BS EN 60601-2-5:2015

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-5:2015. It is identical to IEC 60601-2-5:2009. It supersedes BS EN 60601-2-5:2001, which will be withdrawn on 15 September 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-5

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English Version

Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment (IEC 60601-2-5:2009)

Appareils électromédicaux - Partie 2-5: Exigences particulières pour la sécurité de base et les perfomances essentielles des appareils à ultrasons pour physiothérapie (IEC 60601-2-5:2009)

Medizinische elektrische Geräte - Teil 2-5: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Ultraschall-Physiotherapiegeräten (IEC 60601-2-5:2009)

This European Standard was approved by CENELEC on 2015-09-15. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62D/693/CDV, future edition 3 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 approved by CENELEC as EN 60601-2-5:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-5:2000.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-5:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-36:1997	NOTE	Harmonized as EN 60601-2-36:1997 (not modified).
IEC 61161:2006	NOTE	Harmonized as EN 61161:2007 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replacement in Annex ZA of EN 60601-1:2006:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
-	-		+ corrigendum Mar.	2010
Addition to Annex ZA of EN 60601-1:2006:				
IEC 61689	2007	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	2007
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
IEC 62127-2	2007	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and within its scope the Standard covers all relevant essential requirements given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

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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.

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.

b) The generator shall carry a nameplate, permanently attached, on which is given a unique serial number so that it is individually identified.

c) The TREATMENT HEAD shall be marked with its RATED OUTPUT POWER in watts, the EFFECTIVE RADIATING AREA in square centimetres, the BEAM NON-UNIFORMITY RATIO, the BEAM TYPE, a designation of the specific generator (where applicable, see 201.7.9.2.1, last item) of the equipment for which the TREATMENT HEAD is intended and a unique serial number.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall additionally contain the following:

– information on ACOUSTIC WORKING FREQUENCY or FREQUENCIES in kilohertz or megahertz and EFFECTIVE RADIATING AREA or AREAS in square centimetres of any TREATMENT HEAD or ATTACHMENT HEAD;

– a recommendation calling the USER's attention to the need for periodic maintenance, especially:

  - intervals for regular performance testing and calibration by the user [1][3];
  - inspection of the treatment head for cracks, which may allow the ingress of conductive fluid;
  - inspection of the treatment head cables and associated connectors;

  NOTE Maintenance schemes are given in IEC 62462.

– advice on the procedures necessary for safe operation, drawing attention in the case of TYPE B APPLIED PARTS to the SAFETY HAZARDS which may occur as a result of an inadequate electrical installation;

– advice on the type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR;

– advice drawing the USER's attention to the need for care when handling the TREATMENT HEAD since rough handling may adversely affect its characteristics;

– a list of conditions for which ULTRASOUND treatment is contraindicated;

– a statement of intended use(s);

– information on available TREATMENT HEADS;

– where a TREATMENT HEAD has been designed for interchangeability, such that it is not possible to specify a particular generator unit, this shall be stated and the method by which interchangeability is achieved shall be described.

201.8 *Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 Fundamental rule of protection against electric shock

Addition:

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.

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3) Figures in square brackets refer to the Bibliography.

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Addition:

For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.

201.8.8.3 Dielectric strength

Addition:

aa) For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

Additional paragraphs:

201.10.101 *Ultrasonic energy

The MANUFACTURER shall address the RISKS associated with ultrasonic energy in the RISK MANAGEMENT PROCESS as described in the text of this standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.10.102 *Unwanted ultrasound radiation

The spatial-peak temporal-average intensity (see IEC 62127-1) of unwanted ULTRASOUND radiation from a TREATMENT HEAD intended for hand-held use shall be less than 100 mW/cm^2 when measured as described below.

Compliance shall be checked by the following test:

The front face of the TREATMENT HEAD is immersed in degassed water at a temperature of 22 °C ± 3 °C. The EQUIPMENT is operated at the RATED OUTPUT POWER specified for the TREATMENT HEAD. The unwanted ULTRASOUND radiation is measured by scanning, by hand, the side walls of the TREATMENT HEAD by means of a calibrated hydrophone coupled to the side walls using a coupling gel.

Contrary to the definition in IEC 62127-1 the spatial-peak temporal-average intensity shall be calculated using the approximation:

$$I_{\text{spta}} = \frac{p_{\text{max}}^2}{\rho c} \quad (1)$$

where:

p_{max} is the maximum r.m.s. acoustic pressure (see IEC 61689 Ed2);

ρ is the density of the coupling gel. For simplicity the density of water can be used;

c is the velocity of sound in the medium. For simplicity the velocity of sound in water can be used.

