INTERNATIONAL STANDARD

IEC 60601-2-2

Third edition
1998-09

Withdrawn

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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

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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.
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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.

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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.

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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*

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