

Ultrasonics — Physiotherapy systems — Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz

The European Standard EN 61689:2007 has the status of a
British Standard

ICS 11.040.60

National foreword

This British Standard is the UK implementation of EN 61689:2007. It is identical to IEC 61689:2007. It supersedes BS EN 61689:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics.

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

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2007

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ISBN 978 0 580 54471 2

Amendments issued since publication

Amd. No.	Date	Comments

English version

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

Ultrasons -
Systèmes de physiothérapie -
Spécifications des champs et méthodes
de mesure dans la gamme de fréquences
de 0,5 MHz à 5 MHz
(CEI 61689:2007)

Ultraschall -
Physiotherapiesysteme -
Feldspezifikationen und Messverfahren im
Frequenzbereich von 0,5 MHz bis 5 MHz
(IEC 61689:2007)

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CENELEC

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

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

Foreword

The text of document 87/351/CDV, future edition 2 of IEC 61689, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel Unique Acceptance Procedure and was approved by CENELEC as EN 61689 on 2007-10-01.

This European Standard supersedes EN 61689:1996.

EN 61689:2007 is a result of maintenance on this standard and the referenced standards EN 61161:2007 and EN 62127-1. A relatively large technical change is the determination of the effective radiating area. This is now no longer based on the measurement of four areas but only on one. This change was needed to improve the accuracy of the determination of this parameter for small transducers. Be aware that this change may alter the value obtained for this and related parameters.

This standard is to be used in conjunction with EN 60601-2-5.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2008-07-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2010-10-01 |

NOTE The following print types are used:

- Requirements: in roman type
- *Test specifications: in italic type*
- Notes: in small roman type
- Words in **bold** in the text are defined in Clause 3.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61689:2007 was approved by CENELEC as a European Standard without any modification.

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INTRODUCTION

Ultrasound at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high-frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** consists of a transducer, usually a disk of piezoelectric material, for converting the electrical energy to **ultrasound** and is often designed for contact with the human body.

ULTRASONICS – PHYSIOTHERAPY SYSTEMS – FIELD SPECIFICATIONS AND METHODS OF MEASUREMENT IN THE FREQUENCY RANGE 0,5 MHz TO 5 MHz

1 Scope

This International Standard is applicable to **ultrasonic equipment** designed for physiotherapy consisting of an **ultrasonic transducer** generating continuous or quasi-continuous wave ultrasonic energy in the frequency range 0,5 MHz to 5 MHz.

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 specifies:

- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on reference testing methods;
- characteristics to be specified by manufacturers of **ultrasonic physiotherapy equipment** based on reference testing methods;
- guidelines for safety of the ultrasonic field generated by **ultrasonic physiotherapy equipment**;
- methods of measurement and characterization of the output of **ultrasonic physiotherapy equipment** based on routine testing methods;
- acceptance criteria for aspects of the output of **ultrasonic physiotherapy equipment** based on routine testing methods.

Therapeutic value and methods of use of **ultrasonic physiotherapy equipment** are not covered by the scope of this standard.

2 Normative references

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

IEC 60050-801:1994, *International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics*

IEC 60469-1:1987, *Pulse techniques and apparatus – Part 1: Pulse terms and definitions*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-5:2000, *Medical electrical equipment – Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment*

IEC 61161:2006, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

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

IEC 62127-3:2007, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

acoustic pulse waveform

temporal waveform of the instantaneous acoustic pressure at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or one or more cycles in a continuous wave

NOTE 1 Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

NOTE 2 Definition adopted from IEC 60469-1.

3.2

acoustic repetition period

arp

pulse repetition period for non-automatic scanning systems and the **scan repetition period** for automatic scanning systems, equal to the time interval between corresponding points of consecutive cycles for continuous wave systems

NOTE 1 **Acoustic repetition period** is expressed in seconds (s).

NOTE 2 Definition adopted from IEC 62127-1.

3.3

acoustic frequency

acoustic-working frequency

frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**

NOTE 1 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.3.1 and 3.3.2.

NOTE 2 In a number of cases the present definition is not very helpful or convenient, especially for **broadband transducers**. In that case a full description of the frequency spectrum should be given in order to enable any frequency-dependent correction to the signal.

NOTE 3 Acoustic frequency is expressed in hertz (Hz).

NOTE 4 Definition adopted from IEC 62127-1.

3.3.1

zero-crossing acoustic-working frequency

f_{awf}

this is determined according to the procedure specified in IEC/TR 60854.

