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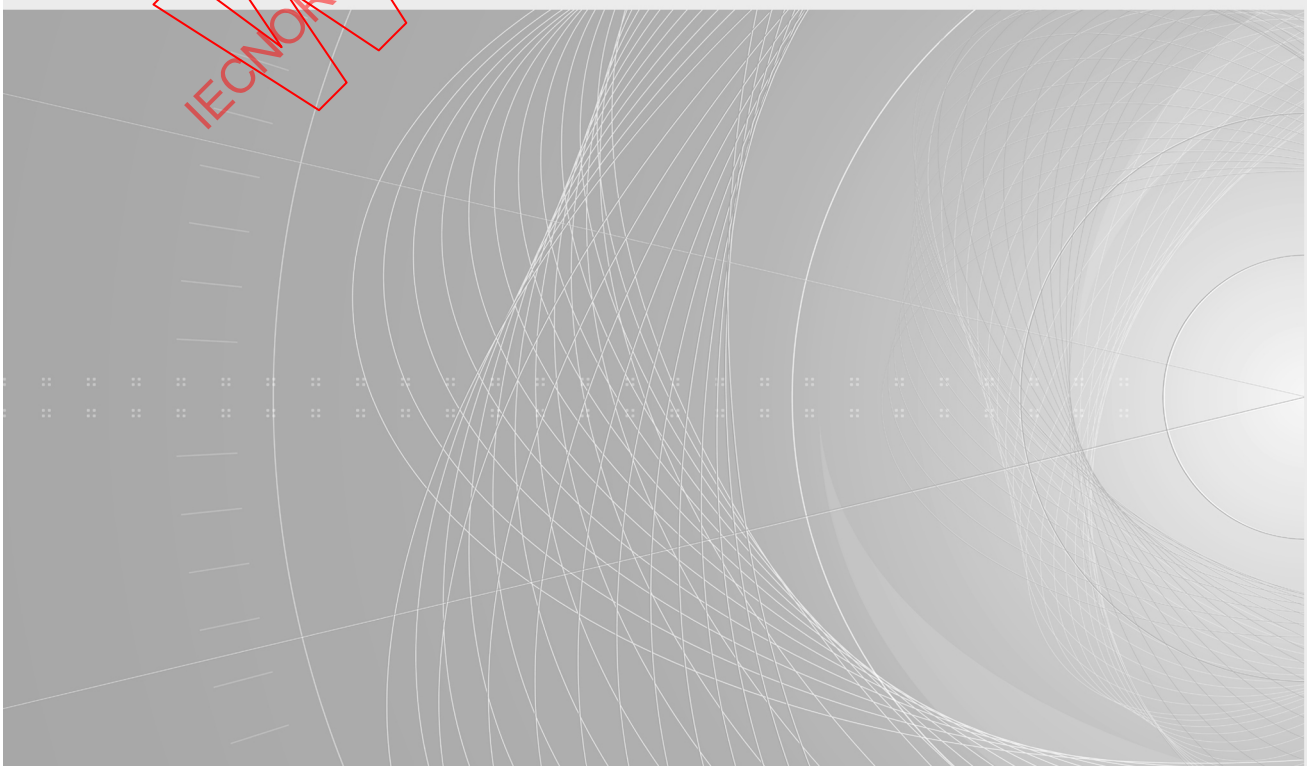
INTERNATIONAL STANDARD

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



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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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International Standard IEC 61689 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition cancels and replaces the first edition published in 1996 and constitutes a technical revision.

This second edition is a result of maintenance on this standard and the referenced standards IEC 61161 (2006) and IEC 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.

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

CDV	Report on voting
87/351/CDV	87/370/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This standard should be read in conjunction with IEC 60601-2-5, which, as indicated in its preface, will be revised in order to be compatible with this standard.

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.

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- withdrawn,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.

