



BS 5724 : Section 2.2 : 1983
IEC 601-2-2 : 1982

UDC [615.47 : 621.313 : 614.8] : [616-72 : 621.3.023]

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British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.2 Specification for high frequency surgical equipment

Appareils électromédicaux

Partie 2. Conditions particulières de sécurité

Section 2.2 Appareils d'électrochirurgie à courant haute fréquence

Elektromedizinische Geräte

Teil 2. Besondere Anforderungen an die Sicherheit

Abschnitt 2.2 Hochfrequenzgeräte für die Chirurgie

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BS 5724 : Section 2.2 : 1983

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*Only clauses with text differing from that given in BS 5724 : Part 1 are included in this list.

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National foreword

This British Standard has been prepared under the direction of the Light Electrical Engineering Standards 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 1982 by the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724 : Part 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, sub-clauses 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, sub-clause or specified paragraph of the General Standard is replaced by the text of this standard.

'Amendment' means that the clause, sub-clause 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.

Terminology and conventions. The text of the international standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards. In particular the following print types are used

Requirements, compliance with which can be tested, and definitions: in roman type

Explanations, advice, general statements, exceptions and references: in small roman type

Test specifications: in *italic type*

Terms defined in clause 2 of the General Standard and this Particular Standard: small capitals.

Wherever page numbers are quoted, they are IEC page numbers.

Cross-reference

International standard	Corresponding British Standard
IEC 601-1 : 1977	BS 5724 Medical electrical equipment
	Part 1 : 1979 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.

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

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Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.2. Specification for high frequency surgical equipment

SECTION ONE — 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 Sub-clause 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 or dispersive electrode.

2.12.101 RATED OUTPUT POWER

Maximum high frequency power which can be fed into a non-reactive load resistor having a resistance between 50 Ω and 2 000 Ω .

2.12.102 CUTTING

Section 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.

4. General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Item b)

Addition:

Additional routine tests: see Appendix B.

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 Sub-clause 51.102 shall be performed prior to the LEAKAGE CURRENT and dielectric strength tests (Clauses C24 and C25 of Appendix C of the General Standard).

5. Classification

This clause of the General Standard applies except as follows:

5.1 Amendment:

Delete CLASS III EQUIPMENT.

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 l). Classification***Addition:*

If relevant (see Sub-clause 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, page 42.

6.1 Item p). Output*Replacement:*

- RATED OUTPUT POWER in watts and the load resistance at which this power is available.
- Operating frequency or frequencies (RATED value of the fundamental frequency or frequencies) in megahertz or kilohertz.

6.3 Marking of controls*Additional item:*

- aa) The output control shall have a scale and/or associated indicator showing relative units of high frequency output. The figure "0" shall not be used unless no power is delivered in this position.

Graduation of the output power control scale in 10 major intervals is recommended.

6.7 Indicator lights and push buttons*Item a). Colours of indicator lights**Addition:*

Where indicator lights are incorporated they shall have the following colours and provide the indications shown:

- a) green: Power supply switched on;
- b) yellow: Output circuit energized, but where CUTTING and COAGULATION output may be separately selected, two lights may be incorporated and, if so, they shall have the following colours:
 - yellow: CUTTING,
 - blue: COAGULATION;
- c) red: Fault condition in the PATIENT circuit.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Additional items:

- aa)* Information concerning the compatibility of high frequency cables in order to prevent the use of unsuitable cables.
- bb)* Notes on the application of HIGH FREQUENCY SURGICAL EQUIPMENT. These shall draw the attention of the USER to certain precautions which are necessary in order to reduce the risk of accidental burns.

In particular, advice shall be given on the following:

1. The NEUTRAL ELECTRODE should be reliably attached with its entire area to the PATIENT's body and as close to the operating field as possible.
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 the body of the PATIENT) should be avoided, for example, by insertion of dry gauze.
4. When HIGH FREQUENCY SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT is used simultaneously on the same PATIENT, any monitoring electrodes not incorporating protective resistors or hf chokes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not 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.
6. For surgical procedures on parts of the body having a relatively small cross sectional area the use of bipolar techniques may be desirable 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 surgical EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the NEUTRAL ELECTRODE or poor contact in its connections.
9. The use of flammable anaesthetics and 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 or ANAESTHETIC-PROOF EQUIPMENT is used. Flammable agents used for cleaning or disinfecting or as solvents of adhesives should be allowed to evaporate before the application of hf 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 the 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 EQUIPMENT.
10. For PATIENTS with cardiac pacemakers or pacemaker electrodes, a possible hazard exists because interference with the action of the pacemaker may occur or the pacemaker may

be damaged. In case of doubt, reference should be made to the cardiology department for advice.

11. The possibility of interference to other MEDICAL ELECTRICAL EQUIPMENT due to the operation of HF SURGICAL EQUIPMENT.

6.8.3 *Technical description*

Additional item:

aa) Output data

1. Diagrams showing the power output at full and half setting of the output control over the range of load resistance 50 Ω to 2000 Ω for the following operating modes if available:
 - 1) CUTTING
 - 2) COAGULATION
 - 3) Blend, any variable "Blend" control being set to the maximum position.
2. Diagrams showing the power output versus the output control setting at a specified load resistance in the range 50 Ω to 2000 Ω for the operating modes listed above.
3. Designation of the APPLIED PART(S) according to Items *a)*, *b)* or *c)* of Sub-clause 19.101 of this Particular Standard.

7. **Power input**

This clause of the General Standard applies except as follows:

7.1 *Amendment:*

The operational settings shall be such that the EQUIPMENT delivers the RATED OUTPUT POWER.

7.3 *Item a), after first paragraph*

Addition:

The EQUIPMENT shall be operated as specified in the test of Sub-clause 50.1 of this Particular Standard.

SECTION TWO — SAFETY REQUIREMENTS

Clauses 8 to 11 of the General Standard apply.

12. **SINGLE FAULT CONDITION**

This clause of the General Standard applies except as follows:

Addition:

- Interruption of the NEUTRAL ELECTRODE circuit (see Sub-clause 101.1).

- A defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see Sub-clause 56.11).
- Any defect which results in the energization of the output circuit (see Sub-clause 101.2).

SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13. General

This clause of the General Standard applies.

14. Requirements related to classification

This clause of the General Standard applies except as follows:

14.3 Does not apply.

14.4 Item a)

Amendment:

Delete CLASS III EQUIPMENT.

14.6 TYPES B, BF and CF EQUIPMENT

Replacement:

HF SURGICAL EQUIPMENT shall be TYPE BF or CF EQUIPMENT.

Clauses 15 to 18 of the General Standard apply.

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.1 General requirements

Item b)

Addition:

With the hf output inoperative but in such a way that the low-frequency LEAKAGE CURRENTS are not affected.

19.2 Item a)

Addition:

- the simulation of a defect in the output switching circuit resulting in an increase of PATIENT LEAKAGE CURRENT (see Sub-clause 56.11).