NOTE Spatial-peak temporal-average intensity is expressed in watts per metre squared (W/m^2).

The hydrophone used shall have an active element of diameter ≤ 1 mm.

The hydrophone used shall be calibrated following IEC 62127-2.

NOTE 1 Neither the principle of this method nor the arrangement used allow an exact determination of the intensity value, however the value as measured does give an indication of the energy available at the sides of the treatment head.

NOTE 2 For requirements concerning OUTPUT POWER and intensity distribution, see Clause 201.12.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2.2 *APPLIED PARTS not intended to supply heat to a PATIENT

Addition:

TREATMENT HEADS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 43 °C in NORMAL CONDITIONS when measured under test conditions 201.11.1.3.101.1.

TREATMENT HEADS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 50 °C when measured under test conditions 201.11.1.3.101.2.

Compliance is checked by operation of the ULTRASONIC PHYSOTHERAPY EQUIPMENT and temperature tests as described in 201.11.1.3.101.

NOTE The PATIENT contact surface includes any part of the APPLIED PART, not just the radiating surface.

201.11.1.3 *Measurements

Addition:

201.11.1.3.101 Test conditions

The TREATMENT HEAD shall be tested under the following conditions:

201.11.1.3.101.1 Simulated use

The APPLIED PART of the TREATMENT HEAD shall be coupled acoustically to, and be initially in thermal equilibrium with, a test object such that the ultrasound emitted from the active surface of the TRANSDUCER ASSEMBLY enters the test object.

The positioning, and heating or cooling of the TREATMENT HEAD shall resemble those corresponding to the intended application of that TREATMENT HEAD. This includes using a typical amount of ultrasound coupling medium appropriate to the intended application.

The temperature shall be measured at the point on the APPLIED PART of the TREATMENT HEAD that contacts the PATIENT during NORMAL USE and where the temperature is a maximum.

The test object shall have thermal and acoustical properties mimicking those of an appropriate tissue. In the case where the TREATMENT HEAD is intended for external use this test object shall account for a skin layer.

For soft tissue, the material of the test object shall have the following properties:

– *specific heat capacity: (3 500 ± 500) J/(kg·K);*
– *thermal conductivity: (0,5 ± 0,1) W/(m·K);*
– *attenuation: (0,5 ± 0,1) dB/cm/MHz.*

NOTE 1 A general guidance for the acoustic properties of appropriate tissue is given in ICRU report 61[2].

NOTE 2 As heat develops differently in tissue surfaces containing skin, bone or soft tissue, careful consideration should be given to the choice of the model in relation to the intended use of the *APPLIED PART*. Additional guidance can be found in Annex AA and reference [3].

The test object shall be designed (for example, using acoustic absorbers) to reduce heating the surface of the TREATMENT HEAD by minimizing ULTRASOUND reflections.

201.11.1.3.101.1.1 Test methods

Test method a) or b) specified below shall be selected.

Test method a) shall be used where the ULTRASOUND PHYSIOTHERAPY EQUIPMENT uses a closed loop temperature monitoring system, as the use of test method b) could result in inappropriate results.

a) Test criteria based on test object near human temperatures.

The initial temperature of the surface of the test object at the object-transducer interface shall be not less than 33 °C and the ambient temperature shall be 23 °C ± 3 °C.

To meet the requirements of this test, the temperature of the surface of the APPLIED PART shall not exceed 43 °C.

b) Test criteria based upon temperature rise measurements

The ambient temperature shall be 23 °C ± 3 °C. The initial temperature of the surface of the test object at the object-transducer interface shall be between 20 °C and 33 °C, and the surface temperature rise of the APPLIED PART shall not exceed 10 °C.

The temperature of the surface determined under the test conditions 201.11.1.3.101.1 shall be the sum of 33 °C and the measured temperature rise.

NOTE When following this test method, the temperature rise is defined as the difference between the temperature of the TREATMENT HEAD just before the test and the maximum temperature of the TREATMENT HEAD during the test as measured according to 201.11.1.3.101.1.

201.11.1.3.101.2 Still air

Suspend the TREATMENT HEAD in still air or place it in a stationary position in an environmental chamber with minimal airflow across the APPLIED PART of the TREATMENT HEAD. Ensure that the output face is clean (no coupling gel applied).

Test criteria are based upon temperature rise measurements.

