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British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.10 Specification for nerve and muscle stimulators

Appareils électromédicaux
Partie 2. Règles particulières de sécurité
Section 2.10 Stimulateurs de nerfs et de muscles — Spécifications

Elektromedizinische Geräte
Teil 2. Besondere Sicherheitsanforderungen
Abschnitt 2.10 Nerven- und Muskelstimulatoren

British Standards Institution

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee. It is identical with IEC Publication 601-2-10 'Medical electrical equipment' Part 2 'Particular requirements for the safety of nerve and muscle stimulators', published in 1987 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, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; the additional appendix is lettered AA, and additional items are lettered 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, 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.

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 and general statements: in small roman type.

Test procedures: 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. These are given in brackets at the foot of each page.

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)

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

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This British Standard, having been prepared under the direction of the Health Care Standards Committee, was published under the authority of the Board of BSI and comes into effect on 31 October 1988.

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Committee (HCC/-) to Technical Committee HCC/94, upon which the following bodies were represented:

British Society for Rheumatology
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British Standard

Medical electrical equipment

Part 2. Particular requirements for safety
Section 2.10 Specification for nerve and muscle stimulators

SECTION ONE — GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular Standard specifies the requirements for the safety of NERVE AND MUSCLE STIMULATORS, as defined in Sub-clause 2.1.101, for use in the practice of physical medicine, hereinafter referred to as STIMULATOR(S).

The following EQUIPMENT is excluded:

- EQUIPMENT intended to be implanted or to be connected to implanted electrodes,
- EQUIPMENT intended for the stimulation of the brain (e.g. electroconvulsive therapy EQUIPMENT),
- EQUIPMENT intended for neurological research,
- cardiac pacemakers,
- body-worn EQUIPMENT,
- STIMULATORS intended for use during surgical procedures,
- EQUIPMENT intended for averaged evoked potential diagnosis,
- EQUIPMENT intended for electromyography,
- EQUIPMENT intended for cardiac defibrillation,
- EQUIPMENT intended only as a transcutaneous nerve and muscle STIMULATOR for pain relief.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

The STIMULATOR electrodes and all parts conductively connected to them.

Additional definitions:

2.1.101 *STIMULATOR*

EQUIPMENT for the application of electric currents via electrodes in direct contact with the PATIENT for the diagnosis and/or therapy of neuromuscular disorders.

2.1.102 *PULSE DURATION*

The duration of the output pulse waveform at 50% of the maximum amplitude.

2.1.103 *WAVEFORM*

The variations in magnitude of an electrical signal (in either voltage or current) as a function of time appearing in the APPLIED PART.

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.

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.

5.6 *Amendment:*

Delete all except CONTINUOUS OPERATION.

6. **Identification, marking and documents**

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside*

j) Power input

Replacement of the fourth paragraph:

The RATED power input of MAINS OPERATED STIMULATORS shall be the maximum power input averaged over any period of 5 s under the conditions set out in Item *aa)* of Sub-clause 7.3.

p) Output

Addition:

EQUIPMENT capable of delivering output values in excess of 10 mA r.m.s. or 10 V r.m.s. averaged over any period of 5 s shall be marked near the electrode connections with the symbol No. 14 (see Appendix D of the General Standard).

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6.7 *Indicator lights and push-buttons*

Addition:

See also Sub-clause 51.103.

6.8 *ACCOMPANYING DOCUMENTS*

6.8.2 *Instructions for use*

Additional item:

aa) The instructions for use shall contain additionally:

a) Information on the output WAVEFORM(S), including any d.c. component, PULSE DURATIONS, pulse repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on these parameters.

b) Advice on the size of electrodes to be used and the method of application for each particular type of treatment for which the STIMULATOR is intended.

c) Advice on any necessary precautions to be taken when the output contains a d.c. component.

d) Advice that a PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.

e) A warning on the following potential hazards:

— Simultaneous connection of a PATIENT to a h.f. surgical EQUIPMENT may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.

— Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy EQUIPMENT may produce instability in the STIMULATOR output.

f) For EQUIPMENT capable of delivering output values in excess of 10 mA r.m.s. or 10 V r.m.s.:

— Information on maximum output values allowed for the electrodes recommended by the manufacturer for use with the STIMULATOR.

— Advice that current densities for any electrodes exceeding 2 mA r.m.s./cm^2 may require the special attention of the USER.

