

Medical electrical equipment —

Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment

The European Standard EN 60601-2-5:2000 has the status of a British Standard.

ICS 11.040.60

National foreword

This British Standard is the official English language version of EN 60601-2-5:2000. It is identical with IEC 60601-2-5:2000. It supersedes BS 5724-2-5:1985 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/111, Ultrasonic diagnostic equipment, 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

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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, the EN title page, pages 2 to 22, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 May 2001

© BSI 05-2001

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 37110 7

English version

Medical electrical equipment
Part 2-5: Particular requirements for the safety of
ultrasonic physiotherapy equipment
(IEC 60601-2-5:2000)

Appareils électromédicaux
Partie 2-5: Règles particulières de
sécurité des appareils à ultrasons
pour physiothérapie
(CEI 60601-2-5:2000)

Medizinische elektrische Geräte
Teil 2-5: Besondere Festlegungen
für die Sicherheit von Ultraschall-
Physiotherapiegeräten
(IEC 60601-2-5:2000)

This European Standard was approved by CENELEC on 2000-09-01. 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 document 62D/361/FDIS, future edition 2 of IEC 60601-2-5, prepared by SC 62D, 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 EN 60601-2-5 on 2000-09-01.

This European Standard supersedes HD 395.2.5 S1:1986.

The following dates were 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) 2001-06-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-09-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-5:2000 was approved by CENELEC as a European Standard without any modification.

CONTENTS

	Page
INTRODUCTION	5
Clause	
SECTION ONE – GENERAL	
1 Scope and object.....	6
2 Terminology and definitions	7
4 General requirements for tests.....	9
5 Classification.....	9
6 Identification, marking and documents	9
7 Power input	10
SECTION TWO – ENVIRONMENTAL CONDITIONS	
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
13 General	11
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength.....	11
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
35 Acoustical energy (including ultrasonics).....	11
36 Electromagnetic compatibility.....	12
SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
42 Excessive temperatures.....	12
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	13
SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
50 Accuracy of operating data	13
51 Protection against hazardous output	14

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56 Components and general assembly.....15

Figure 101.....16

Appendix L 17

Annex AA - General guidance and rationale 18

Annex ZA (normative) Normative references to international publications with their
corresponding European publications 21

Annex ZB (informative) Other international publications mentioned in this standard with the
references of the relevant European publications 22

INTRODUCTION

This Particular Standard specifies requirements and tests for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT. It amends and supplements IEC 60601-1 (second edition, 1988) including Amendments 1 and 2, hereinafter referred to as the General Standard. This Particular Standard takes into account IEC 60601-1-2 and IEC 61689.

A first edition of this Particular Standard was published in 1984, based on the first edition (1977) of IEC 60601-1 and making reference to IEC 60150. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above. The title has been changed to better reflect its scope based on developments in the therapeutic application of ultrasound and in line with changes in the above IEC standards.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the Particular 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 annex does not form part of the requirements of this Standard.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk * before their number.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

1.1 Scope

Addition:

This Particular Standard specifies the requirements for safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

This Particular Standard does not apply to:

- EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry);
- EQUIPMENT in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites) (for information refer to IEC 60601-2-36);
- ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ULTRASOUND pulse waves are used.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard as the “General Standard”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

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