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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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- withdrawn;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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Page 5

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

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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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Page 9

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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Page 11

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".

Page 13

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".

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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).

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Page 19

SECTION SIX – PROTECTION AGAINST HAZARDS OF EXPLOSIONS IN MEDICALLY USED ROOMS

Change title to "SECTION SIX — PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES".

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS, SUCH AS HUMAN ERRORS

Change title to "SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS"

42 Excessive temperatures

This clause of the General Standard applies except as follows:

Amend the compliance test for the requirements of subclauses 42.1 to 42.3 as follows:

5) Test criteria

Additional third paragraph:

Compliance with the requirements for maximum temperatures specified in the General Standard shall be checked under the conditions specified in Item aa) of subclause 7.1.

Page 21

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

In the title, replace "INCORRECT" *by* "HAZARDOUS".

51 Protection against incorrect output

In the title, replace "**incorrect**" *by* "**hazardous**".

Page 23

51.104 Limitation of output parameters

Item a):

Replace twice, in the last paragraph, "output circuit(s)" by "PATIENT CIRCUIT(S)".

Item b)

Delete "For other diagnostic applications, the limits for the output parameters are under consideration".

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SECTION NINE – FAULT CONDITIONS CAUSING OVERHEATING AND/OR MECHANICAL DAMAGE; ENVIRONMENTAL TESTS

Change title to "SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS"

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

57 MAINS PARTS, components and layout

57.3 Mains supply cables or cords

Change title to **"POWER SUPPLY CORDS"**

Page 24

Replace the existing Figure 101 with the new Figure 101:

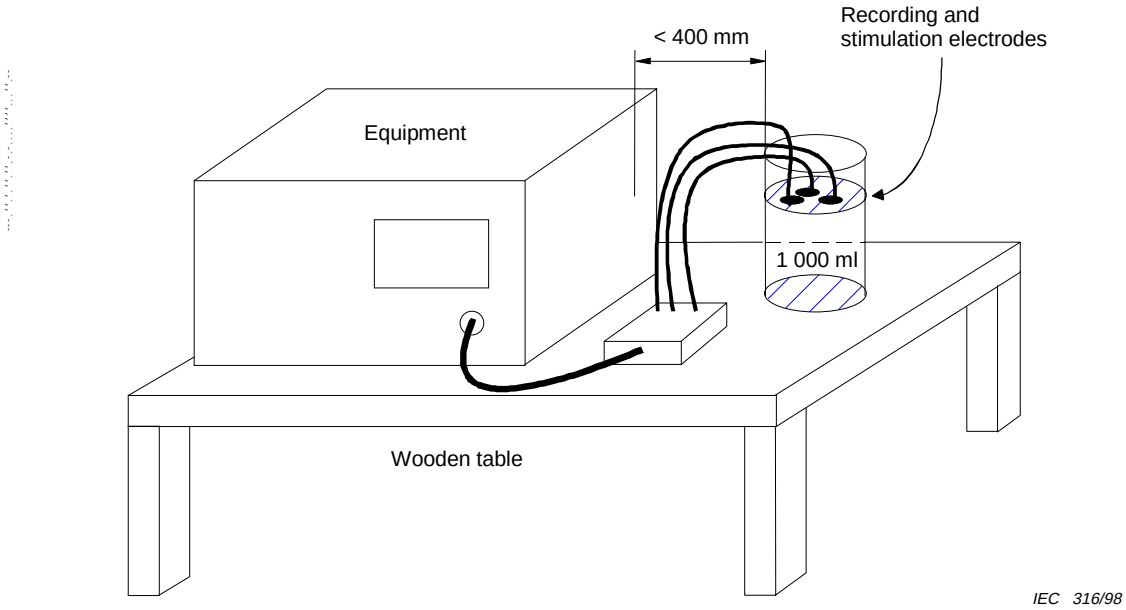


Figure 101 – Layout of testing arrangements (see 36.201.1.7 and 36.202.2.2d)

Page 25

Delete Figure 102.

Page 26

Delete Figure 103.

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Page 29

Replace the entire page by the following:

Appendices A to L of the General Standard apply.

APPENDIX L References – Publications mentioned in this standard

Add the following references:

IEC 60601-2-31:1994, *Medical electrical equipment – Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source*

IEC 60601-2-40:1998, *Medical electrical equipment – Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment*

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APPENDIX AA Rationale

AA.5 Classification

Delete subclause AA.5.1.

AA.6 Identification, marking and documents

AA.6.8.2 aa)

Item e)

Delete second dashed item.

Delete dash at start of first dashed item.

Page 33

Delete subclause AA.14.3.

AA.19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT

Replacement:

Following the definitions in the General Standard, the therapeutic current flowing between the electrodes of a STIMULATOR through the PATIENT is neither a PATIENT AUXILIARY CURRENT nor a PATIENT LEAKAGE CURRENT, but a functional current.

AA.36 Electromagnetic compatibility

Replacement:

The tests using the normal saline-filled phantom (see 36.201.1.7 and 36.202.2.2) are derived from IEC 60601-2-40. Normal saline is standard physiological saline: 0,9 % or 9 g/L or 0,15 M.

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