6.8.3 *Technical description*

Additional item:

aa) The technical description shall specify the parameters mentioned in *a)* of Item *aa)* of Sub-clause 6.8.2. The range of load impedance for which these parameters are valid shall be specified.

7. Power input

This clause of the General Standard applies except as follows:

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7.3 *Additional item:*

aa) The power input shall be measured with a load resistance having a value within the range specified in the technical description (see Sub-clause 6.8.3) and with any accessible output controls set to give maximum power input.

SECTION TWO — SAFETY REQUIREMENTS

Clauses 8 to 12 of the General Standard apply.

SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13. **General**

This clause of the General Standard applies except as follows:

Addition:

In the case of combined EQUIPMENT (e.g. a STIMULATOR provided with a function or an APPLIED PART for ultrasonic therapy), this additional part shall comply with the relevant Particular Standard.

14. **Requirements related to classification**

This clause of the General Standard applies except as follows:

14.3 *CLASS III EQUIPMENT:* Does not apply.

14.4 *Item a)*

Amendment:

Delete CLASS III EQUIPMENT,

14.6 *Replacement:*

STIMULATORS shall be TYPE BF or CF EQUIPMENT.

Clauses 15 to 18 of the General Standard apply.

19. **Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT**

This clause of the General Standard applies except as follows:

Amendment:

The requirements and tests of the General Standard concerning PATIENT AUXILIARY CURRENT are not applicable to STIMULATORS, except that for combined EQUIPMENT (see Clause 13 of this standard) PATIENT AUXILIARY CURRENT shall be measured between each STIMULATOR electrode in turn and any other APPLIED PART.

20. **Dielectric strength**

This clause of the General Standard applies except as follows:

20.2 *Amendment:*

B-b: Not applicable.

B-f: *Addition:*

The electrical insulation of parts B-f need not be investigated if the PATIENT LEAKAGE CURRENT and ENCLOSURE LEAKAGE CURRENT are not higher than the allowable limit for NORMAL CONDITION when a short circuit between the relevant parts of the STIMULATOR is made.

20.3 *Values of test voltages*

Amendment:

B-d: The test voltage shall be not less than 1 500 V even if the reference voltage U is less than 250 V (CLASS I AND CLASS II EQUIPMENT and EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE).

SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

Clauses 21 to 28 of the General Standard apply.

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Clauses 29 to 35 of the General Standard apply.

36. **Electromagnetic compatibility**

This clause of the General Standard applies except as follows:

Addition:

The EQUIPMENT shall be capable of operating in a radio frequency electromagnetic field such as that produced by the normal operation of a shortwave therapy unit.

When the EQUIPMENT is tested as described below the displayed WAVEFORM shall not deviate from the original WAVEFORM in amplitude, pulse duration or repetition frequency by more than 10%. Indication of direct radio frequency break-through on the display shall be ignored.

Compliance shall be checked by Tests 1 to 3. The following test equipment may be used, as shown in Figures 101, 102 and 103, pages 24 to 26:

- *Radio Frequency oscillator covering the ISM frequency, 27.12 MHz without modulation.*
- *Power amplifier capable of not less than 2.5 W output at the above frequency.*
- *R.F. attenuator, of suitable rating.*
- *R.F. power meter and matching unit.*
- *R.F. transformer to match test equipment impedance to 800 Ω.*
- *Load resistances and by-pass capacitors.*
- *Oscilloscope — Band width, d.c. to a.c. not more than 10 MHz.*

— *Low frequency oscillator, to provide external triggering of the oscilloscope, to enable measurement of any change in pulse repetition frequency.*

The EQUIPMENT is operated in each output mode, the output amplitude control(s) being set in turn at maximum, minimum and one intermediate setting during each phase of the tests.

Test 1

The STIMULATOR and test equipment are set up as shown in Figure 101, page 24. In the case of CLASS II and INTERNALLY POWERED EQUIPMENT, the EQUIPMENT shall be placed on an earthed metal plate the area of which is at least that of the base of the STIMULATOR. Any ACCESSIBLE CONDUCTIVE PARTS and the metal plate are connected together.

The R.F. attenuator is adjusted until the power being applied to R1 and the STIMULATOR under test is 2.5 W ± 10% as shown by the wattmeter when the line impedance is matched so that the reflected power is such that the VSWR is less than 1.3 (approximately 2% reflected power).

