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INTERNATIONAL STANDARD

AMENDMENT 1

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

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AMENDMENT 1

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Amendment 1 to IEC 60601-2-28:2017 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62B/1396/CDV	62B/1409/RVC

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

The committee has decided that the contents of this document 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– withdrawn, or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.

NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

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.

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201.1 Scope, object and related standards

Replace, in the existing footnote 1, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012", *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.1.3 Collateral standards

Replace, in the existing second paragraph of the Addition, "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 applies as modified in Clause 203.", *with* "IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply as modified in Clause 203.".

201.1.4 Particular standards

Replace, in the existing third paragraph of the Replacement, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012", *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

Replace, in the existing eighth paragraph of the Replacement, "3.147" *with* "3.154".

201.2 Normative references

Replace the existing reference of the Replacement "IEC 60601-1-3:2008" *with:*

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

Replace the existing reference of the Addition "IEC 60336" *with:*

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

Replace the existing reference of the Addition "IEC 60522" *with:*

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

Add the following reference to the Addition:

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

201.3 Terms and definitions

In the second paragraph, replace the existing reference to "IEC 60522" *with* "IEC 60522-1".

201.7.2.2 Identification

Replace the third dash item by:

– individual identification (e.g. serial number); and

201.7.2.11 Mode of operation

Delete the existing NOTE.

201.7.2.101 Marking of X-RAY TUBES

Replace the existing subclause by:

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

- name or trademark of the MANUFACTURER;
- MODEL OR TYPE REFERENCE; and
- individual identification (e.g. serial number).