The ambient temperature shall be 23 °C ± 3 °C and the initial temperature of the APPLIED PART of the TREATMENT HEAD shall be the ambient temperature. During the test the temperature rise of the APPLIED PART of the TREATMENT HEAD shall not exceed 27 °C.

To meet the requirements of not exceeding a surface temperature of 50 °C, the sum of the surface temperature rise obtained under these test conditions and 23 °C shall be regarded as the surface temperature under the test conditions of this subclause.

201.11.1.3.101.3 Operating settings

Operate the ULTRASONIC PHYSIOTHERAPY EQUIPMENT at a setting that gives the highest surface temperature of APPLIED PART of the TREATMENT HEAD. The requirements of 201.11.1.3.101.1 and 201.11.1.3.101.2 shall be performed using identical transmit parameters. The transmit parameters of the test shall be recorded in the RISK MANAGEMENT FILE.

201.11.1.3.101.4 Test duration

The ULTRASONIC PHYSIOTHERAPY EQUIPMENT is continually operated for the duration of the test.

The test according to 201.11.1.3.101.1 and 201.11.1.2.101.2 shall be conducted for 30 min.

NOTE If the ULTRASONIC PHYSIOTHERAPY EQUIPMENT automatically “freezes” or halts its output earlier than the time period given in this subclause, the ULTRASONIC PHYSIOTHERAPY EQUIPMENT shall be switched on again immediately.

201.11.1.3.101.5 Temperature measurement

The temperature of the TREATMENT HEAD should be measured by any appropriate means such as radiometry or thermocouple methods.

If a thermocouple is used, the thermocouple junction and adjacent thermocouple lead wire should be securely held in good thermal contact with the surface being measured. The thermocouple should be positioned and secured in such a way that it has a negligible effect on the temperature rise of the area being measured.

The size of the temperature measurement area of the sensor should be such that any averaging effect is minimized.

The temperature shall be measured on the surface of the APPLIED PART of the TREATMENT HEAD in those areas that give the highest surface temperature.

The measurement uncertainty shall be recorded in the RISK MANAGEMENT FILE.

NOTE 1 For the estimation of uncertainties, the ISO/IEC *Guide to the expression of uncertainty in measurement* should be used [4].

NOTE 2 Any means to measure the temperature should be a type that is not overly sensitive to direct ultrasonic heating (for example, a thin film or fine wire thermocouple). Additional factors, such as effects of conductive losses, ultrasonic heating and spatial averaging, should be considered when assessing the measurement uncertainty.

NOTE 3 Example means for measuring surface temperature of externally applied TREATMENT HEAD is provided in Annex BB of this standard.

201.11.1.3.101.6 Test criteria

The TREATMENT HEAD shall operate throughout the test as specified in subclause 201.11.1.3.101.3. During the test, the maximum temperature or the maximum temperature rise shall not exceed the limits specified.

Table 201.103 – Overview of the tests noted under 201.11.1.3

Test to be applied		Transducer type: external use
201.11.1.3.101.1 Simulated use test	a) Temperature	*Initially temperature of the surface of the test object at the object / transducer interface shall not be less than 33 °C* The temperature shall not exceed 43 °C
	b) Temperature rise	*Initially the temperature at the object-transducer interface shall be between 20 and 33 °C.* *The ambient temperature shall be (23 ± 3) °C.* The temperature rise shall not exceed 10 °C.
201.11.1.3.101.2 Still air test (no gel)	Temperature rise	*The ambient temperature shall be (23 ± 3) °C.* *Initially the temperature at the surface of the TREATMENT HEAD shall be the ambient temperature* The temperature rise shall not exceed 27 °C.

201.11.6.5 *Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

201.11.6.5.101 Protection from ingress of fluids into the treatment head

The TREATMENT HEAD of EQUIPMENT shall be rated IPX7 according to IEC 60529.

Compliance shall be checked by testing the TREATMENT HEAD including the inlet of the connecting cord according to IEC 60529.

201.11.6.5.102 Protection from ingress of water from pressurized massage

A TREATMENT HEAD specified for ultrasonic therapy in combination with pressurized water massage shall withstand the maximum pressure occurring in this treatment.

Compliance shall be checked by the test mentioned under 201.11.6.5.101) above, but at 1,3 times the maximum pressure occurring in NORMAL USE.

NOTE Parts of the TRANSDUCER ASSEMBLIES not intended to be immersed during NORMAL USE may be temporarily protected for the purposes of the test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 *Accuracy of controls and instruments

Addition:

The accuracy of the data and controls specific to acoustic output shall be specified.

