INTERNATIONAL STANDARD

IEC 60601-2-18

1996

AMENDMENT 1
2000-07

Amendment 1

Medical electrical equipment –

Part 2-18: Particular requirements for the safety of endoscopic equipment

Amendement 1

Appareils électromédicaux –

Partie 2-18: Règles particulières de sécurité pour appareils d'endoscopie

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FOREWORD

This amendment has been prepared by sub-committee 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/360/FDIS	62D/365/RVD

Full information on 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 2002. At this date, the publication will be:

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- withdrawn;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

INTRODUCTION

The only significant amendment relates to the addition of an exclusion from subclause 56.3 c) of Amendment 2 of the General Standard, as this subclause was added to the General Standard amendment after the text of the 2nd edition of IEC 60601-2-18 had been finalized, and was therefore not taken into account during its preparation.

Page 5

CONTENTS

Add the following after the SECTION 10 heading:

Page 11

INTRODUCTION

Replace the text of the first paragraph as follows:

This Particular Standard concerns the safety of ENDOSCOPIC EQUIPMENT. The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in 1.3 and 1.5 respectively.

Page 13

1.3 Particular Standards

Replace the text of the instruction and the first three paragraphs of this subclause as follows:

Replacement:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2 and associated Collateral Standards (see subclause 1.5).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The term "this Standard" covers this Particular Standard, used together with the General Standard and relevant Collateral Standards.

Page 15

In the first line of the fourth paragraph on this page, replace "...clause of subclause...*" by "*...clause or subclause...*" (English version only).*

In the second line of the eighth paragraph on this page, replace "...irrelevant...*" by "*...relevant...*" (English version only).*

In the ninth paragraph on this page, replace the text as follows:

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the corresponding General Requirement(s).

Add, after 1.3 the following new subclause 1.5:

1.5 Collateral Standards

Addition:

The following Collateral Standards apply to ENDOSCOPIC EQUIPMENT:

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

2.1.4 APPLIED PART

Replace the subclause number by 2.1.5 so that it reads:

2.1.5 APPLIED PART

(English version only)

Amend the text at end of subclause 2.1.5, within the existing parentheses, as follows:

", see 17 *a)* and 17 *c)* of the General Standard"

Page 17

***2.1.103** ENDOSCOPIC EQUIPMENT

Delete the asterisk (*) from in front of the subclause number, so that it reads:

2.1.103 ENDOSCOPIC EQUIPMENT

2.1.104 HIGH FREQUENCY SURGICAL EQUIPMENT

Replace "IEC 601-2-2" *by* "IEC 60601-2-2".

2.1.105 LIGHT EMISSION PART

In the second line of this definition, replace "...end..." *by* "...forward...".

***2.5.101 CAPACITIVELY COUPLED HF CURRENT**

In the second line of this definition, replace "...endoscope..." *by* "...ENDOSCOPE..." (English version only).

Page 19

***6 Identification, marking and documents**

In the fourth line of the paragraph headed "Addition", *replace* "...distant..." *by* "...distal..." (English version only).

Page 21

After the item entitled f) MODEL OR TYPE REFERENCE, and before the line which reads "Additional item", add the following subclause title:

6.4 Symbols

aa) Additional markings

In the third line of this requirement, replace "...shall..." *by* "...may...".

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

***bb) Advice when used with HIGH FREQUENCY SURGICAL EQUIPMENT**

In the third line of requirement 1 of this item, on page 23, replace "...for each mode of intended use..." *by* "...for the mode(s) of intended use...".

Page 25

20 Dielectric strength

20.2 Requirements for EQUIPMENT with an APPLIED PART

In the item commencing "B-a", *replace* "...live..." *by* "...LIVE...".

Page 29

42 Excessive temperature

***42.3** *Replacement of requirement only*

In the fourth line of the second paragraph of item c) of this subclause, replace "...issue..." *by* "...tissue..." *(English version only).*

Replace the test requirement by:

Compliance with the above requirements is checked at an ambient temperature of 25 °C.

42.5 Guards

In the third line of this requirement, replace "IEC 417" *by* "IEC 60417".

Page 31

***42.101 Thermal hazards from the use of ENDOSCOPES and ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS OF HIGH FREQUENCY SURGICAL EQUIPMENT**

Replace the text of this subclause as follows:

a) INTERCONNECTION CONDITIONS for high frequency applications

Sufficient protection shall be provided between an ENDOSCOPE AND ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS of HF SURGICAL EQUIPMENT when used together to protect the PATIENT and/or OPERATOR from SAFETY HAZARDS associated with thermal energy.