NOTE This frequency is intended for continuous wave systems only.

3.3.2**arithmetic-mean acoustic-working frequency** f_{awf}

arithmetic mean of the most widely separated frequencies f_1 and f_2 , within the range of three times f_1 , at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

NOTE 1 This frequency is intended for pulse-wave systems only.

NOTE 2 It is assumed that $f_1 < f_2$.

3.4**amplitude modulated wave**

wave in which the ratio $p_p / \sqrt{2} p_{\text{rms}}$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where p_p is the **temporal-peak acoustic pressure** and p_{rms} is the **r.m.s. acoustic pressure**

3.5**attachment head**

accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

NOTE Definition adopted from IEC 60601-2-5.

3.6**beam alignment axis**

straight line joining two points of spatial-peak temporal-peak acoustic pressure on two plane surfaces parallel to the faces of the treatment head. One plane is at a distance of approximately $A_{\text{ERN}}/(\pi\lambda)$ where A_{ERN} is the nominal value of the effective radiating area of the treatment head and λ is the wavelength of the ultrasound corresponding to the nominal value of the acoustic working frequency. The second plane surface is at a distance of either $2A_{\text{ERN}}/(\pi\lambda)$ or $A_{\text{ERN}}/(3\pi\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the treatment head

NOTE 1 If the nominal value of the **effective radiating area** is unknown, then another suitable area may be used to define the **beam alignment axis** such as the area of the active element of the **ultrasonic transducer**.

NOTE 2 As the **beam alignment axis** is used purely for the purposes of alignment, the definitions of specific distances may be relaxed slightly to reflect the constraints of the measurement system employed. For example, some **treatment heads** will have $A_{\text{ERN}}/(\pi\lambda)$ considerably greater than 12 cm, in which case a maximum distance of 12 cm may be used to define the first plane. General guidelines for determining the **beam alignment axis** are given in 8.3.

3.7**beam cross-sectional area** A_{BCS}

minimum area in a specified plane perpendicular to the **beam alignment axis** for which the sum of the **mean square acoustic pressure** is 75 % of the **total mean square acoustic pressure**

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

3.8**beam maximum intensity**

product of the beam non-uniformity ratio and effective intensity

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

3.9

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**. **Beam non-uniformity ratio** is given by:

$$R_{BN} = \frac{p_{\max}^2 A_{ER}}{pms_t A_o} \quad (1)$$

where

- $p_{\max}$ is the **maximum r.m.s. acoustic pressure**;
- A_{ER} is the **effective radiating area**;
- pms_t is the **total mean square acoustic pressure**;
- A_o is the unit area for the raster scan.

3.10

absolute maximum beam non-uniformity ratio

beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the beam non-uniformity ratio

3.11

beam type

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

3.12

collimated

beam for which the **active area coefficient**, Q , obeys the following inequality:

$$-0,05 \text{ cm}^{-1} \leq Q \leq 0,1 \text{ cm}^{-1}$$

3.13

convergent

beam for which the **active area coefficient**, Q , obeys the following inequality:

$$Q < -0,05 \text{ cm}^{-1}$$

3.14

divergent

beam for which the **active area coefficient**, Q , obeys the following inequality:

$$Q > 0,1 \text{ cm}^{-1}$$

3.15

continuous wave

wave in which the ratio $p_p / \sqrt{2} p_{rms}$, at any point in the **far field** on the **beam alignment axis**, is less than or equal to 1,05, where p_p is the **temporal-peak acoustic pressure** and p_{rms} is the **r.m.s. acoustic pressure**

3.16

duty factor

ratio of the pulse duration to the pulse repetition period

NOTE Definition adopted from IEC 60469-1, 5.3.2.4.

3.17 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).

3.18 absolute maximum effective intensity

value of the effective intensity corresponding to the absolute maximum rated output power and the absolute minimum effective radiating area from the equipment

3.19 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, F_{ac} , given by:

$$F_{ac} = 1,354 \quad (2)$$

NOTE 1 The conversion factor F_{ac} is used here in order to derive the area close to the **treatment head** which contains 100 % of the **total mean square acoustic pressure**. The origin of the value of F_{ac} is described in Annex E and bibliographic references [3] and [4].

