INTERNATIONAL STANDARD

IEC 60601-2-5

Second edition
2000-07

Withdrawn

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-5:
Règles particulières de sécurité des appareils à ultrasons pour physiothérapie

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For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) 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.

3) They have the form of recommendations for international use published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

6) The IEC has not laid down any procedure concerning marking as an indication of approval and has no responsibility when an item of equipment is declared to comply with one of its standards.

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International Standard IEC 60601-2-5 has been prepared by sub-committee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1984, and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/361/FDIS	62D/366/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be:

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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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.

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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.

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"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa), bb),* etc.

The term "this standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standards mentioned below.

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – Section 1 – Collateral standard: Safety requirements for medical electrical systems*

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

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

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2 Terminology and definitions

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

2.1.101
ULTRASONIC PHYSIOTHERAPY EQUIPMENT (hereinafter referred to as EQUIPMENT)
EQUIPMENT for the generation and application of ULTRASOUND to a PATIENT for therapeutic purposes

NOTE – Essentially the EQUIPMENT comprises a generator of electric high-frequency power and a transducer for converting this to ULTRASOUND.

2.1.102
ULTRASONIC TRANSDUCER
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range

***2.1.103**
TREATMENT HEAD
assembly comprising an ULTRASONIC TRANSDUCER and associated parts for local application of ULTRASOUND to the PATIENT

NOTE – A TREATMENT HEAD is also referred to as an applicator.

2.1.104
ATTACHMENT HEAD
ACCESSORY intended to be attached to the TREATMENT HEAD for the purpose of modifying the ultrasonic beam characteristics

2.12 MISCELLANEOUS

2.12.101
RATED OUTPUT POWER
Maximum OUTPUT POWER of the EQUIPMENT at any RATED MAINS VOLTAGE [IEC 61689, definition 3.32]

2.12.102
ULTRASOUND
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz) (see 801-21-04 of IEC 60050(801)) [IEC 61689, definition 3.45]

2.12.103
EFFECTIVE RADIATING AREA
beam cross-sectional area extrapolated to the front face of the TREATMENT HEAD and multiplied by a dimensionless factor according to IEC 61689 [IEC 61689, definition 3.20, modified]

NOTE – This may be thought of as the area of the face of the treatment head which contains 100% of the total mean square acoustic power.

2.12.104
EFFECTIVE INTENSITY
ratio of the OUTPUT POWER to the EFFECTIVE RADIATING AREA. It is expressed in watts per square centimetre [IEC 61689, definition 3.18, modified]

2.12.105
ACOUSTIC WORKING FREQUENCY
frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field. The signal is analysed using the zero-crossing frequency technique (see 3.4.1 of IEC 61102) [IEC 61689, definition 3.3]

2.12.106
BEAM NON-UNIFORMITY RATIO
ratio of the square of the maximum r.m.s. acoustic pressure to the spatial average of the square of the r.m.s. acoustic pressure where the spatial average is taken over the EFFECTIVE RADIATING AREA, determined in accordance with IEC 61689 [IEC 61689, definition 3.9, modified]

2.12.107
BEAM TYPE
descriptive classification for the ultrasonic beam in one of three types: collimated, convergent or divergent [IEC 61689, definition 3.11]

2.12.108
DUTY FACTOR
ratio of the PULSE DURATION to the PULSE REPETITION PERIOD (see 5.3.2.4 of IEC 60469-1) [IEC 61689, definition 3.17]

2.12.109
OUTPUT POWER
time-average ultrasonic power radiated by a TREATMENT HEAD of EQUIPMENT into an approximately free field under specified conditions in a specified medium, preferably in water (see 3.5 of IEC 61161) [IEC 61689, definition 3.31]

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