The connections AA (Figure 101) are first connected to each pair of output terminals in turn and the above test is carried out.

Next the connections AA (Figure 101) are connected between the enclosure, or metal plate (in the case of CLASS II and INTERNALLY POWERED EQUIPMENT), and each output terminal in turn, and the above test is repeated.

Test 2

The STIMULATOR and test equipment are set up as shown in Figure 102, page 25. In the case of CLASS II and INTERNALLY POWERED EQUIPMENT, the EQUIPMENT shall be placed on an earthed metal plate the area of which is at least that of the base of the STIMULATOR. Any ACCESSIBLE CONDUCTIVE PARTS and the metal plate are connected together. If the mains cable supplied with the STIMULATOR is in excess of 400 mm in length, it shall be folded to form a bundle not exceeding 400 mm in length.

The R.F. attenuator is adjusted until the power of 1 W ± 10% is applied to the test filter network (Figure 102) as shown by the wattmeter when the line impedance is matched so that the reflected power is such that the VSWR is less than 1.3 (approximately 2% reflected power).

The R.F. input is first applied to points BB of the test filter network (L1, L2, C1, C2) and the above test is carried out. Next the R.F. input connections at BB are reversed and the test is repeated.

Test 3 (for electrically remote-controlled STIMULATOR)

The STIMULATOR and test equipment are set up as shown in Figure 103, page 26. In the case of CLASS II and INTERNALLY POWERED EQUIPMENT, the EQUIPMENT shall be placed on an earthed metal plate the area of which is at least that of the base of the STIMULATOR. Any ACCESSIBLE CONDUCTIVE PARTS and the metal plate are connected together. If the remote control cable supplied with the STIMULATOR is in excess of 400 mm in length, it shall be folded to form a bundle not exceeding 400 mm in length.

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The R.F. attenuator is adjusted until the power of 2.5 W ± 10% is applied to the remote control cable (Figure 103, page 26) as shown by the wattmeter when the line impedance is matched so that the reflected power is such that the VSWR is less than 1.3 (approximately 2% reflected power).

The output from points CC is applied to the remote control cable terminations at the remote control end of the cable (Figure 103), so as to deliver R.F. energy to any two conductors in turn including any screen.

Further tests for the effect of direct radiation of R.F. fields on the internal components and wiring are under consideration.

SECTION SIX — PROTECTION AGAINST HAZARDS OF EXPLOSIONS IN MEDICALLY USED ROOMS

Clauses 37 to 41 of the General Standard apply.

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS, SUCH AS HUMAN ERRORS

42. Excessive temperatures

This clause of the General Standard applies except as follows:

Addition:

Compliance with the requirements for maximum temperatures specified in the General Standard shall be checked under the conditions specified in Item aa) of Sub-clause 7.3.

Clauses 43 to 45 of the General Standard apply.

46. Human errors

This clause of the General Standard applies except as follows:

Additional sub-clause:

46.101 The STIMULATOR shall be so designed that operation into open-circuited or short-circuited electrodes does not impair the ability of the EQUIPMENT to comply with the requirements of this standard.

Compliance shall be checked by the following test:

The STIMULATOR is operated with all output controls set to the maximum position and each pair of output terminals left open-circuited for a period of 10 min and then short-circuited for a further period of 5 min. After this test the EQUIPMENT shall comply with all the requirements of this standard.

Clauses 47 to 49 of the General Standard apply.

SECTION EIGHT — ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

50. Accuracy of operating data

This clause of the General Standard applies except as follows:

50.1 *Addition:*

An output amplitude control shall be incorporated which will control the STIMULATOR output from minimum to maximum continuously, or in discrete increments of not more than 1 mA or 1 V per increment. At its minimum setting, the output shall not exceed 2% of that available at the maximum setting of the control.

Compliance shall be checked by inspection and measurement using the load impedance which is the least favourable within the range specified in the ACCOMPANYING DOCUMENTS.

50.2 *Replacement:*

The values of PULSE DURATIONS, pulse repetition frequencies and amplitudes, including any d.c. component, as described in the ACCOMPANYING DOCUMENTS or indicated on the EQUIPMENT (see Sub-clause 6.8.2), shall not deviate by more than $\pm 30\%$ when measured with an error not exceeding $\pm 10\%$ into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see Sub-clause 6.8.3 of this Standard).

Compliance shall be checked by measurement.

