INTERNATIONAL STANDARD

IEC 60601-2-2

Third edition
1998-09

Medical electrical equipment –

Part 2-2:
Particular requirements for the safety of high frequency surgical equipment

Appareils électromédicaux –

Partie 2-2:
Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* IEC web site http: //www.iec.ch.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-2 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition of IEC 60601-2-2 cancels and replaces the second edition published in 1991, and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/291/FDIS	62D/297/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
– *test specifications: in italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

INTRODUCTION

The revisions for this third edition of the Particular Standard refer mainly to the following:

– Split NEUTRAL ELECTRODES are dealt with in more detail.
– Limitation of incorrect output power in SINGLE FAULT CONDITION.
– The requirements for AP EQUIPMENT are revised.
– White indicator lamps on coloured backgrounds for CUTTING and COAGULATION mode are no longer allowed.
– Limitation of monitoring current to 100 µA for HF SURGICAL EQUIPMENT with BF or CF APPLIED PARTS.
– Revised requirements for CREEPAGE DISTANCE and AIR CLEARANCE of APPLIED PARTS.
– Simultaneous activation of more than one PATIENT CIRCUIT is dealt with in more detail and a compliance test method is now defined.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the safety of high frequency surgical equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of HIGH FREQUENCY SURGICAL EQUIPMENT used in medical practice, as defined in 2.1.101 and hereinafter referred to as HF SURGICAL EQUIPMENT.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this Particular Standard. These exemptions are indicated in the relevant requirements.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of HF SURGICAL EQUIPMENT.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of

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

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*

For brevity, IEC 60601-1 is referred to, in this Particular Standard, either as the “General Standard” or as the “General Requirement(s)”, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-1-4 as the Collateral Standard(s).

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

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk*. These rationales can be found in an informative annex AA. Annex AA should be used in determining the relevance of the requirements addressed but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or of Collateral Standards applies without modification. Where it is intended that any part of the General Standard or Collateral Standards, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

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

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

***2.1.101**
HF SURGICAL EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT including its associated ACCESSORIES intended for the performance of surgical operations, such as the CUTTING or COAGULATION of biological tissue by means of high frequency (h.f.) currents.

2.1.102
ACTIVE ELECTRODE
Electrode intended to produce certain physical effects required in electrosurgery, for example CUTTING and COAGULATION.

2.1.103
BIPOLAR ELECTRODE
Assembly of two ACTIVE ELECTRODES on the same support, so constructed that, when energized, the h.f. current flows mainly between these two electrodes.

2.1.104
NEUTRAL ELECTRODE
Electrode of a relatively large area for connection to the body of the PATIENT, intended to provide a return path for the high frequency current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided.

NOTE – The NEUTRAL ELECTRODE is also known as plate, plate electrode, passive, return or dispersive electrode.

2.1.105
ENDOSCOPICALLY USED ACCESSORY
See definition in IEC 60601-2-18:1996.

NOTE – The reader is referred to IEC 60601-2-18 to ensure that a consistent definition is used.

2.12.101
RATED OUTPUT POWER
The power in watts produced when the h.f. output is fed into the RATED LOAD.

2.12.102
CUTTING
Resection or dissection of body tissue caused by the passage of high frequency current of high current density at the ACTIVE ELECTRODE(S).

2.12.103
COAGULATION
Sealing of small blood vessels or of body tissue caused by the passage of high frequency current at the ACTIVE ELECTRODE(S).

2.12.104
RATED LOAD
The value of non-reactive load resistance that results in the maximum h.f. output power from each operating mode of the HF SURGICAL EQUIPMENT.

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Additional SINGLE FAULT CONDITIONS:

aa) failure in the NEUTRAL ELECTRODE monitoring circuit which would result in a SAFETY HAZARD (see 59.101);

bb) a defect in the output switching circuit resulting in an excessive low frequency PATIENT LEAKAGE CURRENT (see 56.11);

cc) any defect which results in the unwanted energization of the PATIENT CIRCUIT (see 59.102);

dd) any defect which results in a significant increase in output power relative to the output setting (see 51.5).

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

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

This clause of the General Standard applies except as follows:

*5.2 According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

l) *Classification*

Additions:

The relevant symbols required for marking DEFIBRILLATION-PROOF APPLIED PARTS shall be attached to the front panel, but are not required on the APPLIED PARTS.

Connections on the HF SURGICAL EQUIPMENT for the NEUTRAL ELECTRODE leads shall be marked with the following symbols.

 for PATIENT CIRCUITS according to 19.3.101 a) 1)

 for PATIENT CIRCUITS according to 19.3.101 a) 2)