IEC 60601-2-5

Edition 3.0 2009-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

Appareils électromédicaux –
Partie 2-5: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à ultrasons pour physiothérapie

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-5 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2000. This edition constitutes a technical revision.

The numbering was revised to agree with IEC 60601-1:2005 (third edition). Beyond this, essential performance characteristics are defined in 201.4.3.101, guidance on maintenance is added in 201.7.9.2.1, a new requirement regarding dielectric withstand was added in 201.8.8.3. The clause on transducer surface temperature rise, 201.11, has been modified to allow for simulated use conditions. Measurements of ultrasound-related parameters are now referenced to IEC 61689:2007 (second edition). The most important change in the ultrasound-related parameters is the definition of EFFECTIVE RADIATING AREA, 201.3.207. This change will also affect the value of the EFFECTIVE INTENSITY and its uncertainty.

The text of this particular standard is based on the following documents:

Enquiry draft	Report on voting
62D/693/CDV	62D/766/RVC

Full information on the voting for the approval of this particular 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 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

In this particular standard, safety and performance requirements additional to those in the general standard are specified for ULTRASONIC PHYSIOTHERAPY EQUIPMENT.

This particular standard takes into account IEC 61689.

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 * after their number.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC PHYSIOTHERAPY EQUIPMENT as defined in 201.3.216, hereafter referred to as ME EQUIPMENT.

This standard only relates to ULTRASONIC PHYSIOTHERAPY EQUIPMENT employing a single plane unfocused circular transducer per TREATMENT HEAD, producing static beams perpendicular to the face of the TREATMENT HEAD.

This standard can also be applied to ULTRASONIC PHYSIOTHERAPY EQUIPMENT used for compensation or alleviation of disease, injury or disability.

In the case of combined EQUIPMENT (e.g. EQUIPMENT additionally provided with a function or an APPLIED PART for electrical stimulation) such EQUIPMENT shall also comply with any particular standard specifying safety requirements for the additional function.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard.

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 (lithotripters) (for information refer to IEC 60601-2-36);

– ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ultrasound pulse waves are used.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC PHYSIOTHERAPY EQUIPMENT (as defined in 201.3.216).

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and subclause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 61689:2007, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterisation of medical ultrasonic fields up to 40 MHz*

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

NOTE Informative references are listed in the bibliography on page 32.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in the general standard and in IEC 61689 (some of which are repeated here for convenience), as well as the following additional definitions apply:

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101.

Addition:

201.3.201
ACOUSTIC WORKING FREQUENCY
f_{awf}
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

[IEC 61689:2007, definition 3.3, modified]

NOTE Acoustic frequency is expressed in hertz (Hz).

201.3.202
ATTACHMENT HEAD
ACCESSORY intended to be attached to the TREATMENT HEAD for the purpose of modifying the ultrasonic beam characteristics

201.3.203
BEAM NON-UNIFORMITY RATIO
R_{BN}
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

[IEC 61689:2007, definition 3.9, modified]

201.3.204
BEAM TYPE
descriptive classification for the ultrasonic beam in one of three types: collimated, convergent or divergent

[IEC 61689:2007, definition 3.11]

201.3.205
DUTY FACTOR
ratio of the PULSE DURATION to the PULSE REPETITION PERIOD

[IEC 61689:2007, definition 3.16]

201.3.206
EFFECTIVE INTENSITY
I_e

intensity given by $I_e = P/A_{ER}$ where P is the OUTPUT POWER and A_{ER} is the EFFECTIVE RADIATING AREA

NOTE Effective intensity is expressed in watt per centimetre squared (W/cm^2).

[IEC 61689:2007, definition 3.17]

201.3.207
EFFECTIVE RADIATING AREA
A_{ER}
BEAM CROSS-SECTIONAL AREA determined at a distance of 0,3 cm from the front of the TREATMENT HEAD, $A_{BCS}(0,3)$, multiplied by a dimensionless factor, equal to 1,354

[IEC 61689:2007, definition 3.19, modified]

NOTE 1 Beam cross-sectional area is expressed in centimetre squared (cm^2).

NOTE 2 This may be thought of as the area of the face of the treatment head which transmits 100% of the total mean square acoustic power.

201.3.208
OUTPUT POWER
P
time-average ultrasonic power emitted by a TREATMENT HEAD of ULTRASONIC PHYSIOTHERAPY EQUIPMENT into an approximately free field under specified conditions in a specified medium, preferably in water

[IEC 61689:2007, definition 3.30]

NOTE **OUTPUT POWER** is expressed in watt (W).

