INTERNATIONAL STANDARD

IEC 60601-2-31

1994

AMENDMENT 1
1998-01

Amendment 1

Medical electrical equipment –

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

Amendement 1

Appareils électromédicaux –

Partie 2-31:
Règles particulières de sécurité 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/252/FDIS	62D/269/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.

A bilingual version of this amendment may be issued at a later date.

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INTRODUCTION

Replace the text of the first paragraph by the following:

This Particular Standard concerns the safety of PACEMAKERS. The relationship of this Particular Standard with IEC 60601-1 (including its amendments) and the Collateral Standards is explained in 1.3.

Replace the text of the fourth paragraph by the following:

PACEMAKERS differ in the various ways in which they maintain and monitor cardiac activity in different circumstances. The simplest model stimulates the atrium or ventricle independently of the cardiac activity; others detect atrial or ventricular activity and stimulate the atrium or ventricle as and when this is necessary; others, more complex, detect the spontaneous heart activity and stimulate appropriately the atrium and/or the ventricle. Certain PACEMAKERS work on preset frequency values, amplitudes and impulse duration. Others can have several values for parameters.

Delete the sixth paragraph.

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1.3 Particular standards

Replace the text of the first two paragraphs by the following:

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2; IEC 60601-1-1:1992, *Medial electrical equipment – Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems*, amendment 1; IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety, 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests,* and IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety, 4. Collateral Standard: Programmable electronic medical systems.*

For brevity, IEC 60601-1 is referred to in this Particular Standards either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1, IEC 60601-1-2 and IEC 60601-1-4 as the “Collateral Standards”.

The term “this Standard” covers this Particular Standard, used together with the General Standard and Collateral Standards.

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2 Terminology and definitions

Replace the text of 2.1.102 by the following:

2.1.102
MAXIMUM TRACKING RATE
maximum ventricular pacing rate in response to sensed atrial activity

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Replace the text of 2.1.105 by the following:

2.1.105
POST-VENTRICULAR ATRIAL REFRACTOR PERIOD (PVARP)
period after a ventricular event (whether sensed or paced), during which synchronous ventricular pacing is disabled, regardless of any atrial event

6 Identification, marking and documents

6.8 Accompanying documents

6.8.2 Instructions for use

Add, on page 17, the following:

a) Replacement:*

Replace the text of the third dash by the following:

– Instructions for use shall include warnings regarding potential changes in the behaviour of the PULSE GENERATOR caused by electromagnetic or other interference sources (e.g. communication transmitters in hospitals, emergency transport vehicles, cellular telephones, etc.) and the effects of therapeutic and diagnostic energy sources (e.g. external cardioversion, diathermy, TENS devices, high-frequency surgical equipment, magnetic resonance imaging or similar sources) on the PULSE GENERATOR. This shall include advice on recognizing when the behaviour of the PULSE GENERATOR is being influenced by external interference sources and steps to be taken to avoid such interference.

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aa) Supplementary instructions for use

3)* *Replace the text of the fifth indent by the following:*

– sensing amplifier blanking period(s) (if a sensing function is provided);

6)* *Replace the existing text by the following:*

6) Not used.

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12)* *Replace the text of the fourth indent by the following:*

– inspection of the NON-IMPLANTABLE PULSE GENERATOR and PATIENT CABLE for signs of physical damage or contamination, in particular damage or contamination that may have a detrimental effect on the electrical isolation properties of the EQUIPMENT;

Add new items 13) and 14) as follows:

13)* A warning that, before handling the EXTERNAL PULSE GENERATOR, the PATIENT CABLE or indwelling LEADS, steps should be taken to equalize the electrostatic potential between the USER and the PATIENT, for example by touching the PATIENT at a site remote from the pacing LEAD.

14)* A caution that, when clinically indicated, supplemental monitoring of the PATIENT should be considered.

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36* Electromagnetic compatibility

Replace the text of the first two paragraphs by the following:

This clause of the General Standard applies, except as follows:

36.202.1* ELECTROSTATIC DISCHARGE

Replacement:

Construction of the EQUIPMENT shall ensure a sufficient degree of protection against SAFETY HAZARDS caused by repeated exposure to ELECTROSTATIC DISCHARGE.

Replace the last sentence in the third paragraph of the compliance test by the following:

No inappropriate delivery of energy to the APPLIED PART shall occur at any severity level specified in table 102.