applies.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Subclause 11.8 of the general standard does not apply.

NOTE In case of interruption of the power to the X-RAY TUBE ASSEMBLY, it is up to the ME SYSTEM to maintain BASIC SAFETY, ESSENTIAL PERFORMANCE and to prevent HAZARDOUS SITUATIONS; an X-RAY TUBE ASSEMBLY cannot maintain these aspects in this case.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.2 USABILITY of ME EQUIPMENT

Subclause 12.2 of the general standard does not apply.

201.12.3 ALARM SYSTEMS

Subclause 12.3 of the general standard does not apply.

201.12.4 Protection against hazardous output

201.12.4.5 Diagnostic or therapeutic RADIATION

201.12.4.5.2 Diagnostic X-RAY EQUIPMENT

Replacement:

X-RAY TUBE ASSEMBLIES shall comply with IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.

Compliance is checked as SPECIFIED in IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

201.13.1.2 Emission, deformation of ENCLOSURE or exceeding maximum temperature

Addition:

The requirement per the fourth dash of the first paragraph is considered fulfilled, if the temperature of the painted surface of an X-RAY TUBE ASSEMBLY which can unintentionally be touched during INTENDED USE may exceed the values in Table 23 of the general standard but shall not exceed 105 °C.

NOTE 101 The value of 105 °C is based on IEC 61010-1:2010.

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, except as follows:

201.15.1 Arrangement of controls and indicators of ME EQUIPMENT

Subclause 15.1 of the general standard does not apply.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.2 Temperature and overload control devices

201.15.4.2.1 Application

Subclause 15.4.2.1, item d) does not apply.

NOTE In case of the loss of function indicated in item d) it is up to the ME SYSTEM to maintain ESSENTIAL PERFORMANCE and to prevent the HAZARDOUS SITUATIONS described in 13.1 of the general standard; an X-RAY TUBE ASSEMBLY cannot maintain these aspects in case of such loss of function.

201.16 ME SYSTEMS

Clause 16 of the general standard does not apply.

NOTE While subclause 16.3 is applicable in principle, this requirement is covered in 201.7.9.3.101 instead.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard does not apply.

Replacement:

The MANUFACTURER shall address in the RISK MANAGEMENT process the RISKS associated with:

– the electromagnetic phenomena the X-RAY TUBE ASSEMBLY is exposed to during INTENDED USE; and
– the introduction by the X-RAY TUBE ASSEMBLY of electromagnetic phenomena that might degrade the performance of other devices, electrical equipment and systems.

The MANUFACTURER of the X-RAY TUBE ASSEMBLY is not required to assess electromagnetic capability according to IEC 60601-1-2 on the stand-alone X-RAY TUBE ASSEMBLY.

NOTE RISKS for the X-RAY TUBE ASSEMBLY outside the system can only be indicative of RISKS for the system due to the difference in electromagnetic environment.

Compliance is checked by 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 X-RAY TUBE ASSEMBLIES, compliance with this document is to be stated, the statement shall be made in the following form:

X-RAY TUBE ASSEMBLY ..... *), IEC 60601-2-28:2017

* MODEL OR TYPE REFERENCE

If means other than those described in this document have been used to achieve equivalent safety, the variations shall be mentioned in the ACCOMPANYING DOCUMENTS when stating compliance with this document.

203.7 RADIATION QUALITY

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

Addition:

NOTE The requirements for HALF-VALUE LAYERS in 7.1 pertain to X-RAY EQUIPMENT and not to X-RAY TUBE ASSEMBLIES alone.

203.7.3 Indication of FILTER properties

Replacement:

The text in the second paragraph, first dash, is replaced by:

X-RAY TUBE ASSEMBLIES shall be marked with their PERMANENT FILTRATION according to IEC 60522 or with the thickness(es) of the material(s) concerned, together with its/their chemical symbol(s).

