

INTERNATIONAL STANDARD

NORME INTERNATIONALE



AMENDMENT 2 AMENDEMENT 2

**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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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1137/FDIS	62B/1146/RVD

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

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 website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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INTRODUCTION to Amendment 2

The purpose of this second amendment to IEC 60601-2-43:2010 is to introduce changes as follows:

- scope clarification with regards to MOBILE X-ray equipment and applicability of IEC 60601-2-54 subclauses;
- reference to IEC 60601-2-54:2009/AMD2:2018 for common subclauses;
- alignment of 201.7.9.1 with IEC 60601-2-54:2009/AMD2:2018 – 201.7.9.1 is no longer modified;
- inclusion of adapted requirements or recommendations from IEC 60601-2-54:2009/AMD2:2018 for
 - management of radioscopy image storage in 203.6.1.101,
 - display of last image hold (LIH RADIOGRAM) in 203.6.7.101, and
 - graphical indication of the boundaries of the X-RAY FIELD in 203.8.102.2;
- inclusion of a recommendation for protection of gantry enclosures in 201.11.6.5.103;
- inclusion of a requirement for X-RADIATION pulse repetition frequency during radioscopy in 203.6.3.103;