NOTE For the estimation of uncertainties, the ISO/IEC *Guide to the expression of uncertainty in measurement* should be used should be used [4].

Additional subclauses:

201.12.1.101 Quantitative indicators shall be provided on the control panel, each in the form of a meter or a calibrated output control. They shall be given in a numerical form, and show

a) OUTPUT POWER and EFFECTIVE INTENSITY in the case of continuous wave mode of operation, and

b) TEMPORAL-MAXIMUM INTENSITY and TEMPORAL-MAXIMUM OUTPUT POWER in the amplitude modulated wave mode of operation.

Compliance shall be checked by measurement in accordance with Clause 7 of IEC 61689. The above measurements shall be made immediately after any warm-up period specified in the ACCOMPANYING DOCUMENTS.

201.12.1.102 Where any indicator described in 201.12.1.101 utilizes two or more different ranges of measurement, a clear and reliable indication of the range used shall be provided.

Compliance shall be checked by inspection.

201.12.1.103 Any OUTPUT POWER indication described in 201.12.1.101 shall not differ from the actual value by more than ±20 % of the actual value.

Compliance shall be checked by inspection and measurement of the TEMPORAL-MAXIMUM OUTPUT POWER *in amplitude modulated wave mode, and the* OUTPUT POWER *in continuous wave mode. The measurements shall be performed with an indicated value which is greater than 10 % of the maximum indicatable value.*

201.12.1.104 Any EFFECTIVE INTENSITY indication described in 201.12.1.101 shall not differ from the actual value by more than ±30 % of the actual value

Compliance shall be checked by inspection and measurement of the OUTPUT POWER *in continuous wave mode, and the* EFFECTIVE RADIATING AREA*. The measurements shall be performed with an indicated value which is greater than 10% of the maximum indicatable value.*

201.12.1.105 The EFFECTIVE RADIATING AREA as demanded in 201.7.2.101 c) shall not differ from the actual value by more than ±20 % of the actual value.

Compliance shall be checked by measurement with subclause 7.4 of IEC 61689 Ed 2. The above measurements shall be made immediately after any warm-up period specified in the ACCOMPANYING DOCUMENTS.

201.12.4 *Protection against hazardous output

201.12.4.4 *Incorrect output

Addition:

The maximum EFFECTIVE INTENSITY shall not exceed 3 W/cm^2 with any TREATMENT HEAD or ATTACHMENT HEAD provided by the manufacturer. This requirement shall apply in NORMAL CONDITION and in any SINGLE FAULT CONDITION.

Compliance shall be checked by measurement of the EFFECTIVE RADIATING AREA and measurement of the RATED OUTPUT POWER as in 201.12.1.

Additional subclauses:

201.12.4.4.101 *Output control

EQUIPMENT shall incorporate a means (an output control) to enable the OUTPUT POWER to be reduced to not more than 5 % of the RATED OUTPUT POWER.

Compliance shall be checked by measurement of OUTPUT POWER *as in 201.12.1.*

201.12.4.4.102 *Output stability with supply variations

The OUTPUT POWER shall not vary by more than ±20 % for variations of the MAINS VOLTAGE of ±10 %. Manual readjustment of the EQUIPMENT for compliance with this requirement is not permitted.

Compliance shall be checked by measurement of the OUTPUT POWER *as in 201.12.1 at 90 %, 100 % and 110 % of the* RATED *value of the* MAINS VOLTAGE.

201.12.4.4.103 *Timer

EQUIPMENT shall be provided with an adjustable timer which de-energizes the output after a preselected operating period. The timer shall have a range not exceeding 30 min and an accuracy of better than ±10 % of setting.

201.12.4.4.104 *Homogeneity of the radiation field

The BEAM NON-UNIFORMITY RATIO shall not exceed 8,0 with any TREATMENT HEAD or ATTACHMENT HEAD provided by the manufacturer.

Compliance shall be checked by measurement in accordance with subclause 7.4 of IEC 61689.

201.12.4.4.105 Output stability with time

During 30 min of continuous operation at maximum OUTPUT POWER and at RATED MAINS VOLTAGE, in water at 22 °C ± 3 °C, the OUTPUT POWER shall remain constant within ±20 % of its initial value.

201.12.4.4.106 *Acoustic working frequency

The ACOUSTIC WORKING FREQUENCY shall comply with IEC 61689.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies, except as follows:

Additional subclause:

201.13.101 Combined EQUIPMENT

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.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.1 *Construction of connectors

Additional item:

aa) The connecting cord of the TREATMENT HEAD shall be protected against excessive bending at the entries into the TREATMENT HEAD and into the EQUIPMENT or the pertaining connection plug, respectively.