51. Protection against incorrect output

This clause of the General Standard applies except as follows:

Additional sub-clauses:

51.101 *Supply voltage fluctuations*

Supply voltage fluctuations of $\pm 10\%$ shall not affect the STIMULATOR output amplitude, PULSE DURATION or pulse repetition frequency by more than $\pm 10\%$.

Compliance shall be checked by measurement.

51.102 *Output interlock*

A STIMULATOR capable of delivering an output in excess of 10 mA r.m.s. or 10 V r.m.s. shall be so designed that the output cannot be energized unless the output amplitude control(s) is (are) first set to its (their) minimum position.

This requirement shall also apply upon the restoration of the MAINS SUPPLY following a temporary interruption.

Compliance shall be checked by functional check.

51.103 *Output indicator*

An indication of the presence of an output under NORMAL CONDITION and under SINGLE FAULT CONDITION shall be incorporated in EQUIPMENT which can deliver into a load resistance of 1 000 Ω an output in excess of 10 mA r.m.s. or 10 V r.m.s. or pulses having an energy exceeding 10 mJ per pulse. If the indication is by means of a signal lamp, its colour shall be yellow.

Compliance shall be checked by inspection and functional test.

51.104 *Limitation of output parameters*

a) EQUIPMENT intended for therapeutic applications:

With a load resistance of 500 Ω the output current shall not exceed the limits in the table:

Frequency	Current limit r.m.s.
d.c.	80 mA
⩽ 400 Hz	50 mA
⩽ 1 500 Hz	80 mA
> 1 500 Hz	100 mA

In the case of an output having both a.c. and d.c. components, these components shall be measured separately and compared with the allowable limits.

For pulse durations of less than 0.1 s the pulse energy with a load resistance of 500 Ω shall not exceed 300 mJ per pulse. For higher values of the pulse duration, the above-mentioned current limit for d.c. applies.

Additionally, the output voltage shall not exceed a peak value of 500 V, when measured under open-circuit condition.

Where the APPLIED PART(S) is (are) energized by more than one output circuit simultaneously (for example for interferential therapy), the above limits shall apply to each of these output circuits.

b) EQUIPMENT intended for diagnostic applications:

For EQUIPMENT intended for dentistry and ophthalmology the d.c. current with a load resistance of 2 000 Ω shall not exceed 10 mA.

For other diagnostic applications, the limits for the output parameters are under consideration.

Compliance shall be checked by measurement.

SECTION NINE — FAULT CONDITIONS CAUSING OVERHEATING AND/OR MECHANICAL DAMAGE; ENVIRONMENTAL TESTS

Clauses 52 and 53 of the General Standard apply.

SECTION TEN — CONSTRUCTIONAL REQUIREMENTS

Clauses 54 to 56 of the General Standard apply.

57. MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

57.3 *Mains supply cables or cords*

Item c)

Addition:

For CLASS II EQUIPMENT having a RATED current not exceeding 3 A the nominal cross-sectional area of the conductors in the mains cord shall be not less than 0.5 mm².

Compliance shall be checked by inspection.

Clauses 58 and 59 of the General Standard apply.

