

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-43: Particular requirements for the basic safety and essential performance
of X-ray equipment for interventional procedures**

**Appareils électromédicaux –
Partie 2-43: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à rayonnement X lors d'interventions**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

FOREWORD

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International standard IEC 60601-2-43 has been prepared by IEC 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 2000. This edition constitutes a technical revision.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on the third edition of IEC 60601-1 and relevant collaterals. The present edition is extended to become a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

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

FDIS	Report on voting
62B/779/FDIS	62B/792/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.

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 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.

Withdrawn

INTRODUCTION

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES may subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT may be the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

Interventional procedures of the type envisaged are well established in clinical fields such as:

- invasive cardiology;
- interventional RADIOLOGY;
- interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

Withdrawing