IEC 60601-2-28

Edition 2.0 2010-03

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 60601-2-28:2010

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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 second edition cancels and replaces the first edition published in 1993. This edition constitutes a technical revision.

The second edition of this particular standard has been prepared to fit IEC 60601-1:2005 (the third edition of IEC 60601-1), which is referred to as the general standard.

When the first edition was developed, mainly X-RAY TUBE ASSEMBLIES holding a glass insert were considered and IEC 60601-1:1988 (the second edition of the general standard) was in place. While the variety of modern X-RAY TUBE ASSEMBLIES and technologies has increased, the third edition of the general standard requires the MANUFACTURER to perform RISK MANAGEMENT. The technical modifications versus the first edition of IEC 60601-2-28 account for these changes.

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

FDIS	Report on voting
62B/778/FDIS	62B/784/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 Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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 amendment and the base 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 International Standard 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.

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 International Standard 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 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 and IEC 60601-1-11 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 and IEC 60601-1-11.

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

201.1.4 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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

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*

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

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

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 be considered ESSENTIAL PERFORMANCE, depends on the X-ray system and HIGH-VOLTAGE GENERATOR characteristics combined with the X-RAY TUBE ASSEMBLY.

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.

201.5.7 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.

201.6 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

201.7.2.5 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.

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.

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.

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).

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 is allowed to perform the work, so safe operation is assured.

201.7.9 ACCOMPANYING DOCUMENTS

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

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) NOMINAL FOCAL SPOT VALUE(S) according to IEC 60336;

e) PERMANENT FILTRATION according to IEC 60522;

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

NOTE 1 The preceding two FILTRATION requirements cover the 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 cooling unit, or a fan), appropriate for the safe application of the X-RAY TUBE ASSEMBLY as defined in the RISK MANAGEMENT FILE;

k) CATHODE EMISSION CHARACTERISTIC;

NOTE 2 For the 4 preceding items, 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) precautions to be observed before the first LOADING upon completion of the installation of an X-RAY TUBE ASSEMBLY, and special procedures for conditioning the X-RAY TUBE, if appropriate;

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

NOTE 3 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 standard, the technical description of the X-RAY TUBE ASSEMBLY in this chapter 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:

201.8.7 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.

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.

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:

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.

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. X-RAY TUBE ASSEMBLY MANUFACTURERS may test for pressure-related RISKS, but, as protective means may also be provided by the system, and as the application of the X-RAY TUBE ASSEMBLY is system-dependent, these test results are only indicative of the RISK at system level. Considerations on the tests which may be applied are given in Annex AA.