



INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Medical electrical equipment –
Part 2-31: Particular requirements for the basic safety and essential performance
of external cardiac pacemakers with internal power source**

**Appareils électromédicaux –
Partie 2-31: Exigences particulières pour la sécurité de base et les performances
essentielle des stimulateurs cardiaques externes à source d'énergie interne**





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

FOREWORD

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This publication is published as a double logo standard.

This third edition cancels and replaces the second edition published in 2008 and Amendment 1:2011. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) The requirement for testing for energy reduction has been removed;
- b) The test for exposure to external defibrillation has been completely revised;

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- c) The exclusion for testing ESD immunity only with respect to air discharges has been removed;
- d) Alignment with the latest edition of ISO 14708-2 for pacemakers, as well as the associated EMC standard ISO 14117;
- e) Additional rationale for all changes.

The text of this International Standard is based on the following documents of IEC:

FDIS	Report on voting
62D/1719/FDIS	62D/1732A/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 10 P members out of 10 having cast a vote.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, 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;
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- "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.);
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