

Medical electrical equipment —

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

The European Standard EN 60601-2-2:2000 has the status of a
British Standard

ICS 11.040.30

National foreword

This British Standard is the official English language version of EN 60601-2-2:2000. It is identical with IEC 60601-2-2:1998. It supersedes BS EN 60601-2-2:1993 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/97, Electrosurgical equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 April 2001

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Medical electrical equipment
Part 2-2: Particular requirements for the safety
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(IEC 60601-2-2:1998)

Appareils électromédicaux
Partie 2-2: Règles particulières de
sécurité pour des appareils
d'électrochirurgie à courant haute
fréquence
(CEI 60601-2-2:1998)

Medizinische elektrische Geräte
Teil 2-2: Besondere Festlegungen
für die Sicherheit von Hochfrequenz-
Chirurgiegeräten
(IEC 60601-2-2:1998)

This European Standard was approved by CENELEC on 2000-08-01. 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, Czech Republic, 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

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Foreword

The text of document 62D/291/FDIS, future edition 3 of IEC 60601-2-2, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-2 on 2000-08-01.

This European Standard supersedes EN 60601-2-2:1993.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2001-05-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-08-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA is normative and annexes AA and ZB are informative.

Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-2:1998 was approved by CENELEC as a European Standard without any modification.

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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 μ A 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

1) 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)

**p) Output*

Replacement:

- RATED OUTPUT POWER, in watts, and RATED LOAD, in ohms, for each operating mode.
- Operating frequency or frequencies (RATED VALUE of the fundamental frequency or frequencies), in megahertz or kilohertz.

***6.3 Marking of controls and instruments**

Additional item:

- aa) The output control shall have a scale and/or associated indicator showing the relative units of high frequency output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of $\pm 20\%$ over the total load resistance range specified in 6.8.3.

The numeral "0" shall not be used unless no h.f. power in excess of 10 mW is delivered from an ACTIVE or BIPOLAR ELECTRODE in this position.

NOTE – The compliance test is the application of clause 50.

***6.7 Indicator lights and push-buttons**

a) Colours of indicator lights

Addition:

Where certain functions are indicated by lights, these indicator lights shall have the following colours:

green	power supply switched on;
red	FAULT CONDITION, for example in the PATIENT CIRCUIT;
yellow	CUTTING mode activated;
blue	COAGULATION mode activated.

Blue and yellow lights shall not be used simultaneously for 'blend' modes. The colour shall be similar to the colour coding of the pushbutton of the fingerswitch or of the footswitch-pedal which is activated at the same time.

NOTE – Blended outputs are regarded as a CUTTING mode.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Additional items:

- *aa) Information concerning the use of suitable cables, ACCESSORIES, ACTIVE and NEUTRAL ELECTRODES, including values for the highest allowed h.f. peak voltage, in order to avoid incompatibility and unsafe operation.

Advice for the OPERATOR to ensure that connected ACCESSORIES are rated for at least the maximum peak output voltage of the HF SURGICAL EQUIPMENT set at the intended output control setting in the intended operating mode, with reference to the diagrams required by 6.8.2 ee).

*bb) Notes on the application of HF SURGICAL EQUIPMENT. These notes shall draw the attention of the OPERATOR to certain precautions which are necessary in order to reduce the risk of accidental burns. In particular, advice, when appropriate, shall be given on the following:

- *1) The entire area of the NEUTRAL ELECTRODE should be reliably attached to the PATIENT'S body and as close to the operating field as possible (see notes 1 and 2).
- *2) The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
- *3) Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze (see notes 1 and 2).
- *4) When HF SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

In all cases, monitoring systems incorporating high frequency current-limiting devices are recommended.

- *5) The cables to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads is avoided.

Temporarily unused ACTIVE ELECTRODES should be stored so that they are isolated from the PATIENT.

- *6) For surgical procedures where the h.f. current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.

- 7) The output power selected should be as low as possible for the intended purpose.

- *8) Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections. In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power (see notes 1 and 2).

- 9) The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N₂O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible.

Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of h.f. surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.

- 10) For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.

- 11) For HF SURGICAL EQUIPMENT with an operating mode as described in 46.103 b), a warning is required to the effect that the output from either ACTIVE ELECTRODE may change during use.

NOTE 1 – This requirement does not apply to HF SURGICAL EQUIPMENT only incorporating bipolar output.

NOTE 2 – This requirement does not apply to HF SURGICAL EQUIPMENT intended for use without a NEUTRAL ELECTRODE.

- cc) A warning that interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic EQUIPMENT.
- dd) Advice for the USER regularly to inspect the ACCESSORIES. In particular, electrode cables and ENDOSCOPICALLY USED ACCESSORIES should be checked for possible damage to the insulation.
- *ee) Information shall include diagrams showing the maximum possible peak output voltage of the HF SURGICAL EQUIPMENT versus the output control setting for all operating modes available.
- ff) A warning that failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.

*6.8.3 Technical description

Additional items:

- *aa) *Power output data – monopolar output (for all operating modes available, any variable “blend” control being set to the maximum position)*
 - 1) Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 100 Ω to 2 000 Ω , but extended as necessary to include the RATED LOAD.
 - 2) Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.
- *bb) *Power output data – bipolar output (for all operating modes as defined in item aa))*
 - 1) Diagrams showing the power output at full and half output control settings minimally over the range of load resistance 10 Ω to 1 000 Ω , but extended as necessary to include the RATED LOAD.
 - 2) Diagrams showing the power output versus the output control setting at a specified load resistance in the range as defined above.
- cc) *Voltage output data – monopolar and bipolar output (for all operating modes available)*
Diagrams showing the maximum possible peak output voltage versus the output control setting.
- *dd) *Designation of the APPLIED PART(S) according to 19.3.101 of this Particular Standard.*
Where HF SURGICAL EQUIPMENT is specified for use without a NEUTRAL ELECTRODE, this shall be stated.

7 Power input

This clause of the General Standard applies except as follows:

7.1

Amendment:

The operational settings shall be such that HF SURGICAL EQUIPMENT delivers the RATED OUTPUT POWER on all outputs which may be activated simultaneously.

HF SURGICAL EQUIPMENT shall be operated as specified in the test of 50.1.