203.12 Protection against LEAKAGE RADIATION

203.12.5 LEAKAGE RADIATION when not in the LOADING STATE

Addition:

Subclause 12.5 is not applicable for X-RAY TUBE ASSEMBLIES where X-RAY production is not possible in the non-loading state, e.g. for X-RAY TUBE ASSEMBLIES designed for primary HIGH VOLTAGE switching operation.

Annexes

The annexes of the general standard apply.

Additional annex:

Annex AA
(informative)

Test of X-RAY TUBE ASSEMBLIES for expelled parts-related and/or tube implosion-related RISKS

AA.1 Overview

The kinetic and thermal energy stored in the rotating system of the ANODE, coupled with a malfunction, are potential sources of pressure and of disintegration of the X-RAY TUBE, and in consequence of parts being expelled or liquids being spilled. The evaluation of the concomitant RISKS determines whether or not testing is required. If this evaluation concludes that testing is required, this particular standard does not prescribe a mandatory, generally-valid test for expelled parts, pressure, X-RAY TUBE implosion or explosion, because there are too many different types of X-RAY TUBES, X-RAY TUBE ASSEMBLIES, X-RAY SOURCE ASSEMBLY and X-RAY EQUIPMENT configurations, with – consequently – different test setups. Instead, the tests and conditions indicated in this annex are for information only. As the tests are based on long-standing practice and experience, they may nevertheless often be considered representative.

MANUFACTURERS can choose to perform the test mentioned in this annex, as long as the RISK MANAGEMENT FILE states and reasons, that the test so performed is appropriate.

AA.2 General considerations

Whether a test is appropriate depends on many conditions. These conditions are mentioned with the test performed, based on a reasoning (calculations, experience, …) as to the appropriateness of the conditions.

All known weak spots of the X-RAY TUBE HOUSING are subject to testing. More than one test set-up may be necessary to fulfil this requirement.

Regarding the conditions for a test, at least the following aspects should be considered:

a) temperature of the ANODE;

b) ANODE SPEED;

c) type of medium enveloping the X-RAY TUBE (oil, water, …);

d) temperature of medium enveloping the X-RAY TUBE;

e) electrical condition of the X-RAY TUBE:

- HIGH VOLTAGE (on or off, value of voltage, …);
- filament supply (on or off, value of current, …);
- rotor-unit energized or not;

f) weak spots of the X-RAY TUBE HOUSING (weakest spot can be the RADIATION APERTURE, or mechanical joints, …);

g) parts to be contained (fractured ANODE, medium enveloping the X-RAY TUBE, …);

h) X-RAY EQUIPMENT configuration (BEAM LIMITING DEVICE, protective covers, location of the X-RAY TUBE ASSEMBLY i.e. under table, overhead, in a CT-gantry, etc.).

AA.3 Test procedure

Out of the list of start conditions for the test below, it will be clear that certain safety devices (e.g. temperature-cut-out) would be made in-active for some test conditions or combinations of test conditions. The following conditions simulate the result of demanding applications:

a) the X-RAY TUBE has been loaded such that the maximum permitted temperature for the medium enveloping the X-RAY TUBE has been attained and has been maintained for at least 10 min;

b) the ANODE of the ROTATING ANODE X-RAY TUBE rotates at the maximum SPECIFIED ANODE SPEED;

c) HIGH VOLTAGE is on;

d) filament is energized;

e) rotor unit is energized;

f) the X-RAY TUBE shall then be further loaded for 2 min at the corresponding highest SPECIFIED ANODE INPUT POWER.

The implosion of the X-RAY TUBE is then induced by disintegration of the ENVELOPE of the X-RAY TUBE, e.g. by mechanical impact on the ENVELOPE. The evaporation of the cooling liquid while hitting the hot ANODE will lead to pressure which may force deformation of the housing and cooling liquid spilled or (ENVELOPE-) fragments being expelled. There is also a chance on disintegration of the ANODE – in that case this test would also determine whether ANODE-fragments are expelled. However, for a well-designed X-RAY TUBE, disintegration of the ANODE is very unlikely. So, disintegration of the ANODE is induced by applying conditions beyond the SPECIFIED ANODE ratings, e.g. higher than SPECIFIED ANODE SPEED, or by defects that may weaken the ANODE (notches, etc.).