Compliance shall be checked by application of the test for mains cords specified in 8.11.3.6 of the general standard to the two ends of this connection cord.

201.16 ME SYSTEMS

Clause 16 of the general standard applies**.**

201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies except as follows:

Addition*:*

ULTRASONIC PHYSIOTHERAPY EQUIPMENT shall comply with the requirements of IEC 60601-1-2 as modified below.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows:

202.6 Electromagnetic compatibility

202.6.1 EMISSIONS

202.6.1.1 Protection of radio services

202.6.1.1.2 Tests

Replacement:

CISPR test methods shall be used. The following operating conditions apply during the test:

– maximum and half setting of the OUTPUT POWER, the TREATMENT HEAD being immersed in water.

202.6.2 IMMUNITY

202.6.2.1 General

202.6.2.1.10 *Compliance criteria

Replacement of the tenth and eleventh dashes::

– the disturbance shall not produce unintended or excessive ultrasound output

– the disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of this standard and is intended for those who are familiar with the subject of this standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of this standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.3.214 TREATMENT HEAD

Multi-element transducers are commonplace in diagnostic and hyperthermia applications, but are virtually unknown nowadays in ULTRASONIC PHYSIOTHERAPY EQUIPMENT. For this reason, and additionally because of the problems of applying suitable test methods for determination of the key acoustic parameters, the scope of IEC 61689 was restricted to “single plane circular transducers”. This restriction has been maintained in this revision of IEC 60601-2-5.

Subclause 201.5.1 Type Tests

The testing during manufacture (see rationale in 5.1 of the general standard) should include verification of the RATED OUTPUT POWER according to the test method specified in 201.12.1.101 and a test for watertightness of the TREATMENT HEAD as specified in 201.11.6.5.

Since the test of 201.12.1.101 is inadequate for detection of hotspots, the manufacturer is recommended to perform the more extensive tests specified in Clause 8 of IEC 61689 on a sample basis.

Clause 201.7 ME EQUIPMENT identification, marking and documents

The most important output characteristics, the knowledge of which may be important for safe use, has to be displayed on the EQUIPMENT. Other output parameters may be specified in the ACCOMPANYING DOCUMENTS. It is recommended that these include the estimated uncertainties at the 95 % confidence level for

a) the indicated EFFECTIVE RADIATING AREA in 201.7.2.101 c),
b) the indicated RATED OUTPUT POWER in 201.7.2.101 c),
c) the acoustic working frequency,
d) the beam non-uniformity ratio,
e) the pulse duration,
f) the pulse repetition period,
g) the quantitative indication of OUTPUT POWER in 201.12.1.101 and
h) the quantitative indication of EFFECTIVE INTENSITY in 201.12.1.101.

In practice it is anticipated that manufacturers will declare nominal values of a range of parameters in accordance with Clause 5 of IEC 61689.

Clause 201.8 Protection against electrical HAZARDS from ME EQUIPMENT

In combined EQUIPMENT, this particular standard is applicable only to the ultrasonic part.

However, in combined EQUIPMENT, for example where the TREATMENT HEAD forms one of the electrodes of an electric stimulator, earthing of the TREATMENT HEAD may not be allowed.

Subclause 201.10.101 Ultrasonic energy

This particular standard places the responsibility for guiding the user on the safe use of ULTRASOUND on the MANUFACTURER based on risk analysis.

Subclause 201.10.102 Unwanted ultrasound radiation

The figure of 100 mW/cm^2 incorporates a reasonable safety factor due to the low efficiency of coupling to the OPERATOR's hand, in NORMAL USE, in comparison with the test conditions. If the OPERATOR's fingers were wet or covered in gel, then temperature rises of a few degrees Celsius could occur. In practice, this is an unlikely situation but remains an important issue for the OPERATOR.

Neither the principle of this method nor the arrangement used allow an exact determination of the intensity value, however the value as measured does give an indication of the energy available at the sides of the treatment head.

Subclause 201.11.1.2.2 APPLIED PARTS not intended to supply heat to the PATIENT

TRANSDUCER ASSEMBLIES are not intended to supply heat but do so because of energy loss within the TRANSDUCER ASSEMBLY and ultrasound absorption in the PATIENT.

NOTE General guidance for the acoustic properties of appropriate tissue is available in the literature [8].

