

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-54: Particular requirements for the basic safety and essential performance
of X-ray equipment for radiography and radioscopy**

**Appareils électromédicaux –
Partie 2-54: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à rayonnement X utilisés pour la radiographie et la
radioscopie**



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Withdrawn

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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IEC 60601-2-54 has been developed for use with the third edition of IEC 60601-1 (2005). It replaces and supersedes IEC 60601-2-7 and IEC 60601-2-32, as well as IEC 60601-2-28:1993 (currently under revision), all of which were developed to amend earlier editions of IEC 60601-1 and consequently no longer apply to this particular standard.

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

FDIS	Report on voting
62B/735/FDIS	62B/750/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.

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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 maintenance result 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.

The contents of the corrigenda of March 2010 and June 2011 have been included in this copy.

INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

Withdrawn