INTERNATIONAL STANDARD

IEC 60601-2-31

1994

AMENDMENT 1
1998-01

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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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Page 9

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.*

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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.

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.

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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.

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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.

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Annex AA
(informative)

General guidance and rationale

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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.

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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).

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Add new items 6.8.2 aa) 13) and 6.8.2 aa) 14) as follows:

6.8.2 *aa)* 13) Although believed to be, at best, a rare complication of pacing, there is a theoretical possibility that a static discharge to the EXTERNAL PULSE GENERATOR or a PATIENT CABLE connected to it could transfer minimally sufficient energy to the PATIENT to produce cardiac depolarization. If this were to occur in an electrically unstable PATIENT during the vulnerable portion of the cardiac cycle, a potentially lethal arrhythmia might be induced. No documented cases or anecdotal reports of such an event are known. It should be noted that there are ways that one or more asynchronous pulses may be delivered to the PATIENT (e.g. noise reversion, loss of sensing) all of which are much more likely and which typically are cautioned about in the labelling. While only rarely have these common occurrences precipitated an arrhythmia, medical literature leaves no doubt as to the potential for serious consequences. Therefore, a warning that care should be taken to discharge any static electricity that has accumulated on the attending health care professional or the PATIENT before touching the EQUIPMENT is appropriate.

6.8.2 *aa)* 14) The pulse energy delivered to the PATIENT is a consequence of the setting of the EXTERNAL PULSE GENERATOR and interaction of that output with a dynamic PATIENT/LEAD environment. The acute load presented by the temporary PATIENT/LEAD system can vary over a range of several hundred ohms. While much of this variation may be clinically inconsequential, “significant” departures from the pre-set level of energy output can occur. Since what constituted a “significant” departure from the pre-set level of energy output will vary widely from PATIENT to PATIENT depending on many factors, including the pre-set margin of safety for capture, selecting a limit that could be monitored by the EQUIPMENT and that would apply to all PATIENTS would necessarily leave other PATIENTS largely unprotected. The output circuitry cannot readily determine if the output resulted in capture of the heart.

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Subclause 19.4 *j)* 4)

Replace the text of the second paragraph by the following:

NON-IMPLANTABLE PULSE GENERATORS may provide a “recharge” pulse whose area (integral of amplitude over time) is equal to that of the pacing pulse and of opposite polarity. The purpose of a recharge pulse is to make the net current through the tissue and the LEAD zero. Since the “recharge” pulse would immediately follow the pace pulse, the measurement for PATIENT AUXILIARY CURRENT (d.c. offset) is performed just before the start of the pace pulse so that the “recharge” pulse is not included in the measurement.

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36 Electromagnetic compatibility

Add, after the first paragraph on page 57, the following:

This test is intended to demonstrate that the insulation resistance is high enough and the capacitance is low enough that the energy is not conducted through the ENCLOSURE to the circuitry causing inappropriate energy to be sent to the APPLIED PART.

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Add the following new subclause:

51.1 Intentional exceeding of safety limits

If high pacing rates are used in specific circumstances, extra precautions should be taken to prevent accidental high rate stimulation and to prevent the EQUIPMENT from being inadvertently left with the runaway rate protection feature disabled.

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Replace 51.104 a) by 51.104.

Delete 51.104 b).

Replace 51.106 by the following:

51.106 If DUAL CHAMBER modes incorporating atrial-synchronous ventricular pacing are available in the EQUIPMENT, a means should be provided to limit the ventricular pacing rate in response to sensed atrial activity to prevent deterioration of the haemodynamic state of the PATIENT. This value is independent of the runaway limit which is intended to prevent an excessively high pacing rate in the event of a SINGLE FAULT CONDITION.

Delete 56.3 aa).

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