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

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http: //www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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.

Page 11

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.

Page 13

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.

Page 25

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.

Page 33

51 Protection against hazardous output

Add the following:

51.1* Intentional exceeding of safety limits

Replacement:

If the EQUIPMENT incorporates features which require PULSE RATES above the rate limit (see 51.104), the runaway rate protection may be disarmed when the feature is in use. The means for disarming the runaway rate protection shall require the USER to engage continuously the activating mechanism.

Compliance is checked by inspection and by a functional test.

Page 35

51.104 Rate limit (runaway protection)

Add an asterisk to the subclause number, delete "a)" and delete paragraph b).*

51.106* MAXIMUM TRACKING RATE

Replace the text of the first paragraph by the following:

In DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing, a means shall be provided to set a limit at which the ventricle is paced in response to sensed atrial activity. The EQUIPMENT shall respond to sensed atrial activity above the MAXIMUM TRACKING RATE in a manner stated by the manufacturer.

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56 Components and general assembly

56.3 Connections – General

Delete "Addition" and the two paragraphs that follow.

Annex AA
(informative)

General guidance and rationale

Page 43

Hazard analysis

Replace the text of the first paragraph by the following:

EXTERNAL PACEMAKERS are used to treat PATIENTS who have symptomatic or acute bradycardia as well as for temporary pacing related to other medical procedures. PATIENT safety is affected by the medical procedure involved, by the understanding of EQUIPMENT function by the clinician and by EQUIPMENT function. The requirements as specified in this Standard are considered to provide for an acceptable level of safety.

Page 45

Table AA.1, change the fourth entry under "Unwanted stimulation" to read:

Unwanted stimulation	Noise	Noise reversion Warnings	6.8.2 *aa)* 3) and 51.105 6.8.2 *a)* Third dash

Table AA.1, change the second entry under "Micro/macro shock" to read:

Micro/macro shock	Injection current	Warnings	6.8.2 *a)* Third dash, 6.8.2 *aa)* 5), 6.8.2 *aa)* 7) and 6.8.2 *aa)* 8)

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Add a new subclause as follows:

6.8.2 *a)* Sources of electrical interference may affect the operation of the EQUIPMENT. In the presence of excessive levels of interference, the EQUIPMENT may:

– fail to pace,

– revert to asynchronous pacing, or

– inappropriately track the interference as cardiac activity.

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Delete 6.8.2 aa) 6).