

Medical electrical equipment —

Part 2.10: Particular requirements for the safety of nerve and muscle stimulators

The European Standard EN 60601-2-10:2000, with the incorporation of amendment A1:2001, has the status of a British Standard

ICS 11.040.55; 11.040.60

**BS EN
60601-2-10:2001**

*Incorporating
Amendment No. 1*

**BS
5724-2.10:1988**

*Incorporating
Amendment No. 1 and
Amendment No. 2
(renumbers the BS as
BS EN 60601-2-10:2001)*

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
- Chartered Society of Physiotherapy
- Department of Health and Social Security
- Electro Medical Trade Association Limited
- Institute of Physical Sciences in Medicine
- Ministry of Defence
- Royal Society of Medicine

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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National foreword

This British Standard is the official English language version of EN 60601-2-10:2000, including amendment A1:2001. It is identical with IEC 60601-2-10:1987, including amendment 1:2001 and Corrigendum February 2002.

The start and finish of text introduced or altered by IEC amendment 1 is indicated in the text by tags **A1** **A1**. Tags indicating changes to text carry the number of the amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

This Particular Standard amends and supplements BS EN 60601-1:1990 *Medical electrical equipment — Part 1: General requirements for safety*, hereinafter referred to as 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.

In the 60601 series of publications, the Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (for example, radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (for example, Electromagnetic Compatibility).

The numbering of sections, clauses and subclauses of this standard corresponds with that of the General Standard. For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

In this Standard, 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 smaller roman type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS STANDARD: SMALL CAPITALS.

IEC Corrigendum February 2002 replaces the text of 4.2.

An asterisk preceding a clause or subclause number signifies that there is a corresponding rationale statement in Appendix AA.

The UK participation in its preparation was entrusted to Technical Committee HCC/94, 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.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its 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 and ii, the EN title page, the EN foreword page, pages 1 to 25 and a back cover.

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English version

Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

(includes amendment A1:2001)

(IEC 60601-2-10:1987 + A1:2001)

Appareils électromédicaux —

Partie 2-10: Règles particulières de sécurité pour
stimulateurs de nerfs et de muscles

(inclut l'amendement A1:2001)

(CEI 60601-2-10:1987 + A1:2001)

Medizinische elektrische Geräte —

Teil 2-10: Besondere Festlegungen für die Sicherheit
von Geräten zur Stimulation von Nerven und
Muskeln

(enthält Änderung A1:2001)

(IEC 60601-2-10:1987 + A1:2001)

This European Standard was approved by CENELEC on 2000-04-01 and amendment A1 was approved by CENELEC on 2001-11-01. 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

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of the International Standard IEC 60601-2-10:1987, prepared by SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC TC 62, Electrical equipment in medical practice, was approved by CENELEC as HD 395.2.10 S1 on 1988-09-13.

This Harmonization Document was submitted to the formal vote for conversion into a European Standard and was approved by CENELEC as EN 60601-2-10 on 2000-04-01.

The following date was 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) 2001-04-01

Foreword to amendment A1

The text of document 62D/413/FDIS, future amendment 1 to IEC 60601-2-10:1987, prepared by SC 62D¹⁾, 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 amendment A1 to EN 60601-2-10:2000 on 2001-11-01.

The following dates were fixed:

- latest date by which the
amendment has to be
implemented at national
level by publication of an
identical national
standard or by
endorsement (dop) 2002-08-01
- latest date by which the
national standards
conflicting with the
amendment have to be
withdrawn (dow) 2004-11-01

¹⁾ The foreword of EN 60601-2-10:2000 mistakenly indicated SC 62C as the technical body that drafted the text of the International Standard.

Section 1. 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 subclause **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 **[A1]** (partly covered by IEC 60601-2-31) **[A1]**;
- body-worn equipment;
- stimulators intended for use during surgical procedures;
- equipment intended for averaged evoked potential diagnosis **[A1]** (covered by IEC 60601-2-40) **[A1]**;
- equipment intended for electromyography **[A1]** (covered by IEC 60601-2-40) **[A1]**;
- equipment intended for cardiac defibrillation;
- equipment intended only as a transcutaneous nerve and muscle stimulator for pain relief.

[A1] 1.3 Particular Standards

This Particular Standard for NERVE AND MUSCLE STIMULATORS is to be read in conjunction with the following standard:

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

The requirements of this Particular Standard take priority over the above-mentioned standard and its amendments, hereinafter referred to as the General Standard.

1.5 Collateral Standards

The following Collateral Standards apply:

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems.*

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests.*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral Standard: Programmable electrical medical systems.*
Amendment 1 (1999) **[A1]**

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 [A1] WAVEFORM [A1] 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 [A1] a PATIENT CIRCUIT [A1]

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 [A1] Text deleted [A1]**[A1] 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. [A1]

5 Classification

This clause of the General Standard applies except as follows:

5.1 [A1] Text deleted [A1]***5.2 Amendment:**

[A1] Delete TYPE B APPLIED PART [A1].

***5.6 Amendment:**

Delete all except continuous operation.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

[A1] 6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts [A1]*j) Power input**

Replacement of the fourth paragraph:

The rated power input of [A1] mains operated [A1] stimulators shall be the maximum power input averaged over any period of 5 s under the conditions set out in Item aa) of subclause 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, [A1] Table D1 [A1] of the General Standard).

**6.7 Indicator lights and push-buttons**

Addition:

See also subclause 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.
 -  — Application of electrodes near the thorax may increase the risk of cardiac fibrillation. 
- 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 subclause 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:

7.1 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 subclause 6.8.3) and with any accessible output controls set to give maximum power input.