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

3.20 absolute minimum effective radiating area

effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.21 end-of-cable loaded sensitivity end-of-cable loaded sensitivity of a hydrophone (or hydrophone-assembly)

$M_L(f)$

ratio of the instantaneous voltage at the end of any integral cable or output connector of a **hydrophone** or **hydrophone-assembly**, when connected to a specified **electric load impedance**, to the **instantaneous acoustic pressure** in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

NOTE 1 **End-of-cable loaded sensitivity** is expressed in volts per pascal (V/Pa).

NOTE 2 Definition adopted from IEC 62127-3.

3.22 far field

acoustic (sound) field at distances from an **ultrasonic transducer** where the values of the **instantaneous acoustic pressure** and particle velocity are substantially in phase [see also IEC 60050-801, 801-03-30]

NOTE 1 Definition adopted from IEC 62127-1.

NOTE 2 For the purposes of this standard, the far field is at a distance greater than $A_{ERN}/(\pi\lambda)$ where A_{ERN} is the nominal value of the effective radiating area of the treatment head and λ is the wavelength of the ultrasound corresponding to the acoustic working frequency. This differs from IEC 62127-1.

3.23 hydrophone

transducer that produces electrical signals in response to waterborne acoustic signals

NOTE Definition adopted from IEC 60050-801, 801-32-26 (1994).

3.24

instantaneous acoustic pressure

$p(t)$

pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field (see also IEC 60050-801, 801-01-19)

NOTE 1 **Instantaneous acoustic pressure** is expressed in pascal (Pa).

NOTE 2 Definition adopted from IEC 60050-801, 801-21-19 (1994).

3.25

active area coefficient

Q

quotient of the **active area gradient**, m , and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{BCS}(0,3)$

NOTE **Active area coefficient** is expressed in per centimetre (cm^{-1}).

3.26

active area gradient

m

gradient of the line connecting the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{BCS}(0,3)$, and the **beam cross-sectional area** at the position of the last axial maximum acoustic pressure, $A_{BCS}(Z_N)$, versus distance

NOTE **Active area gradient** is expressed in centimetre (cm).

3.27

mean square acoustic pressure

mean square of the **instantaneous acoustic pressure** at a particular point in the acoustic field. The mean is taken over an integral number of **acoustic repetition periods**

NOTE 1 In practice, the mean value is often derived from rms measurements.

NOTE 2 **Mean square acoustic pressure** is expressed in pascal squared (Pa^2).

3.28

total mean square acoustic pressure

pms_t

sum of the **mean square acoustic pressure** values, each with a specified incremental area, in a specified plane over specified limits of summation

NOTE **Total mean square acoustic pressure** is expressed in pascal squared (Pa^2).

3.29

modulation waveform

temporal envelope waveform of the **amplitude modulated wave** at the point of **peak r.m.s. acoustic pressure** on the **beam alignment axis** and displayed over a period sufficiently long to include all significant acoustic information in the **amplitude modulated wave**

3.30

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

NOTE 1 Definition adopted from IEC 61161:2006.

NOTE 2 **Output power** is expressed in watt (W).

3.31**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).

3.32**absolute maximum rated output power**

sum of the **rated output power**, the 95 % confidence overall uncertainty in the **rated output power**, and the maximum increase in the **rated output power** for a ± 10 % variation in the rated value of the mains voltage

NOTE 1 The possibility of variation in the **rated output power** resulting from ± 10 % variation in the rated value of the mains voltage should be checked by using a variable output transformer between the mains voltage supply and the **ultrasonic physiotherapy equipment**. See A.2 for further guidance.

NOTE 2 **Absolute maximum rated output power** is expressed in watt (W).

3.33**temporal-maximum output power**

P_{tm}

in the case of an **amplitude modulated wave**, the **temporal-maximum output power** is given by:

$$P_{tm} = 1/2 \left(\frac{p_p}{p_{rms}} \right)^2 P \quad (3)$$

where

P is the actual **output power** under **amplitude modulated wave** conditions;

p_p is the **temporal-peak acoustic pressure**;

p_{rms} is the true **r.m.s. acoustic pressure**.

Both p_p and p_{rms} are measured under **amplitude modulated wave** conditions and at a specified point on the **beam alignment axis**

NOTE **Temporal-maximum output power** is expressed in watt (W).

3.34**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

NOTE 1 This definition differs from that of 3.48 of IEC 62127-1, from which it is derived, to account for incomplete modulation.

NOTE 2 **Pulse duration** is expressed in seconds (s).

3.35**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).