Sufficient protection will be achieved if the insulation material is stable when subjected to thermal stress and the necessary dielectric strength is present.

The insulation may be provided either on the ENDOSCOPICALLY-USED ACCESSORY or on the ENDOSCOPE or a proportion on each.

This requirement replaces subclause 59.103.2 of IEC 60601-2-2, 3rd edition, for the INTERCONNECTION CONDITIONS of ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS of HF SURGICAL EQUIPMENT.

Compliance is checked as follows:

The tests shall be performed at a test voltage related to the RATED high frequency recurring peak voltage(s) specified by the manufacturer of the ENDOSCOPE and/or ENDOSCOPICALLY-USED ACCESSORY in the instructions for use (see 6.8.2 bb)), as detailed in the following test methods.

The purpose of these tests is:

– *to check the stability of the insulation material when subjected to thermal stress; and*

– *to check the dielectric strength of the insulation.*

Test samples representative of all the different insulation types and configurations used in the ENDOSCOPE *and/or* ENDOSCOPICALLY-USED ACCESSORY *shall be prepared and preconditioned by immersion in physiological saline solution for a period of at least 12 h, but no longer than 24 h, immediately prior to the tests.*

Those parts of the test samples which are not insulated in NORMAL USE shall be adequately protected against contact with the saline solution during preconditioning, and this protection shall be left in place during the tests.

1) Insulation material thermal stability test

A quantity of transformer oil is added to the saline solution, just sufficient to produce a visible continuous film on the surface, in order to reduce the curvature of the meniscus.

The test samples are partially immersed in physiological saline solution, so that a part of the relevant insulated portion of each test sample is positioned at the surface of the saline solution. Test samples which are long and flexible may be looped for this test.

Tests shall be performed on test samples for each of the main operating modes (or high frequency voltage modes with physically equivalent effects) specified in the instructions for use of the ENDOSCOPE *and/or* ENDOSCOPICALLY-USED ACCESSORY*, in accordance with the test procedures detailed below.*

The test voltage is applied for 30 s in such a manner that it stresses the insulation of the test sample.

– *Cut mode*

Apply an approximately sinusoidal voltage at a frequency of 400 kHz ± 100 kHz at 110 % of the RATED recurring peak voltage for cut mode specified by the manufacturer of the ENDOSCOPE *or* ENDOSCOPICALLY-USED ACCESSORY*.*

– *Coagulation burst mode*

Apply an approximately sinusoidal voltage with a decaying waveform at a frequency of 400 kHz ± 100 kHz at 110 % of the RATED recurring peak voltage for coagulation burst mode specified by the manufacturer of the ENDOSCOPE *or* ENDOSCOPICALLY-USED ACCESSORY*, such that the repetition rate of the peak pulse is 40 kHz ± 4 kHz. If the repetition rate is less than 40 kHz – 4 kHz, the test period of 30 s shall be increased so that the same number of bursts are experienced by the test sample as if a repetition rate of 40 kHz had been used.*

– *Coagulation spray mode*

Apply an approximately sinusoidal voltage with a decaying waveform at a frequency of 400 kHz ± 100 kHz at 110 % of the RATED recurring peak voltage for coagulation spray mode specified by the manufacturer of the ENDOSCOPE or ENDOSCOPICALLY-USED ACCESSORY such that the amplitude of the second pulse of the waveform is less than 50 % of the amplitude of the first pulse and the repetition rate of the peak pulse is 20 kHz ± 2 kHz. If the repetition rate is less than 20 kHz – 2 kHz, the test period of 30 s shall be increased so that the same number of bursts are experienced by the test sample as if a repetition rate of 20 kHz had been used, however a repetition rate less than 10 kHz shall not be used.

No breakdown of the insulation material shall occur in any mode tested.

2) Dielectric strength test

Immediately after the test(s) performed in accordance with 1) above, the following test shall be performed.

The same part(s) of the relevant insulated portion(s) of the test sample(s) are immersed in physiological saline solution.

Apply a DC or mains frequency peak test voltage to the test sample(s) which is 1 000 V greater than the maximum RATED recurring peak voltage specified by the manufacturer of the ENDOSCOPE *or* ENDOSCOPICALLY-USED ACCESSORY*.*

The test voltage is applied for 30 s in such a manner that it stresses the insulation of the test sample.

No breakdown of the insulation shall occur.

b) CAPACITIVELY COUPLED HF CURRENT from the eyepiece

The eyepiece of an ENDOSCOPE intended for use with ENDOSCOPICALLY-USED ACCESSORIES which are the APPLIED PARTS of HF SURGICAL EQUIPMENT shall be isolated in order to protect the OPERATOR from the thermal effects of CAPACITIVELY COUPLED HF CURRENT.