When carrying out a risk analysis for the ULTRASOUND PHYSIOTHERAPY EQUIPMENT the user of this standard must take into account that the temperature limit of 43 °C in the general standard is only applicable for long-term (more than 10 min) contact with healthy skin of adults. Special consideration should be taken for an application on children. The influence of drugs and the condition of the patient are factors that should be also considered in the risk-benefit analysis. It is assumed that the safe use of temperatures higher the 41 °C on children, inside the body and on patients with possible risky conditions should also be based on clinical experience.

The allowable maximum temperature of 43 °C for parts having contact with the PATIENT for more than 10 min is consistent with the general standard. This represents a safety factor of 2 relative to the threshold for thermally induced chronic damage to the kidney, one of the most sensitive mammalian tissues [5].

Net tissue temperature rise results from the following mechanisms:

– heat conduction from the transducer;
– absorption of ultrasound in the tissue;
– cooling by heat conduction to other parts of the tissue;
– cooling by heat transport due to blood perfusion.

All TREATMENT HEADS require test conditions and criteria appropriate to the unique clinical scanning environment encountered by the device.

As ULTRASOUND PHYSIOTHERAPY EQUIPMENT generally are used in temperature-controlled locations, the ambient temperature of 23 °C ± 3 °C has been chosen for the environment during the measurement of transducer surface temperature.

In NORMAL USE, typically hand-held probes do not operate while surrounded by tissue; the body of the probe assembly is in contact with ambient air temperature, while only the small portion of the probe intended to contact the patient will be exposed to an ambient temperature determined by patient's core body temperature.

Subclause 201.11.1.3 Measurements (surface temperature)

Removal of the TREATMENT HEAD from contact with the PATIENT is likely during treatment and may result in an increase in the temperature of the radiating surface of the TREATMENT HEAD. A test with the TREATMENT HEAD radiating into air for 30 minutes is therefore specified. The test method specified minimizes measurement errors due to the heating of the temperature measuring device by ULTRASOUND radiation.

This scenario will not arise with modern physiotherapy equipment which senses acoustic coupling and automatically switches off, or significantly reduces the OUTPUT POWER.

Regarding the test method, for typical systems generating 12 watts RATED OUTPUT POWER, a 15 min insonation will transfer almost 12 kJ of energy into the absorbing material, possibly giving rise to a high temperature rise in the material. There are two consequences of this: the absorber may become damaged and also, convection currents may be set-up which will carry the heat up to the transducer, which is also the case in a real treatment situation.

In the still-air test of 11.1.3 of the general standard, essentially all of the electrical energy would be converted into heat within a TREATMENT HEAD, since ultrasound radiation into air (unlike that into the body) is highly inefficient. Due to the use of coupling gel and the usually low heat capacity of the TREATMENT HEAD surface layer, it can be expected that, from the free-air situation into the normal use situation, the surface temperature would drop quickly. The modification of 201.11.1.3 to allow for a 50 °C limit in the still-air test is appropriate to ensure that in normal use conditions the temperature can drop to 43 °C within 1 min. (See 11.1.1, Table 24 of the general standard.)

Tissue-mimicking material (TMM) with thermal and acoustical properties similar to human tissue most appropriate to the typical use of the TREATMENT HEAD under test should be used. The TMM is intended both to inhibit cooling by convection and to model the acoustic properties of a specific tissue. The use of three different types of models can be justified:

– a model with a bone mimic close to the surface;
– a model with a skin mimic at the surface;
– a model consisting of a soft tissue mimic.

The test object should be designed such that increasing the size will have a negligible effect on the surface temperature of the TREATMENT HEAD

When the surface of the TREATMENT HEAD is curved, care should be taken to ensure that the whole surface is in contact with the model used to mimic the intended use.

Alternative materials may be used where the results can be shown to be comparable; most significantly, however, the material used has to exhibit an ultrasonic absorption coefficient and thermal properties appropriate to the intended model.

Subclause 201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Watertightness of the TREATMENT HEAD is necessary not only for the case of treatment under water, but also to prevent the ingress of oils or creams used for coupling of the TRANSDUCER face to the PATIENT'S skin during treatment outside of a water bath. The depth of immersion during the test covers methods used in clinical practice.

Subclause 201.12.1 Accuracy of controls and instrumentation

Actual OUTPUT POWER and EFFECTIVE INTENSITY are the most important quantities for safe treatment, hence their direct indication is considered necessary. Operators should be able to rely on the indicated values when treating PATIENTS. The specified accuracy is considered to provide an adequate degree of safety and also takes into account the uncertainties inherent in ultrasound power measurements.