AA.4 Pass/fail criteria

Pass/fail criteria are based on the results of the RISK MANAGEMENT process. Whether expelled parts or fragments, or the escape of insulating/cooling medium poses a RISK, depends on the X-RAY TUBE ASSEMBLY and system-configuration.

Bibliography

IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

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*

IEC 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

ISO 13732-1, *Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Part 1: Hot surfaces*

Index of defined terms used in this particular standard

NOTE The definitions used in this particular standard can be viewed at <http://std.iec.ch/glossary>.

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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La Norme Internationale IEC 60601-2-28 a été établie par le sous-comité 62B: Appareils d'imagerie de diagnostic, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2010. Cette édition constitue une révision technique.

La troisième édition de la présente norme particulière a été établie pour correspondre à l'IEC 60601-1:2005 et à l'IEC 60601-1:2005/AMD1:2012 (troisième édition amendée de l'IEC 60601-1), qui est désignée comme la norme générale. Outre les modifications relatives à l'amendement de l'IEC 60601-1, les modifications relatives aux améliorations techniques sont également incluses.

Le texte de cette norme est issu des documents suivants:

FDIS	Rapport de vote
62B/1040/FDIS	62B/1051/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme particulière.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains.

– *modalités d'essais: caractères italiques.*

– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères.

– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure de la présente norme, le terme

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans la présente norme, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans la présente norme, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité à la présente norme;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-28: Exigences particulières pour la sécurité de base et les performances essentielles des gaines équipées pour diagnostic médical

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique, avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des GAINES EQUIPEES et de leurs composants, destinés au diagnostic médical et à l'imagerie.

Lorsque la norme générale IEC 60601-1 et la norme collatérale IEC 60601-1-3, font référence aux APPAREILS EM, cela doit être interprété comme une référence aux GAINES EQUIPEES dans la présente norme particulière. Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, son titre et son contenu l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

NOTE Le présent document est également applicable aux aspects relatifs aux GAINES EQUIPEES des ENSEMBLES RADIOGENES A RAYONNEMENT X et des TETES DES TUBES RADIOGENES.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières relatives à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des GAINES EQUIPEES pour diagnostic médical.

201.1.3 Normes collatérales

Addition:

La présente norme particulière se réfère aux normes collatérales applicables spécifiées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-3:2008 et l'IEC 60601-1-3:2008/AMD1:2013 s'applique telle que modifiée par l'Article 203. L'IEC 60601-1-2, l'IEC 60601-1-6, l'IEC 60601-1-8, l'IEC 60601-1-9, l'IEC 60601-1-10, l'IEC 60601-1-11 et l'IEC 60601-1-12 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

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1 La norme générale est l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

NOTE 101 L'IEC 60601-1-2 ne s'applique pas parce que les RISQUES pour la GAINE EQUIPEE à l'extérieur du système peuvent n'offrir qu'une valeur indicative des RISQUES pour le système, en raison de la différence d'environnement électromagnétique.

NOTE 102 L'IEC 60601-1-6 et l'IEC 60601-1-8 ne s'appliquent pas parce que les GAINES EQUIPEES ne sont pas exploitées en tant que dispositifs autonomes.

NOTE 103 Les GAINES EQUIPEES ne sont pas dans le domaine d'application de l'IEC 60601-1-10, de l'IEC 60601-1-11 ni de l'IEC 60601-1-12.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012 est désignée dans la présente norme particulière par le terme "norme générale". Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe "20x", où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont spécifiées par l'utilisation des termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"*Addition*" signifie que le texte de la présente norme particulière est complémentaire aux exigences de la norme générale ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière".

