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INTERNATIONAL STANDARD

CONSOLIDATED VERSION

**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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

IEC 60601-2-28 edition 3.1 contains the third edition (2017-06) [documents 62B/1040/FDIS and 62B/1051/RVD] and its amendment 1 (2026-09) [documents 62B/1396/CDV and 62B/1409/RVC].

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

International Standard IEC 60601-2-28 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 document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION to the Amendment

This first amendment to the third edition of IEC 60601-2-28 has been prepared to provide a complete set of safety requirements for X-RAY TUBE ASSEMBLIES, based on the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. It corrects references to actual standards (e.g. IEC 60336, IEC 60522-1, and the IEC 60601 series) and clarifies single requirements within the standard.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

201.1 Scope, object and related standards

Clause 1 of the general standard¹ 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, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 ~~applies~~ 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.

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

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 3.147154, 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

IEC 60601-1-3:2008/AMD2:2021

Addition:

IEC 60336, *Medical electrical equipment - X-ray tube assemblies for medical diagnosis - ~~Characteristics of focal spots~~ Focal spot dimensions and related characteristics*

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

IEC 60522-1, *Medical electrical equipment - Diagnostic X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration*

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

IEC 60806, *Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis*

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

Bibliography

IEC 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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*

IEC Guide 117:2010, *Electrotechnical equipment - Temperatures of touchable hot surfaces*

IEC TR 60552-2:2020, *Medical electrical equipment - Diagnostics X-rays - Part 2: Guidance and rationale on quality equivalent filtration and permanent filtration*

ISO 13732-1:2006, *Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces*

ISO TR 24971:2020, *Medical devices - Guidance on the application of ISO 14971*