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

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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