

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.2 Specification for high frequency surgical equipment

The European Standard EN 60601-2-2:1993 has the status of a
British Standard

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/97, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of Clinical Pathologists
- British Anaesthetic and Respiratory Equipment Manufacturers Association
- British Dental Trade Association
- British Surgical Trades Association
- Department of Health
- Electro Medical Trade Association Limited
- Institute of Physical Sciences in Medicine
- Medical Sterile Products Association
- Ministry of Defence
- Royal College of Surgeons of England

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC Publication 601-2-2 “Medical electrical equipment — *Part 2: Particular requirements for the safety of high frequency surgical equipment*”, published in 1991 by the International Electrotechnical Commission (IEC). The differences between this British Standard and the 1983 edition include the following.

In 1993 the European Committee for Electrotechnical Standardization (CENELEC) accepted IEC 601-2-2:1991 as European Standard EN 60601-2-2:1993. As a consequence of implementing the European Standard this British Standard is renumbered as BS EN 60601-2-2 and any reference to BS 5724-2.2 should be read as a reference to BS EN 60601-2-2.

- It refers to the current, second edition (1988) of the General Standard for safety of medical electrical equipment (IEC Publication 601-1).
- It deals with output circuits for bipolar application in more detail.
- It accepts neutral electrodes capacitively coupled to the patient.
- An alternative requirement and method of test has been introduced for high frequency leakage current in order to improve reproducibility

This Particular Standard amends and supplements BS 5724-1 hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of the General Standard.

As in the General Standard the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that 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. The changes from the text of the General Standard are specified by the use of the following words.

“Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

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

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

A rationale for the most important requirements is given in Appendix AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This appendix does not form part of the standard.

Cross-references

International standard	Corresponding British Standard
IEC 601-1:1988	BS 5724 Medical electrical equipment Part 1:1989 Specification for general safety requirements (Technically equivalent)

There is no corresponding British Standard to CISPR Publication 11. The Technical Committee has reviewed the provisions of CISPR Publication 11, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 24, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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English version

Medical electrical equipment
Part 2: Particular requirements for safety
Section 2.2 Specification for 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

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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.

Section 1. General

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.

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).

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 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.

4.11 Sequence

Replacement:

The test called for in 51.102 shall be performed prior to the LEAKAGE CURRENTS and dielectric strength tests (clauses C24 and C25 of Appendix C of the General Standard).

Additional subclauses:

4.101 Routine tests

The testing during manufacture (see rationale on 4.1 of the General Standard) should include:

1. Measurement of the d.c. resistance between the ACTIVE and NEUTRAL ELECTRODE terminals or between the two terminals for a BIPOLAR ELECTRODE respectively (see 101.5).
2. Functional test of any monitoring circuit.
3. Measurement of the RATED OUTPUT POWER.
4. For category ap EQUIPMENT the tests specified in APPENDIX CC.

5 Classification

This clause of the General Standard applies as follows:

5.2 Amendment:*

Delete TYPE B EQUIPMENT.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside**6.1 Item I). Classification***

Addition:

If relevant (see 51.102 of this Particular Standard) the symbol indicating the type of protection against electric shock shall also indicate that protection against the effects of defibrillator discharge is incorporated (see Figure 101).

6.1 Item p). Output*

Replacement:

- RATED OUTPUT POWER in watts and the load resistance at which this power is available for all output circuits.