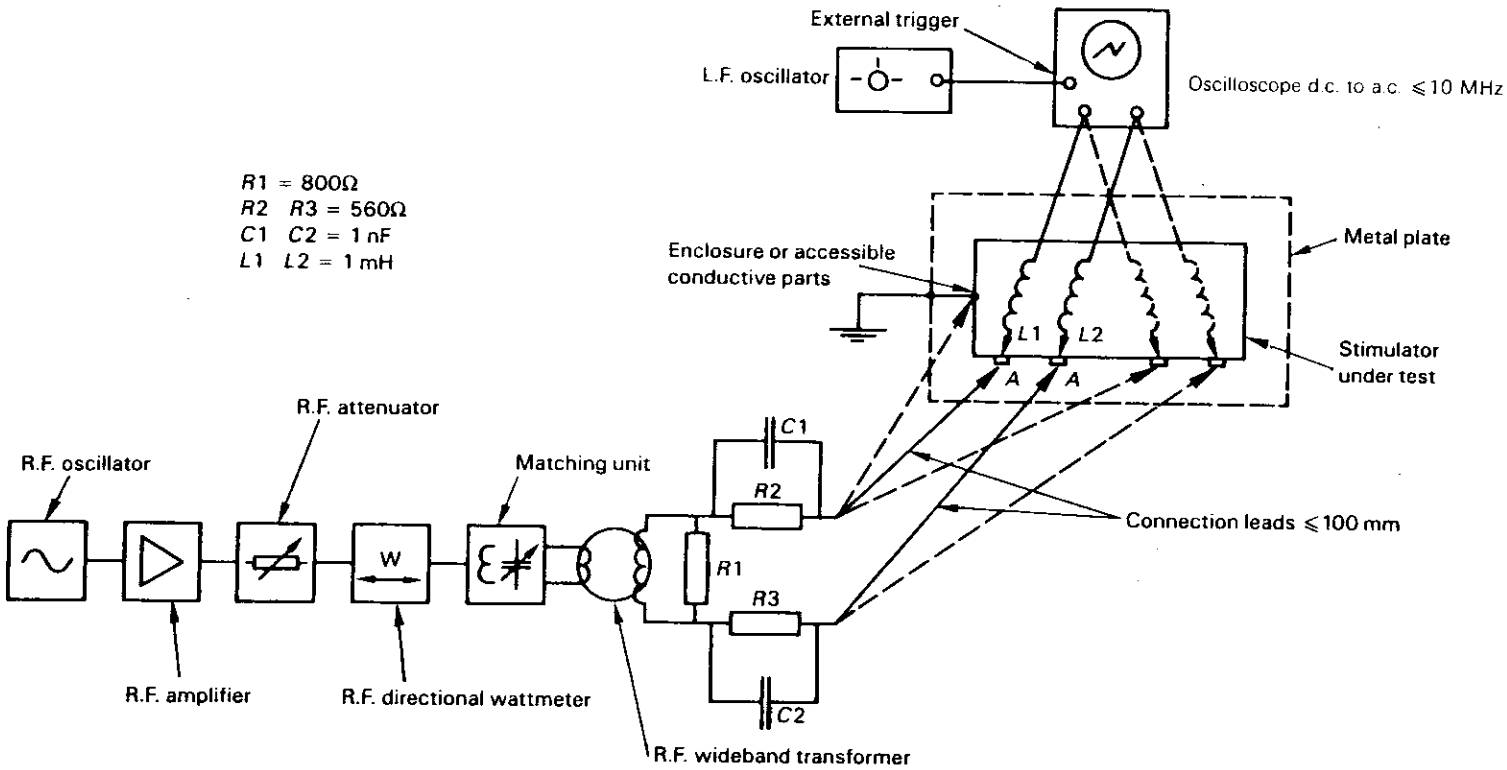

FIG. 101. — Lay-out of test equipment (see Clause 36, Test 1).

