

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 1  
AMENDEMENT 1

**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:

| CDV          | Report on voting |
|--------------|------------------|
| 62B/1012/CDV | 62B/1037/RVC     |

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

## INTRODUCTION to the Amendment

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

- refer to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its applicable collateral standards;
- refer to IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 and consequent subclause adaptations;
- include a requirement to have a maximum time of 10 min to recover all functions after a recoverable failure in 201.4.101;
- include several aspects from IEC 61910-1:2014 and remove the reference to IEC PAS 61910-1:2007 in 201.4.102;
- include an alternative way of testing in 201.11.6.5.103;
- include a clarification for tableside controls in 201.12.4.106.

In addition, a number of technical errors have been corrected.

### 201.1 Scope, object and related standards

*Replace the text of the existing footnote by the following:*