3.36

pulse repetition rate

prr

reciprocal of the pulse repetition period

NOTE 1 See also IEC 60469-1:1987, 5.3.2.2.

NOTE 2 The **pulse repetition rate** is expressed in hertz (Hz).

NOTE 3 The **pulse repetition rate** is equal to the repetition frequency of the modulated waveform.

3.37

rms acoustic pressure

p_{rms}

root-mean-square (rms) of the **instantaneous acoustic pressure** at a particular point in an acoustic field

NOTE 1 The mean should be taken over an integral number of **acoustic repetition periods** unless otherwise specified.

NOTE 2 Definition adopted from IEC 62127-1.

NOTE 3 **rms acoustic pressure** is expressed in pascal (Pa).

3.38

maximum rms acoustic pressure

p_{max}

maximum value of the **rms acoustic pressure** detected by a **hydrophone** over the entire acoustic field

NOTE **Maximum rms acoustic pressure** is expressed in pascal (Pa).

3.39

peak rms acoustic pressure

maximum value of the **rms acoustic pressure** over a specified region, line or plane in an acoustic field

NOTE **Peak rms acoustic pressure** is expressed in pascal (Pa).

3.40

temporal-maximum intensity

I_m

in the case of an amplitude modulated wave, the temporal-maximum intensity is given by:

$$I_m = \frac{P_{tm}}{A_{ER}} \quad (4)$$

where

P_{tm} is the **temporal-maximum output power**;

A_{ER} is the **effective radiating area**.

NOTE **Temporal-maximum intensity** is expressed in watt per centimetre squared (W/cm²).

3.41

temporal-peak acoustic pressure

p_{tp}

maximum value of the modulus of the **instantaneous acoustic pressure** at a particular point in an acoustic field

NOTE 1 Definition adopted from IEC 62127-1.

NOTE 2 **Temporal-peak acoustic pressure** is expressed in pascal (Pa).

3.42 treatment head

assembly comprising one **ultrasonic transducer** and associated parts for local application of **ultrasound** to the patient

NOTE Definition adopted from IEC 60601-2-5.

3.43 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

NOTE Definition adopted from IEC 62127-1.

3.44 ultrasound

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

NOTE Definition adopted from IEC 60050-801 (1994).

3.45 ultrasonic physiotherapy equipment; equipment

equipment for the generation and application of **ultrasound** to a patient for therapeutic purposes

NOTE Definition adopted from IEC 60601-2-5.

4 List of symbols

a	Geometrical radius of the active element of a treatment head
A_{BCS}	Beam cross-sectional area
$A_{\text{BCS}}(0,3)$	Beam cross-sectional area evaluated at 0,3 cm from the front face of the treatment head
$A_{\text{BCS}}(z_{\text{N}})$	Beam cross-sectional area evaluated at the position of the last axial maximum, z_{N}
A_{ER}	Effective radiating area of a treatment head
A_{ERN}	Nominal value of the effective radiating area of a treatment head
a_{g}	Geometrical radius of the active element of a hydrophone
A_{g}	Geometrical area of the face of a treatment head
a_{max}	Maximum hydrophone effective radius defined by IEC 62127-3
A_{o}	Unit area for a raster scan
b	Minimum radius of a target for a radiation force balance
c	Speed of sound in water
f	Acoustic working frequency
F_{ac}	Conversion factor to convert $A_{\text{BCS}}(0,3)$ to A_{ER}

I_e	Effective intensity
I_m	Temporal maximum intensity
k	($= 2\pi/\lambda$) Circular wave number
m	Active area gradient
M_L	End-of-cable loaded sensitivity of a hydrophone
P	Output power of a treatment head
P_{tm}	Temporal-maximum output power
p_p	Temporal-peak acoustic pressure
p_{max}	Maximum r.m.s. acoustic pressure
p_{rms}	RMS acoustic pressure
pms_t	Total mean square acoustic pressure
$pms_t(z)$	Total mean square acoustic pressure determined in the specific plane z
Q	Active area coefficient
R	Ratio of the peak r.m.s. acoustic pressure to the r.m.s. acoustic pressure averaged over the beam cross-sectional area in a specified plane
R_{BN}	Beam non-uniformity ratio
S	Step size for a raster scan
$S(z)$	Step size for raster scan in the specific plane z
U	End-of-cable voltage for a hydrophone
U_i	Hydrophone signal for the i -th scan point
U_p	Maximum value of the hydrophone voltage
z	Distance from the face of the treatment head to a specified point on the beam alignment axis
z_j	Distance from the face of the treatment head to the measurement plane (perpendicular to the beam alignment axis) of interest
z_N	Distance of the last axial maximum from the face of the treatment head
z_p	Distance of the peak r.m.s. acoustic pressure from the front face of the treatment head
λ	Ultrasonic wavelength
ρ	Density of water

Uncertainties are specified throughout this standard at the 95 % confidence level.

