SLOVENSKI STANDARD
SIST EN 60601-2-2:1995

01-maj-1995

Medical electrical equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment (IEC 601-2-2:1991)

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

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Hochfrequenz-Chirurgiegeräten

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

Ta slovenski standard je istoveten z: **EN 60601-2-2:1993**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN 60601-2-2:1995 **en**

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPÄISCHE NORM

EN 60601-2-2

April 1993

UDC 621.3:615.47.001.25:615.472:
621.3.023-777.001.2.001.4(083.71):614.825.001.25

Supersedes HD 395.2.2 S1:1985

Descriptors: Medical electrical equipment, h.f. surgery, instructions for use, electrical safety, testing, construction, definitions, requirements

ENGLISH VERSION

Medical electrical equipment
Part 2: Particular requirements for the safety of high frequency surgical equipment
(IEC 601-2-2:1991)

Appareils électromédicaux
Deuxième partie: Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence
(CEI 601-2-2:1991)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Hochfrequenz-Chirurgiegeräten
(IEC 601-2-2:1991)

This European Standard was approved by CENELEC on 1992-12-09. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

FOREWORD

At the request of the CENELEC Technical Committee TC 62, Electrical equipment in medical practice, the International Standard IEC 601-2-2:1991 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992 for acceptance as a European Standard.

The text of the International Standard was approved by CENELEC as EN 60601-2-2 on 9 December 1992.

This European Standard supersedes HD 395.2.2 S1:1985.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1993-09-15
- latest date of withdrawal of conflicting national standards	(dow)	1993-09-15

For products which have complied with HD 395.2.2 S1:1985 before 1993-09-15, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1998-09-15.

Annexes designated "normative" are part of the body of the standard. In this standard, annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-2:1991 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
601-1	1977	Safety of medical electrical equipment	HD 395.1 S2	1988
A1	1984	Part 1: General requirements	+ A1	1993
601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
601-2-2	1982	Part 2: Particular requirements for the safety of high frequency surgical equipment	HD 395.2.2 S1	1985
CISPR 11 (mod)	1990	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency	EN 55011*	1991

---

* The title of EN 55011:1991 is: Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-2

Deuxième édition
Second edition
1991-09

Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité pour appareils d'électrochirurgie à courant haute fréquence

Medical electrical equipment

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

Bureau Central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève, Suisse

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE W

Pour prix, voir catalogue en vigueur
For price, see current catalogue

CONTENTS

Clause Page

SECTION 8 - ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION 9 - ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION 10 - CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Particular Standard has been prepared by Sub-Committee 62D: Electromedical equipment of IEC Technical Committee No. 62: Electrical equipment in medical practice.

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

Six Months' Rule	Report on Voting	Two Months' Procedure	Report on Voting
62D(CO)51	62D(CO)57	62D(CO)60	62D(CO)63

Full information on the voting for the approval of this standard can be found in the Voting Reports indicated in the above table.

The following IEC publications are quoted in this Standard:

Publications Nos. 601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.

601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.

601-2-2 (1982): Medical electrical equipment. Part 2: Particular requirements for safety of high frequency surgical equipment.

Other publication:

CISPR 11 (1975): Limits and methods of measurement of radio interference characteristics of industrial, scientific and medical (ISM) radio-frequency equipment (excluding surgical diathermy apparatus).

MEDICAL ELECTRICAL EQUIPMENT

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

INTRODUCTION

This Particular Standard concerns the safety of high frequency surgical equipment. It amends and supplements IEC 601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled "Medical electrical equipment, Part 1: General requirements for safety".

A first edition of this Particular Standard was published in 1982, based on the first edition (1977) of IEC 601-1 now both revised. The revisions for this second edition refer mainly to the following:

1. Output circuits for bipolar application are dealt with in more detail.

2. The reproducibility of high frequency (hf) leakage current measurements is improved.

3. Neutral electrodes capacitively coupled to the patient are now accepted.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard.

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

In this Standard, the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;
- 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.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in appendix AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the 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 appendix does not form part of the requirements of this standard. The subclauses which have corresponding rationale statements are marked with an * after their number.

SECTION 1 - GENERAL

1 Scope and object

This clause of the General Standard applies except as follows:

Addition:

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

EQUIPMENT having a rated output power not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempted from certain of the requirements of this Standard. These exemptions are indicated in the relevant requirements.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

Output circuit including ACTIVE, NEUTRAL and BIPOLAR ELECTRODES.

Additional definitions:

2.1.101 *HIGH FREQUENCY (HF) SURGICAL EQUIPMENT*

MEDICAL ELECTRICAL EQUIPMENT including its associated accessories intended for the performance of surgical operations, such as CUTTING or COAGULATION of biological tissue by means of high frequency (hf) currents.

The use of frequencies above 0,3 MHz avoids the unwanted stimulation of nerves and muscles which would result from the use of low frequency current. Normally frequencies above 5 MHz are not used in order to minimize the problems associated with high frequency LEAKAGE CURRENTS. However, higher frequencies may be used in the case of BIPOLAR techniques.

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 and so energized that the hf current flows mainly between these two electrodes.

2.1.104 *NEUTRAL ELECTRODE*

Electrode of relatively large area for connection to the body of the PATIENT 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.

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

2.12.101 *RATED OUTPUT POWER*

Rated maximum high frequency power which can be fed into a non-reactive load resistor having a resistance between 50 Ω and 2 000 Ω in case of a monopolar output circuit and between 10 Ω and 1 000 Ω in case of a bipolar output circuit.

2.12.102 *CUTTING*

Resection of body tissue caused by the passage of high frequency current of high current density at the point of the ACTIVE ELECTRODE.

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.

3 General requirements

This clause of the General Standard applies except as follows:

3.6 *Addition:*

Additional SINGLE FAULT CONDITIONS:

- interruption of the NEUTRAL ELECTRODE circuit (see 101.1);
- a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 56.11);
- any defect which results in the energization of the output circuit (see 101.2).