201.3.209
PULSE DURATION
time interval beginning at the first time the pressure amplitude exceeds a reference value and ending at the last time the pressure amplitude returns to that value. The reference value is equal to the sum of the minimum pressure amplitude and 10 % of the difference between the maximum and minimum pressure amplitude

[IEC 61689:2007, definition 3.34]

NOTE **PULSE DURATION** is expressed in seconds (s).

201.3.210
PULSE REPETITION PERIOD
prp
time interval between two equal moments in time of successive pulses or tone-bursts

NOTE 1 This applies to single element non-automatic scanning systems and automatic scanning systems. See also IEC 60469-1:1987, 5.3.2.1.

NOTE 2 **PULSE REPETITION PERIOD** is expressed in seconds (s).

[IEC 61689:2007, definition 3.35]

201.3.211
RATED OUTPUT POWER
maximum OUTPUT POWER of the ultrasonic physiotherapy EQUIPMENT at the rated value of the mains voltage, with control settings configured to deliver maximum OUTPUT POWER

NOTE Rated output power is expressed in watt (W).

[IEC 61689:2007, definition 3.31]

201.3.212
TEMPORAL-MAXIMUM INTENSITY
I_m
in the case of an amplitude modulated wave, the ratio of the TEMPORAL-MAXIMUM OUTPUT POWER to the EFFECTIVE RADIATING AREA

[IEC 61689:2007, definition 3.40, modified]

201.3.213
TEMPORAL-MAXIMUM OUTPUT POWER
p_{tp}
in the case of an amplitude modulated wave, a function of the actual OUTPUT POWER, the temporal-peak acoustic pressure and the r.m.s. acoustic pressure, which is determined as specified in IEC 61689

[IEC 61689:2007, definition 3.33, modified]

201.3.214
***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.

201.3.215
ULTRASOUND
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 16 kHz)

[IEV 802-01-01[2)], modified]

201.3.216
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.

201.3.217
ULTRASONIC TRANSDUCER
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy

[IEC 62127-1:2007, definition 3.73]

Table 201.101 – List of symbols used in this standard

Symbol	Term	Reference
$A_{BCS}(0,3)$	BEAM CROSS-SECTIONAL AREA evaluated at 0,3 cm from the front face of the TREATMENT HEAD	3.7 of IEC 61689
A_{ER}	EFFECTIVE RADIATING AREA	201.3.206
f_{awf}	ACOUSTIC WORKING FREQUENCY	201.3.201
I_e	EFFECTIVE INTENSITY	201.3.206
I_m	TEMPORAL MAXIMUM INTENSITY	201.3.212
P	OUTPUT POWER	201.3.208
P_{tm}	TEMPORAL-MAXIMUM OUTPUT POWER	201.3.213
prp	PULSE REPETITION PERIOD	201.3.210
R_{BN}	BEAM NON-UNIFORMITY RATIO	201.3.203

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC PHYSIOTHERAPY EQUIPMENT and the subclauses in which the requirements are found.

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2) IEC 60050-802, *International Electrotechnical Vocabulary – Part 802: Ultrasonics,* to be published.

Table 201.102 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Free from the display of incorrect[a] numerical values associated with the therapy to be performed.	201.12.1
Free from the production of unwanted ultrasound output.	201.10.102
Free from the production of excessive ultrasound output.	201.12.4
Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.	201.11
[a] "Incorrect" in the sense that the displayed value is different from what is produced or intended	

201.4.11 Power input

Addition:

This subclause of the general standard applies with EQUIPMENT operated at maximum OUTPUT POWER.

NOTE Complying to power input requirements may depend on the OUTPUT POWER LEVEL

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.1 *TYPE TESTS

Addition:

NOTE See Annex AA.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 *ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.2.101 Device type specific markings

a) The generator of an EQUIPMENT shall additionally be provided with the following markings:
   - ACOUSTIC WORKING FREQUENCY or FREQUENCIES in MHz (in kHz for frequencies below 1 MHz)
   - waveform (continuous, amplitude modulated (or pulsed))
   - if amplitude modulated (or pulsed), a description or picture of the output waveforms, along with values for the PULSE DURATION, PULSE REPETITION PERIOD, and DUTY FACTOR for each modulation setting.