5 Ultrasonic field specifications

In addition to the general requirements specified in IEC 60601-1 and specific requirements specified in IEC 60601-2-5, manufacturers shall specify nominal values for the following parameters in the accompanying literature for each type of **treatment head**.

- rated output power (± 20 %);
- effective radiating area (A_{ERN}) of the treatment head (± 20 %);
- effective intensity at the same equipment settings as the nominal value of the rated output power (± 30 %);
- acoustic working frequency (± 10 %);
- beam non-uniformity ratio (R_{BN}) (± 30 %);
- beam maximum intensity (± 30 %);
- beam type;
- pulse duration, pulse repetition period, duty factor and the ratio of the temporal maximum output power to the output power for each modulation setting (± 5 %);
- modulation waveform for each modulation setting.

The numbers given in brackets are the tolerances defining the range of acceptable values for the results of either the type testing reference measurements specified in Clause 7 or the routine measurements specified in Clause 8. If the published tolerance requirement cannot be met, then the 95 % confidence level that is achievable should be reported. It shall then be demonstrated that the reported value, when incorporated with the tolerance so as to produce the 'worst case' value, remains within the range of acceptable values, as specified in IEC 60601-2-5, and on which guidance is provided in Annex A.

The temperature range shall be specified for the parameters specified above. The range of line voltages shall also be specified.

For **ultrasonic physiotherapy equipment** using a **treatment head** capable of operating at more than one nominal value of **acoustic working frequency**, the parameters listed above shall be specified for each nominal value of **acoustic working frequency**.

In addition, for **ultrasonic physiotherapy equipment** which can use an **attachment head**, the parameters listed above shall be specified for each combination of **attachment head** and **treatment head**.

NOTE This document does not contain requirements relating to safety: these are covered in IEC 60601-2-5. Guidance on performance and safety can be found in Annex A of this document.

6 Conditions of measurement and test equipment used

6.1 General

All measurements shall be undertaken under approximately free-field conditions at a temperature of $22\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$.

If measurements are carried out at any other temperature, a test shall be undertaken to show that the results, determined in accordance with 7.6 and 8.3, are not dependent on the temperature at which the tests were undertaken.

Degassed water shall be used for the measurement of ultrasonic power, see 7.2. Degassed water is not essential for the **hydrophone** measurements, see 7.3.

NOTE Degassed water is essential to avoid cavitation when the physiotherapy units are operated at or near full **output power**. Information on preparation of water suitable for physiotherapy measurements may be found in IEC 61161, and in bibliographic reference [10].

All measurements shall be made after the warm-up period specified by the manufacturer. If no such period is specified, a period of 30 min shall be used.

6.2 Test vessel

The test vessel used for all **hydrophone** measurements shall be large enough to allow the immersion of both the **treatment head** and the **hydrophone**. The tank size should conform to IEC 62127-1.

The relative position and angular orientation of the **treatment head** and **hydrophone** should be adjustable for the purposes of alignment in accordance with IEC 62127-1. Full degrees of freedom of movement of both may be provided, although the minimum requirement is that either the **treatment head** or the **hydrophone** should possess three independent degrees of translational movement. The measurements should be performed under free-field conditions. To achieve these conditions it may be necessary to line the walls of the test vessel as well as the mounts used to hold the **treatment head** and the **hydrophone** with absorbers or angled reflector(s) and absorber(s) of higher absorption and lower scatter. The free-field conditions will be met sufficiently when the overall echo is reduced by more than 25 dB. Various methods can be used to check the compliance for echo reduction of the tank lining materials used. One example to check the absorbing or scattering materials used is given below.