Subclause 201.12.4 Protection against hazardous output

IEC 61689 uses the term *absolute maximum/minimum* to refer to a quantity which is the measured value plus/minus the uncertainty of the measurement. This standard sets specific values and does not mention measurement uncertainty (apart from disclosure requirements); ability to demonstrate compliance with required values is considered to take such uncertainties into account in line with published IEC guidelines.

Subclause 201.12.4.4 Incorrect output

The maximum value of 3 W/cm^2 specified is a well-established value taking clinical practice and safety considerations into account. However, lower values dependent on the clinical application used may be necessary for particular treatments. (see [6])

Subclause 201.12.4.4.101 Output control

All EQUIPMENT should be suitable for treatment of the PATIENT with low OUTPUT POWER.

Subclause 201.12.4.4.102 Output stability with supply variations

This modest requirement should protect against excessive output variations with MAINS VOLTAGE fluctuations likely to be encountered in practical use.

Subclause 201.12.4.4.103 Timer

The accuracy requirement for the timer is considered adequate in view of the accuracy requirement for the OUTPUT POWER.

Subclause 201.12.4.4.104 Homogeneity of the radiation field

Excessive local peaks in the ULTRASOUND intensity could constitute a SAFETY HAZARD and should be avoided. See also Annex F of IEC 61689 Ed2. The limiting value of eight has been identified in this International Standard for the following reasons:

- in ultrasound physiotherapy the dose (output, duration and frequency) used is based on an ultrasonic beam behaving normally, following theoretical expectations. Evaluating the dose for a treatment is currently difficult to define. Accordingly, a relaxation of the ideal R_{BN} value of four is appropriate. Relaxing the theoretical value of R_{BN} by a factor of 2 seems to be quite reasonable.
- physiotherapists have no current requirement for a focused transducer. If a transducer is focused, the R_{BN} will easily exceed the value eight;

- from a quality point of view, taking the theory into account, there is no justification at all for having a R_{BN} greater than eight;
- it can be calculated that a R_{BN} value of 8,0 (limiting value) results in a maximum pressure at the maximum allowed output setting (3 W/cm^2) in the range of 1 MPa, a spatial-peak temporal-peak intensity (I_{sptp}) of 48 W/cm^2 and a spatial-peak temporal-average intensity (I_{spta}) of 24 W/cm^2. It can be expected that higher values cause unwanted biological effects.

Subclause 201.12.4.4.106 ACOUSTIC WORKING FREQUENCY

This requirement represents an accuracy of ±10 %, which is considered sufficient for therapeutic applications.

Subclause 201.15.4.1 Construction of connectors

The connection cord of the TREATMENT HEAD is flexed continuously in practical use, consequently protection against excessive bending is necessary.

Subclause 201.17 Electromagnetic compatibility

The EQUIPMENT is not allowed to cause electromagnetic interference above a certain level under any conditions of practical use nor to degrade in safety and performance in a "normal" electromagnetic environment. The test under half output power is necessary, since higher levels of interference may be produced under this operating condition.

Annex BB
(informative)

Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES

BB.1 General

The test object set-up described below is a result of measurements presented in the report [3,7]. For at least 10 different transducers, the surface temperatures of the transducers as measured when radiating into human under-arms were compared with the set-up described.

Basically the set-up consists of a piece of soft tissue-mimicking material (TMM) covered by a slab of silicone rubber on which a (thin film) thermocouple is placed (see Figure BB.1). The TMM is placed on a piece of material that absorbs all acoustic energy.

The set-up of the test object may depend on the transducers to be tested. In this specific example of the test object the surface that is in contact with the transducer is at least 2 cm wider than the transducer front. The depth of the test object is such that the heat developed due to ultrasound absorption at the acoustic absorber at the bottom (5) is not affecting the surface temperature. An adequate depth for setting up the acoustic absorber at the bottom (5) is usually 10 cm from the surface.

The properties of the materials used will be those of silicon and TMM as listed in Table BB.1.