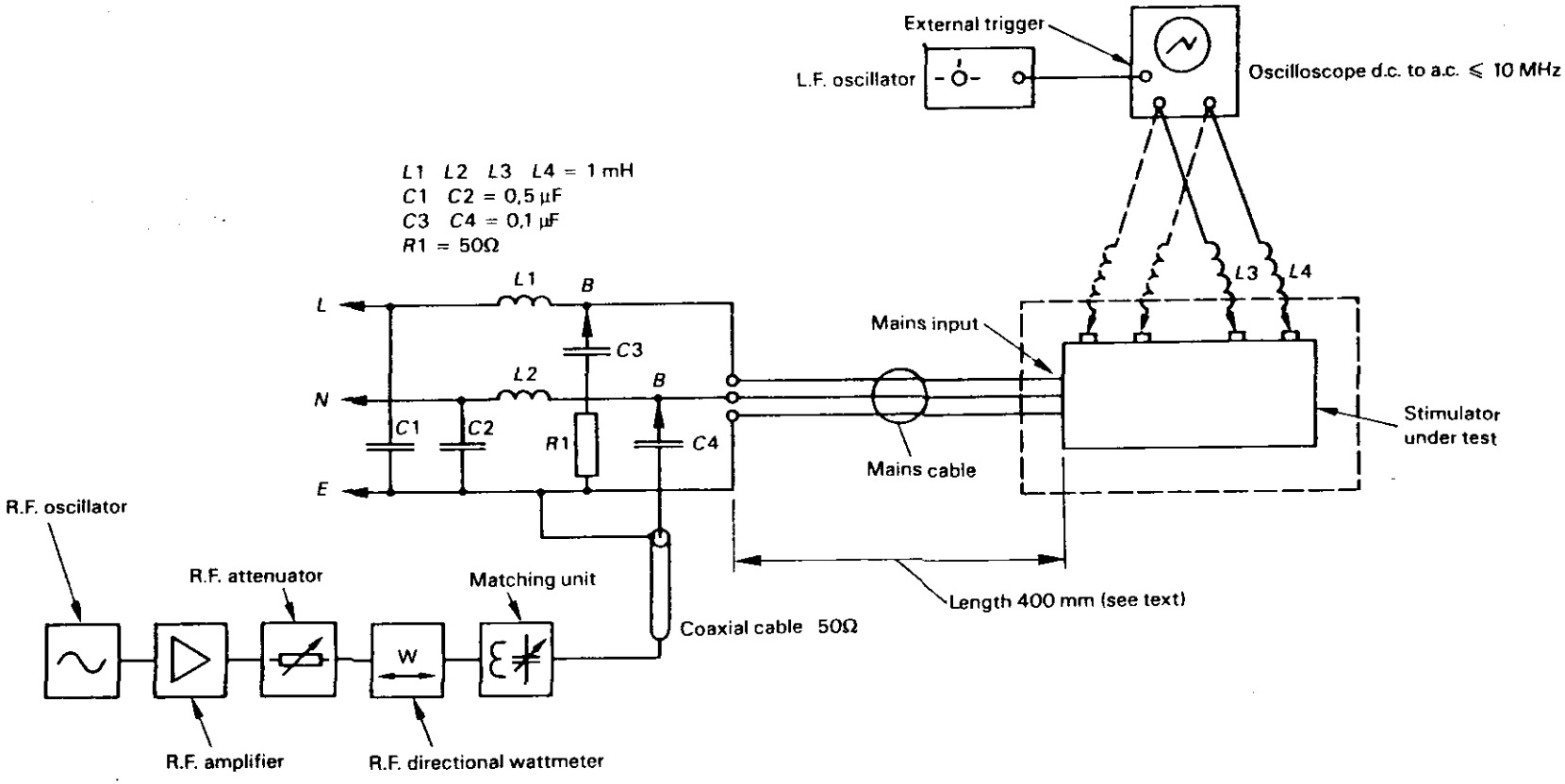

FIG. 102. — Lay-out of test equipment (see Clause 36, Test 2).