*Compliance for overall echo reduction of an acoustic absorber may be checked using the following procedure. Echo reduction should be measured at the **acoustic working frequency** of the **treatment head** under test using tone-burst **ultrasound**, with the acoustic absorber located in the **far-field** of the separately driven **ultrasonic transducer**. The resulting **hydrophone** signal (peak-to-peak or rms), produced by the reflection from the front surface of the acoustic absorber, U_{absorber} , is compared to that from a perfect planar reflector, $U_{\text{reflector}}$. The acoustic absorber and the perfect reflector should be aligned near normal to the **beam alignment axis** but angled so that the reflected signal can be intercepted by the hydrophone. The echo reduction is calculated using:*

$$\text{echo reduction} = -20 \log_{10} \left[\frac{U_{\text{absorber}}}{U_{\text{reflector}}} \right] \quad (5)$$

A stainless steel reflector of minimum thickness 25 mm may be used to provide a good approximation to a completely reflecting surface.

Compliance of the test vessel to free-field conditions is checked by noting the invariance of the product $pms_t \cdot s^2$ (see 7.4.7) after completing the measurements specified in Clause 7.

NOTE For some **treatment heads**, ultrasound reflected back to the **treatment head** may affect **output power**, particularly in the case of coherent reflections from absorbers with planar smooth surfaces. In these instances, an improved approximation to free-field conditions may be obtained by using acoustic absorbers with textured surfaces.

6.3 Hydrophone

Measurements of **effective radiating area** shall use a needle **hydrophone**, with the active element made from either polyvinylidene fluoride (PVDF) or piezoceramic (PZT). The electrical signal from the **hydrophone** may be amplified for adequate measurement accuracy. The maximum effective radius of the **hydrophone** used for the measurements shall be a_{max} so that:

$$\lambda/a_{\text{max}} \geq 2,5 \quad (6)$$

NOTE For more information on the use of hydrophones, see IEC 62127-1.

6.4 RMS or peak signal measurement

The measured end-of-cable voltage, U , at the **hydrophone** shall be related to the **instantaneous acoustic pressure**, p , by:

$$p = U/M_L \quad (7)$$

where M_L is the **end-of-cable loaded sensitivity of the hydrophone**. However, in practice, the absolute values of the acoustic pressure are not required as the analysis of measured data throughout this standard is based on relative **hydrophone** measurements.

Subsequent reference to acoustic pressure will refer to the **r.m.s. acoustic pressure** for convenience. In fact, measurements may be based on either **r.m.s.** or **peak-to-peak acoustic pressure** providing, whichever is used, all measurements are based on the chosen method of measurement.

NOTE Distortion caused by nonlinear propagation effects is usually negligible, in which case the peak acoustic pressure is proportional to the **rms acoustic pressure**. Therefore either the **rms acoustic pressure** or the **temporal-peak acoustic pressure** can be measured.

The linearity of the response of the combination of **hydrophone**, **hydrophone/amplifier** and the rms or peak detection system shall be determined and, if appropriate, corrections shall be made to the measured data.

*Compliance for linearity is checked using a separate **ultrasonic transducer** operating in tone-burst mode and measuring the signal received by the **hydrophone** and measuring system as a function of voltage excitation applied to the **ultrasonic transducer**.*

7 Type testing reference procedures and measurements

7.1 General

The procedures specified in 7.2 to 7.4 shall be used for the determination of type testing reference values for the parameters specified in 7.5.

NOTE Any **ultrasonic physiotherapy equipment** which includes circuits that control the acoustic output of the **ultrasonic transducer** in response to changes in the acoustic impedance of the propagation medium should be configured so that the control circuitry is switched off.

7.2 Rated output power

Output power of the **ultrasonic physiotherapy equipment** shall be determined in accordance with IEC 61161. **Rated output power** shall be determined by setting all controls of the **equipment** to yield the maximum **output power**. To avoid cavitation, degassed water shall be used between the output face of the **treatment head** and the entrance of the power measurement system. Overall uncertainty of measurement expressed at the 95 % confidence level shall be determined (see 9.1) and should be better than ± 15 %. Measurements should be traceable to national measurement standards. The **absolute maximum rated output power** shall be determined from the sum of the **rated output power** and the overall uncertainty in the mean value of the measured **rated output power** and the maximum increase in the **rated output power** for a ± 10 % variation in the nominal line voltage.

See Annex F.

7.3 Hydrophone measurements

The **treatment head** shall be set up in the test vessel in accordance with Clause 6.

Some **treatment heads** are known to produce reproducibly asymmetrical beams. In these cases the **treatment head** shall bear a mark on its housing identifying the direction yielding the maximum deviation of the value of the **beam cross-sectional area** determined from individual half line scans relative to the mean value, in both planes of measurement. One of the **hydrophone** translational axes shall be parallel to this direction (see 7.4.3).