Les paragraphes, les figures ou les tableaux qui viennent s'ajouter à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, comme les définitions dans la norme générale sont numérotées 3.1 à 3.147, les définitions complémentaires dans la présente norme sont numérotées à partir de 201.3.201. Les annexes complémentaires sont référencées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le numéro final de la référence de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression « le présent document » est utilisée pour faire référence à la norme générale, à toute norme collatérale applicable et à la présente norme particulière, prises comme un tout.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-3:2008, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*
IEC 60601-1-3:2008/AMD1:2013

Addition:

IEC 60336, *Appareils électromédicaux – Gaines équipées pour diagnostic médical – Caractéristiques des foyers*

IEC 60522, *Détermination de la filtration permanente des gaines équipées*

IEC 60613:2010, *Caractéristiques électriques et de charge des gaines équipées pour diagnostic médical*

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

201.3 Termes et définitions

L'Article 3 de la norme générale s'applique, avec les exceptions suivantes:

Pour les besoins du présent document, les termes et les définitions donnés dans la norme générale, les normes collatérales applicables, l'IEC 60613:2010, l'IEC 60522, l'IEC 60336 et l'IEC TR 60788:2004, ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

201.3.71
UTILISATION NORMALE

Addition:

Note 1 à l'article: Lorsqu'il est utilisé dans la présente norme, le terme défini UTILISATION NORMALE est compris comme s'appliquant uniquement à la GAINE EQUIPEE fonctionnant dans un APPAREIL A RAYONNEMENT X.

201.4 Exigences générales

L'Article 4 de la norme générale s'applique, avec les exceptions suivantes:

201.4.3 PERFORMANCE ESSENTIELLE

Addition:

L'entité GAINE EQUIPEE elle-même n'a pas de PERFORMANCES ESSENTIELLES. Le fait de devoir considérer les caractéristiques d'une GAINE EQUIPEE comme des PERFORMANCES ESSENTIELLES dépend des caractéristiques du système à rayonnement X et du GENERATEUR RADIOLOGIQUE combinées à la GAINE EQUIPEE.

201.4.4 DUREE DE VIE PREVUE

Addition:

La DUREE DE VIE PREVUE peut aussi être basée sur des mesures relatives à l'utilisation.

NOTE 101 Exemples d'utilisation: nombre d'images obtenues par scanner, radiographies, examens de patients.

NOTE 102 Les GAINES EQUIPEES sont des consommables, c'est-à-dire que leur utilisation aboutit finalement à leur remplacement. De par sa conception, la GAINE EQUIPEE assure la SECURITE DE BASE tout au long de son cycle de vie et de son remplacement.

NOTE 103 La DUREE DE VIE PREVUE caractérise les délais de remplacement estimés d'une population de GAINES EQUIPEES. La DUREE DE VIE PREVUE est basée sur une analyse statistique de survie, par exemple, de 5 % des GAINES EQUIPEES dans la population.

201.4.11 Puissance absorbée

Le paragraphe 4.11 de la norme générale ne s'applique pas.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique, avec l'exception suivante:

201.5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence

Addition à l'alinéa 5.5 f):

Un GENERATEUR RADIOLOGIQUE non spécifié dans les DOCUMENTS D'ACCOMPAGNEMENT peut être utilisé si les caractéristiques essentielles pour un essai donné sont équivalentes aux caractéristiques du GENERATEUR RADIOLOGIQUE SPÉCIFIÉ.

201.5.7 Pré-conditionnement humide

Addition:

Pour les GAINES EQUIPEES qui ne doivent être utilisées que dans des environnements contrôlés, comme cela doit être SPECIFIE dans les DOCUMENTS D'ACCOMPAGNEMENT, aucun préconditionnement humide n'est exigé.

201.5.9 Détermination des PARTIES APPLIQUEES et des PARTIES ACCESSIBLES

201.5.9.2 PARTIES ACCESSIBLES

Le paragraphe 5.9.2 de la norme générale ne s'applique pas.

