INTERNATIONAL STANDARD

IEC 60601-2-3

1991

AMENDMENT 1
1998-09

Amendment 1

Medical electrical equipment –

Part 2:
Particular requirements for the safety of short-wave therapy equipment

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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/292/FDIS	62D/298/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.

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INTRODUCTION

This amendment contains a series of revisions to IEC 60601-2-3 (second edition, 1991) taking into account amendments 1 and 2 of the General Standard, which include reference to the collateral standards. The technical content remaining essentially unchanged.

NOTE – The page numbers referenced in this amendment are those in IEC 60601-2-3:1991.

Page 3

CONTENTS

Delete clauses 13 and 18 from the Contents.

Page 5

Replace "FIGURES 101 à 104" *by* "FIGURES 101 to 104"

Page 9

INTRODUCTION

Replace in the last sentence "...an * after..." *by* "...an asterisk (*) before...".

Page 11

1 Scope and object

Add, after the introductory sentence of this clause, the following subclause heading:

1.1 Scope

Replace, in the existing text of the first paragraph of the Addition, "Sub-clause 2.1" *by* "subclause 2.1.101".

Replace the second paragraph of the Addition by the following:

"LOW POWER EQUIPMENT as defined in subclause 2.2.101 is exempted from certain requirements of this standard".

Add the following subclause to the Particular Standard:

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. 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*

2 Terminology and definitions

Add, after 2.1.103, the following new definition:

2.2.101 LOW POWER EQUIPMENT

EQUIPMENT having a RATED OUTPUT POWER not exceeding 10 W.

Page 13

4.11 Sequence

In the Amendment replace "temperature-rise test of Sub-clause 42.4" *by* "compliance test which follows subclause 42.3".

***5.2 Amendment:**

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

Page 15

6.1 Marking on the outside of EQUIPMENT

p) Output

In the text of the first dash of the Replacement, replace "power in watts" *by* "POWER in watts".

6.8.2 Instructions for use

Page 17

Replace the introductory sentence before item aa) 2. c) by the following:

For all EQUIPMENT except LOW POWER EQUIPMENT:

Replace the text of item aa) 2. d) by the following:

Short-wave therapy should not be applied to PATIENTS through clothing. Additionally, it should not be applied to PATIENTS wearing metallic objects like jewellery or clothing containing metallic material (for example metallic buttons, clips or thread).

In the text of item aa) 2. h) replace "or conductive" *by* "or with conductive".

6.8.3 Technical description

In the parenthetical text of Additional item aa), replace "Sub-clause 50.2" *by* "clause 50".

7 Power input

In the second line replace "*Item a)* of the compliance test" *by* "Compliance test, first dash, first sentence".

In the third line replace "Amendment:" *by* "Replacement:".

Page 19

14.6 Replacement:

Replace the existing text by the following:

APPLIED PARTS of SHORT-WAVE THERAPY EQUIPMENT shall be TYPE BF or CF.

17 Separation

In the first line of item aa) replace "LIVE PARTS" *by* "LIVE parts" *and, at the beginning of the second sentence, replace* "protectively earthed" *by* "PROTECTIVELY EARTHED".

Page 21

19.2 *Item b)*

In the Addition, replace "between the APPLIED PART" *by* "between APPLIED PARTS".

Page 23

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Replace the title "INTRODUCTION" *by* "General".

Delete the first paragraph of the Addition.

36 Electromagnetic compatibility

Replace the title "Replacement:" *by* "36.201.1 Radiofrequency (RF) EMISSIONS, Addition:"

Delete the first paragraph.

In the compliance text delete "Sub-clause 5.3.1.1 of".

Page 25

42 Excessive temperatures

Replace the title "Tests, addition:" *by* "42.3 compliance test, additional item 6):".

In the fourth line of the text replace "Sub-clause 50.2" by "clause 50".

In the fifth line of the text replace "Sub-clause 42.4" by "the compliance test which follows subclause 42.3".

*50 Accuracy of operating data

In the third paragraph of the Replacement, replace "EQUIPMENT having a RATED OUTPUT POWER not exceeding 10 W" by "LOW POWER EQUIPMENT".

*Replace, on page 27, in the second paragraph of the second note of the Replacement "*The test circuit consisted*" by "*The test circuit consists*".*

Page 27

***51.2** Replacement:

*At the end of the first paragraph replace "*Sub-clause 50.2*" by "*clause 50*"*

Page 29

After the title "Additional sub-clauses:" delete the introductory sentence.

***51.101**

In the text, replace "The EQUIPMENT" *by* "EQUIPMENT other than LOW POWER EQUIPMENT".

***51.102**

In the text, replace "The EQUIPMENT" *by* "EQUIPMENT other than LOW POWER EQUIPMENT".

***51.103**

In the text, replace "EQUIPMENT" *by* "EQUIPMENT other than LOW POWER EQUIPMENT".

Page 39

AA50 Accuracy of operating data

In the first line of the last paragraph, replace "EQUIPMENT with a RATED OUTPUT POWER not exceeding 10 W" *by* "LOW POWER EQUIPMENT".

AA51.2

In the first sentence, replace "Safety hazards" *by* "SAFETY HAZARDS".

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