SLOVENSKI STANDARD
SIST HD 395.2.10 S1:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987)

Medical electrical equipment -- Part 2: Particular requirements for the safety of nerve and muscle stimulators

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Geräten zur Stimulation von Nerven und Muskeln

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité pour stimulateurs de nerfs et de muscles

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MEDICAL ELECTRICAL EQUIPMENT
PART 2:
PARTICULAR REQUIREMENTS FOR THE SAFETY OF NERVE AND MUSCLE STIMULATORS.

Appareils électromédicaux
Deuxième partie:
Règles particulières
de sécurité
pour stimulateurs de nerfs
et de muscles

Medizinische elektrische Geräte
Teil 2:
Besondere Festlegungen für die
Sicherheit von Geräten
zur Stimulation von Nerven und
Muskeln

BODY OF THE HD

The Harmonization Document consists of:

- IEC 601-2-10 (1987) ed 1; IEC/SC 62D, not appended

-09- 1998

This Harmonization Document was approved by CENELEC on 1988-09-13.

The English and French versions of this Harmonization Document are provided by the text of the IEC publication and the German version is the official translation of the IEC text.

According to the CENELEC Internal Regulations the CENELEC member National Committees are bound:

to announce the existence of this Harmonization Document at national level **by or before 1989-04-01**

to publish their new harmonized national standard **by or before 1989-10-01**

to withdraw all conflicting national standards **by or before 1989-10-01.**

Harmonized national standards are listed on the HD information sheet, which is available from the CENELEC National Committees or from the CENELEC Central Secretariat.

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

NORME INTERNATIONALE
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Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité
pour stimulateurs de nerfs et de muscles

Medical electrical equipment

Part 2:
Particular requirements for the safety
of nerve and muscle stimulators

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of nerve and muscle stimulators

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 upon the following documents:

Six Months' Rule	Report on Voting
62D(CO)29	62D(CO)32

Further information can be found in the Report on Voting indicated in the table above.

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977): Safety of medical electrical equipment, Part 1: General Requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard will be changed in the next edition to read: Medical electrical equipment, Part 1: General requirements for safety. This change is anticipated in the title of this Particular Standard.

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

Sub-clauses 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.

Following the decision taken by Sub-Committee 62D at the meeting in Washington in 1979, 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.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of nerve and muscle stimulators

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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).

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./cm² 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:

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: