# INTERNATIONAL STANDARD

# IEC 60601-2-10

1987

AMENDMENT 1
2001-09



Amendment 1

## Medical electrical equipment –

## Part 2-10: Particular requirements for the safety of nerve and muscle stimulators



*Amendement 1*

*Appareils électromédicaux –*

*Partie 2-10:*
*Règles particulières de sécurité*
*pour stimulateurs de nerfs et de muscles*



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PRICE CODE J

*For price, see current catalogue*

# 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/413/FDIS | 62D/420/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 the base publication and its amendments will remain unchanged until 2004. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of January 2002 have been included in this copy.



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PREFACE



*Replace the final two paragraphs of the Preface with the following new text:*

A rationale for the more important requirements, where appropriate, is given in annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this standard.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk (*) before their number.

*The numbers of the following clauses should be preceded by an asterisk in the main body of the text:*

*1.1, 5.2, 5.6, 6.1, 6.8.2 aa), 14.6, 19, 20.2, 46.101, 50.1, 50.2, 51.101, 51.102, 50.103, 51.104, 57.3*

SECTION ONE – GENERAL

Page 7

## 1 Scope and object

### 1.1 Scope

*At the end of the 4th dashed item add:* (partly covered by IEC 60601-2-31)

*At the end of the 7th dashed item add:* (covered by IEC 60601-2-40)

*At the end of the 8th dashed item add:* (covered by IEC 60601-2-40)

*Add the following subclauses:*

### 1.3 Particular Standards

*Add the following new text:*

This Particular Standard for NERVE AND MUSCLE STIMULATORS is to be read in conjunction with the following standard:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

The requirements of this Particular Standard take priority over the above-mentioned standard and its amendments, hereinafter referred to as the General Standard.



### 1.5 Collateral Standards

*Add the following new text:*

The following Collateral Standards apply:

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*
Amendment 1 (1999)

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**2.1.102 Pulse duration**

*Replace* “waveform” *by* “WAVEFORM”.

**2.1.103 Waveform**

*Replace* "the APPLIED PART" *by* "a PATIENT CIRCUIT".

## 4 General requirements for tests

**4.1** Item b)

*Delete 4.1, Item b.*

*Add the following new text:*

**4.6** *Additional Item:*

*aa) Where reference is made in test specifications to electrode cables and/or electrodes, those supplied or recommended by the manufacturer shall be used.*

## 5 Classification

**5.1** *Amendment:*

*Delete subclause 5.1.*

**5.2** *Amendment:*

*Replace* "TYPE B EQUIPMENT" *by* "TYPE B APPLIED PART".

## 6 Identification, marking and documents

**6.1 Marking on the outside**

*Replace the existing title with* “**Marking on the outside of EQUIPMENT or EQUIPMENT parts**".

**6.1 j) Power input**

*Replace* "MAINS OPERATED" *by* "mains operated".

**6.1 p) Output**

*Replace* "Appendix D" *by* "Appendix D, Table DI".

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### 6.8 Accompanying documents

#### 6.8.2 Instructions for use

*Item aa) e):*

*Add the following new dashed item:*

– Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

## 7 Power input

*Replace, on page 13, first line, the numbering of subclause* "7.3" *by* "7.1".

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SECTION TWO – SAFETY REQUIREMENTS

*Change title to* "SECTION TWO — ENVIRONMENTAL CONDITIONS".

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS



## 14 Requirements related to classification

### 14.3 Class III equipment

*Delete subclause 14.3.*

### 14.4 *Item a)*

*Delete subclause 14.4*

### 14.6 *Replacement:*

*In the text replace* "STIMULATORS shall be TYPE BF or CF EQUIPMENT". *by* "THE APPLIED PARTS of STIMULATORS shall be TYPE BF or TYPE CF APPLIED PARTS".

## 20 Dielectric strength

### 20.3 Values of test voltages

*In the text, on page 15, replace* "EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE" *by* "INTERNALLY POWERED EQUIPMENT".

# SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATIONS

## 36 Electromagnetic compatibility

*Replace the existing text by:*

*Replacement:*

IEC 60601-1-2 applies except as follows:

### 36.201 EMISSIONS

### 36.201.1 Radio-frequency (RF) EMISSIONS

**36.201.1.7** *Replacement:*

For the radiated radio-frequency emissions test, all relevant electrodes shall be connected and applied to the contents of a 1 000 ml capacity normal saline-filled phantom, positioned within 400 mm of the EQUIPMENT (see figure 101).

### 36.202 IMMUNITY

### 36.202.2 Radiated radio-frequency electromagnetic fields

#### 36.202.2.1 Requirements

Item a)

*Replace the text of this item by the following:*

For radiated radio-frequency electromagnetic fields, the EQUIPMENT and/or system shall:

– continue to perform its intended function as specified by the manufacturer at a level up to 3 V/m for the frequency range of 26 MHz to 1 GHz, and

– continue to perform its intended function as specified by the manufacturer or fail without creating a safety hazard at levels between 3 V/m and 10 V/m for the frequency range of 26 MHz to 1 GHz.

#### 36.202.2.2 Test conditions

Item d)

*Replace the text of this item by the following:*

*For the radiated radio-frequency electromagnetic field test, all relevant electrodes shall be connected and applied to the contents of a 1 000 ml capacity normal saline-filled phantom, positioned within 400 mm of the EQUIPMENT (see figure 101).*