Non-conducting coatings, such as lacquer and the like, which cannot provide durable isolation, shall not be used for isolation of the eyepiece.

Compliance is checked as follows :

– *by inspection alone*

  (i) if the eyepiece is made from non-conductive material; or

  (ii) if under NORMAL USE and SINGLE FAULT CONDITION it is determined that it is not possible to conduct a CAPACITIVELY COUPLED HF CURRENT from the ENDOSCOPICALLY-USED ACCESSORY to the eyepiece

– *by the following test if the eyepiece is made of conductive material and condition (ii) above is not satisfied:*

Measure the CAPACITIVELY COUPLED HF CURRENT using the circuit and layout shown in figure 102. The CAPACITIVELY COUPLED HF CURRENT shall not exceed 50 mA.

Page 35

Add the following clause and subclause to SECTION TEN:

56 Components and general assembly

56.3 Connections – General

**c)*

Addition:

Subclause 56.3 *c)* of the General Standard does not apply to ENDOSCOPES, ENDOSCOPICALLY-USED ACCESSORIES or their ACCESSORIES.

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

Replace the text of this subclause as follows:

Additional subclause:

*aa) The requirements of 57.10 do not apply to secondary LIVE circuits isolated from MAINS VOLTAGE by DOUBLE INSULATION or REINFORCED INSULATION within ENDOSCOPES or to INTERCONNECTION CONDITIONS, but the requirements of IEC 60664-1, pollution degree 1, shall be met.

Page 37

Figure 101 - Identification of LIGHT EMISSION PART

Replace "End viewing ENDOSCOPES" *by* "Forward viewing ENDOSCOPES".

Page 41

Appendix L References – Publications mentioned in this standard

Replace the text of this appendix as follows:

Appendix L of the General Standard applies except as follows:

Amendment:

Amend all reference numbers for IEC publications by prefacing them with "60".

Addition:

To the reference to IEC 60601-1-1:1992, add "Amendment 1 (1995)"

IEC 60601-2-2:1998, *Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment*

IEC 60601-2-37, *Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic diagnostic and monitoring equipment* (to be published)

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

CISPR 11:1997, *Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement*

Page 43

Annex AA (informative) Rationale

2 Definitions

2.1.101 ENDOSCOPE

In the second paragraph of this subclause, replace "IEC 601-2-37" by "IEC 60601-2-37".

2.1.106 SUPPLY UNIT

In the last line of this subclause, replace "IEC 601-1-1" by "IEC 60601-1-1".

Page 45

3 General requirements

3.102 *In this subclause, replace* "IEC 601-2-37" *by* "IEC 60601-2-37".

6 Identification, marking and documents

6.8.2 Instructions for use

bb) Advice when used with HIGH FREQUENCY SURGICAL EQUIPMENT

In the second paragraph of this subclause, on page 47, replace "IEC 601-2-2" by "IEC 60601-2-2".

Page 49

42 Excessive temperatures

42.3

Modify the first line of the fourth paragraph by deleting "...b) and c)..." *and adding* "...the" *before* "requirements".

42 Excessive temperatures

42.101

Replace the second paragraph on page 51 as follows:

The test requirements differ from those in IEC 60601-2-2 because neither the manufacturers of the ENDOSCOPE nor those of the ENDOSCOPICALLY-USED ACCESSORY have control over the specification of the HF SURGICAL UNIT being used. The individual components or representative test samples should therefore be tested independently or together at a test voltage related to the RATED recurring peak voltage of the ENDOSCOPE and/or ENDOSCOPICALLY-USED ACCESSORY, not the maximum open circuit HF voltage of the HF SURGICAL UNIT.

Because of the difficulty in testing some finished devices (for instance, working channels of ENDOSCOPES), it is considered acceptable to test representative samples of all insulation types and configurations used in the final product in lieu of the finished device.

When conducting the HF test on large samples immersed in saline, it may be difficult to maintain the test voltage due to the large capacitive load applied to the test equipment. In this case, shorter representative samples should be used in order to restore the test voltage.

Page 51

Add the following:

56 Components and general assembly

56.3 *c)* Endoscopic procedures require constant supervision by suitably trained medical personnel. PATIENTS are not left unattended with ENDOSCOPIC EQUIPMENT attached to them, nor are they moved from one location to another with ENDOSCOPIC EQUIPMENT attached. As a result, the misconnection of APPLIED PART connectors to other than compatible EQUIPMENT is considered to be very unlikely.

57 MAINS PARTS, components and layout

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

In the first paragraph of item aa), replace "IEC 664-1" *by* "IEC 60664-1".