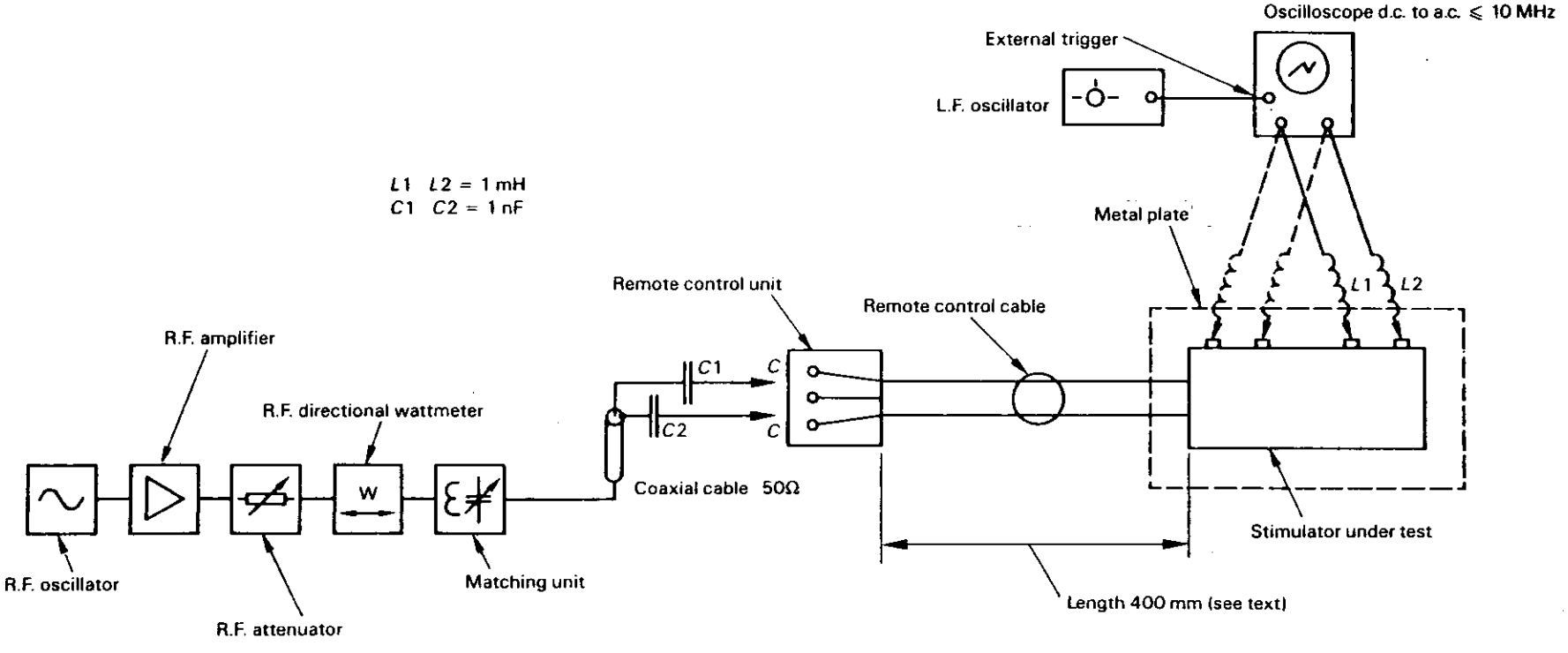

FIG. 103. — Lay-out of test equipment (see Clause 36, Test 3).

APPENDIX AA

RATIONALE

This appendix provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA1.1 *Scope*

The types of EQUIPMENT which are excluded from the scope of this standard differ considerably with respect to technique and/or application from the EQUIPMENT normally used in physical medicine; therefore these types require different safety measures.

AA5. **Classification**

AA5.1 According to the definition of CLASS III EQUIPMENT in the General Standard, the safety of CLASS III EQUIPMENT relies on its supply. As the supply circuit is not in the scope of this standard such EQUIPMENT has had to be excluded.

AA5.2 The APPLIED PART must be isolated to avoid unwanted current paths through the PATIENT due to the capacitance or a possible conductive connection to earth.

AA5.6 The EQUIPMENT is usually operated with one PATIENT for periods up to 15 min and may be subsequently used immediately with the next PATIENT. Therefore it must be suitable for CONTINUOUS OPERATION.

AA6. **Identification, marking and documents**

AA6.1 *p)* The USER is particularly alerted to consult the instructions for use because of the higher levels of output allowed.

AA6.8.2 *aa)*

a) Because of the electrolytic effects, any d.c. components of the WAVEFORMS must be declared.

b) Electrodes of inadequate size or unsuitable application could provoke skin reactions or burns.

d) Interference to the implanted devices by the stimulating current could create a hazard.

e) — The scope excludes STIMULATORS intended for use during surgical procedures; however, the case that a STIMULATOR may be brought into an operating room cannot be excluded.

— Clause 36 provides for the protection against r.f. interference at a distance of greater than 1 m.

f) The USER should be warned that stimulation with excessive current densities may be a hazard to the PATIENT.

minimum setting of the output control enables the USER to commence the treatment to the PATIENT from a low output level.

AA50.2 An accuracy of $\pm 30\%$ is considered to provide adequate safety for therapeutic application, since the values selected are mainly determined by the subjective reaction of the PATIENT. However, for diagnostic purposes a considerably higher accuracy may be needed.

AA51.101 *Supply voltage fluctuations*

Supply voltage fluctuations not exceeding the limit of the General Standard shall not influence the output parameters excessively.

AA51.102 *Output interlock*

To avoid excessive stimulation of the PATIENT, sudden increases in the output current must be avoided in NORMAL USE and in the case of interruption and restoration of the MAINS SUPPLY.

AA51.103 *Output indicator*

As the presence of an unintended voltage on the electrodes due to a fault in the STIMULATOR cannot be excluded, the indication is required for this type of SINGLE FAULT CONDITION.

AA51.104 *Limitation of output parameters*

Experience in physical medicine shows that the limits specified allow all known therapeutic and/or diagnostic applications to be carried out without greatly exceeding the values needed.

AA57. MAINS PARTS, **components and layout**

AA57.3 For small CLASS II EQUIPMENT a mains cable with more flexibility is desirable and does not *impair safety*.

[IEC page 35]

Publications referred to

See national foreword.