NOTE L'accessibilité des parties de la GAINE EQUIPEE devra nécessairement être évaluée sur des parties intégrées à un APPAREIL A RAYONNEMENT X spécifique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique, avec l'exception suivante:

201.6.2 Protection contre les chocs électriques

Addition:

Les GAINES EQUIPEES doivent être classées comme appareils de la CLASSE I.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique, avec les exceptions suivantes:

201.7.1 Généralités

201.7.1.1 APTITUDE A L'UTILISATION de l'identification, du marquage et de la documentation

Le paragraphe 7.1.1 de la norme générale ne s'applique pas.

NOTE L'interface utilisateur fait partie de l'APPAREIL A RAYONNEMENT X, mais pas de la GAINE EQUIPEE.

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.2 Identification

Remplacement du premier alinéa par:

La GAINE EQUIPEE doit être marquée:

– du nom ou de la marque commerciale et de l'adresse du FABRICANT;
– de la REFERENCE DU MODELE OU DU TYPE;
– de l'identification individuelle;
– de la date de fabrication.

NOTE 101 Voir l'ISO 15223-1 pour les symboles correspondant au FABRICANT, au numéro de série, au lot, à l'année de fabrication et à la date limite d'utilisation.

NOTE 102 Voir également 201.7.2.102.

201.7.2.5 APPAREILS EM destinés à être alimentés par d'autres appareils

Le paragraphe 7.2.5 de la norme générale ne s'applique pas.

NOTE Pour les exigences applicables, voir 201.7.9.3.101.

201.7.2.11 Mode de fonctionnement

Le paragraphe 7.2.11 de la norme générale ne s'applique pas.

NOTE Les GAINES EQUIPEES ne sont pas mises en fonctionnement en tant que dispositifs autonomes.

201.7.2.14 DISPOSITIFS DE RACCORDEMENT HAUTE TENSION

Remplacement:

Les raccordements de câbles HAUTE TENSION entre la GAINE EQUIPEE et le GENERATEUR RADIOLOGIQUE accessible en UTILISATION NORMALE doivent être marqués du symbole de l'IEC 60417-5036 (2002-10) (voir le Tableau D.1, symbole 24) à moins qu'un OUTIL ne soit exigé pour le retrait du raccordement de câble.

201.7.2.15 Conditions de refroidissement

Addition:

Le marquage des conditions de refroidissement n'est pas exigé si l'unité de refroidissement et la GAINE EQUIPEE ont été conçues pour être compatibles.

NOTE Une unité de refroidissement est un dispositif autonome ou bien fait partie intégrante de la GAINE EQUIPEE, et assure l'augmentation de la capacité de refroidissement de la GAINE EQUIPEE.

Paragraphes complémentaires:

201.7.2.101 Marquage des TUBES RADIOGENES

Les marquages sur le TUBE RADIOGENE doivent rester lisibles lorsque le TUBE RADIOGENE est démonté de la GAINE RADIOGENE après une période d'UTILISATION NORMALE.

Les marquages doivent permettre la corrélation des produits individuels, séries ou types avec les DOCUMENTS D'ACCOMPAGNEMENT.

Les TUBES RADIOGENES doivent être fournis avec les marquages suivants:

- le nom ou la marque commerciale du FABRICANT;
- la REFERENCE DU MODELE OU DU TYPE;
- l'identification individuelle.

Les marquages ci-dessus peuvent être faits sous forme d'identification combinée telle qu'elle est précisée dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.2.102 Marquage sur l'extérieur des GAINES EQUIPEES

Les GAINES EQUIPEES doivent être fournies avec les marquages suivants:

- la HAUTE TENSION NOMINALE pour laquelle la GAINE EQUIPEE est conçue;
- s'il y a plusieurs réceptacles du câble HAUTE TENSION, l'indication de la polarité des réceptacles du câble HAUTE TENSION;
- la (les) taille(s) du FOYER. Si la (les) taille(s) du FOYER est (sont) dans la plage des VALEUR(S) NOMINALE(S) DU FOYER de l'IEC 60336, marquer alors la (les) taille(s) du FOYER comme VALEUR(S) NOMINALE(S) DU FOYER conformément à l'IEC 60336.

NOTE Voir également 201.7.2.2 et 203.7.3.