Table BB.1 – Acoustic and thermal properties of tissues and materials

Tissue/ material	Velocity c m/s	Density ρ kg/m^3	Attenuation coefficient α dB/cm-MHz	Acoustic impedance Z 10^6 kg/m^2-s	Special heat capacity C J/kg-K	Thermal conductivity κ W/ kg-K	Thermal diffusivity D 10^{-6} m^2/s	Source
Skin	1 615	1 090	2,3 – 4,7 3,5 [7)]	1,76	3 430	0,335	0,09	ICRU rep.61 1998 [2] Chivers 1978 [9]
Soft tissue	1 575	1 055	0,6 – 2,24 [a]	1,66	3 550	0,525	0,150	ICRU rep.61 1998 [2]
Soft tissue fatty	1 465	985	0,4	1,44	3 000	0,350	0,135	ICRU rep.61 1998 [2]
Cortical bone[b]	3 635	1 920	14 - 22	6,98	1 300	0,3 - 0,79	0,32	ICRU rep.61 1998 [2]
Silicone	1 021	1 243	1,8[c]	1,3		0,25		TNO / Dow Corning
TMM	1 540	1 050	0,5[c]	1,6	3 800	0,58	0,15	TNO (soft tissue model)

a Frequency dependence: $f^{1,2}$

b Wide uncertainty has been reported in bone properties [10].

c Determined at 3 MHz.

BB.2 Preparation of the soft tissue-mimicking material (TMM)

A mixture is made from the materials provided in Table BB.2 (weight % pure components).

Table BB.2 – Weight % pure components

Component	Weight %
Glycerol	11,21
Water	82,95
Benzalkonium chloride	0,47
Silicon carbide (SiC (-400 mesh))	0,53
Aluminium oxide (Al_2O_3 (0,3 μm))	0,88
Aluminium oxide (Al_2O_3 (3μm))	0,94
Agar	3,02
Sum	100,00

- **Recipe to prepare the soft tissue-mimicking material and the set-up**

(1) Mix all components listed in the table and degas at laboratory temperature. A magnetic stirrer will work well.

(2) Heat, while stirring, until 90 °C.
To avoid evaporation and hence a change in components ratio, the mixture should be covered during this process.

(3) Cool the mixture, while stirring as long as the viscosity allows, until about 47 °C.
To avoid evaporation and hence a change in components ratio, the mixture should be covered during this process.

(4) Pour the mixture quickly into a mould and let it further cool down while the mould is covered.

(5) The TMM is now ready for use. To prepare the total measurements set-up, the TMM should be covered with a slab of silicone rubber with a thickness of 1,5 mm. Take care that there is no air between the TMM and the silicon rubber. (This will result in similar measurement results to those achieved using human under-arms). Although figure BB.1 shows a set-up for a flat transducer surface, a curved surface is easily obtained by cutting the curvature in the TMM.

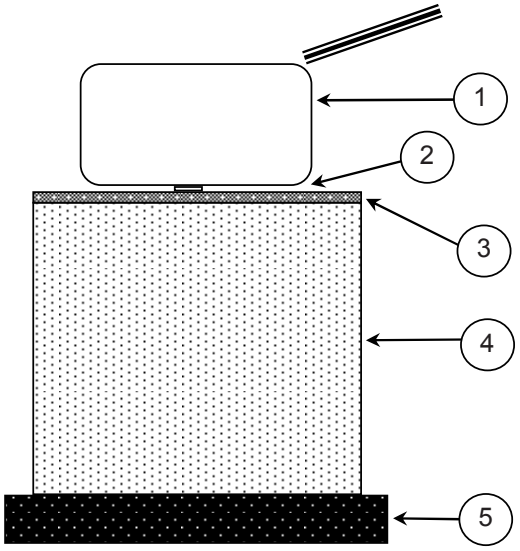
(6) A (thin film) thermocouple is to be placed on top of the silicone rubber layer.

(7) Finally the transducer under test has to be placed, coupled with acoustic coupling gel.

- **Maintenance**

The material should be stored in a closed container under normal laboratory conditions (18 °C – 25 °C). While stored, keep the material in a water/glycerol mixture to prevent it from drying out and to avoid air contact. This mixture should contain 88,1 % (weight) demineralised water and 11,9 % (weight) glycerol (purity >99 %).

The shelf life of the material if it is preserved without air contact is at least one year. The addition of a 0,5 % (weight) solution of benzalkonium chloride acts as an antifungal agent extending the life of the phantom. With produced samples shelf lives over 2 years were found.



Components

1. ULTRASONIC TRANSDUCER under test, coupled to the test object using acoustic coupling gel
2. Thermal sensor, e.g. thin film thermocouple
3. Silicone rubber, thickness: 1,5 mm
4. Soft tissue mimicking material (TMM)
5. Acoustic absorber

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Figure BB.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers

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4) To be published.

Index of defined terms used in this particular standard

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