

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**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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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical 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
62D/918/FDIS	62D/931/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 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- withdrawn,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.

INTRODUCTION

The purpose of this amendment is to address comments received during the process of harmonizing the standard in Europe, update several references to defined terms that were not printed in SMALL CAPS, and improve terminology usage.

INTRODUCTION

Replace the term "IMPLANTABLE" in the first and third lines of the third paragraph with the same term in normal case

Replace the defined terms "pacemaker" and "patient" in the fourth line of the fifth paragraph with the same terms in SMALL CAPS.

201.1.1 Scope

Replace the second paragraph with:

This standard applies to PATIENT CABLES as defined in 201.3.109, but does not apply to LEADS as defined in 201.3.106.

Delete the third paragraph.