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

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 $p_p / \sqrt{2} p_{rms}$ 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 $A_{ERN}/(\pi\lambda)$ 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 $2A_{ERN}/(\pi\lambda)$ or $A_{ERN}/(3\pi\lambda)$, 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 $A_{ERN}/(\pi\lambda)$ 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:

$$R_{BN} = \frac{p_{max}^2 \, A_{ER}}{pms_t \, A_o} \tag{1}$$

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:

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

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:

$$I_{\mathrm{m}} = \frac{P_{\mathrm{tm}}}{A_{\mathrm{ER}}} \tag{4}$$

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/cm^2).

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**
$A_{BCS}(0,3)$	Beam cross-sectional area evaluated at 0,3 cm from the front face of the **treatment head**
$A_{BCS}(z_N)$	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 $A_{BCS}(0,3)$ 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 with 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 °C ± 3 °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, $U_{reflector}$. 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 $pms_t.s^2$ (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:

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

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).

All measurements of **effective radiating area** should be undertaken with the **equipment** set in **continuous wave** mode at intensities less than 0,5 W/cm^2 to avoid cavitation. Degassed water is therefore not necessary for these measurements although care should be taken to ensure air bubbles are not present on the face of the **treatment head** or on the **hydrophone**.

NOTE 1 Measurements of **beam cross-sectional area** are performed at low powers to protect the probe **hydrophones** used. The validity of extrapolating these values to higher power levels more typical of therapeutic treatment is demonstrated in Annex G.

NOTE 2 To reduce the likely effects of acoustic reflections on the received **hydrophone** signal, it is permissible to make **hydrophone** measurements with the **ultrasonic physiotherapy equipment** operating in tone-burst mode producing an **amplitude modulated wave**. If measurements are carried out in this way, it should be demonstrated that the derivation of the measured parameters from the **amplitude modulated wave** acoustic field are equivalent to those determined in the **continuous wave** case. The effect of making measurements in the **amplitude modulated wave** acoustic field case on the uncertainties in the nominal values of the parameters listed in Clause 5 should also be assessed.

The **beam alignment axis** of the **treatment head** shall be established in accordance with IEC 62127-1. The second plane surface (see 3.6) should initially be chosen as $A_{ERN}/(3\pi\lambda)$. If it is not possible to locate a single peak at or close to this distance, the larger distance of $2A_{ERN}/(\pi\lambda)$ should be chosen. If this latter distance is too large, locate another measurement plane sufficiently far from the first in order to establish reliably the **beam alignment axis**. Once aligned, an axial plot shall be performed along the **beam-alignment axis** and the distance of the plane of **maximum r.m.s. acoustic pressure**, z_p, and the position of the last axial maximum, z_N, shall be determined.

The step size of the axial plot should be typically between 0,5 mm and 1,0 mm, and shall not be greater than 2 mm.

The **acoustic working frequency** shall be determined with the **hydrophone** at a distance z_p from the **treatment head**.

With the **hydrophone** positioned at the same place, the **pulse duration**, **pulse repetition period** and **duty factor** shall be determined and the **modulation waveform** shall be recorded for the different modulation settings of the **equipment**. The quotient of the **temporal-peak acoustic pressure** to the **rms acoustic pressure** shall be determined for each modulation setting. The **temporal-maximum output power** shall then be determined using the **output power** determined from 7.2.

7.4 Effective radiating area

7.4.1 General

Effective radiating area, A_{ER}, of the **treatment head** shall be determined by undertaking a raster scan of the acoustic field in a plane perpendicular to the **beam alignment axis** at a distance of 0,3 cm from the output face of the treatment head, using a **hydrophone**. From this scan, the **effective radiating area** of the **treatment head** is derived from the **beam cross-sectional area**, A_{BCS}. The general requirements for raster scans are given in B.1 and B.2. The actual procedure for the reference measurements and the analysis of the results are given in 7.4.1 to 7.4.7. Under normal test conditions, the results using the test methods described should produce an overall uncertainty in the determination of **effective radiating area** (at the 95 % confidence level) of ±10 %.

For the determination of the **beam non-uniformity ratio**, R_{BN}, under normal test conditions, the test methods should achieve a measurement uncertainty (at the 95 % confidence level) of less than ±15 %.

7.4.2

With the **hydrophone** at distance z_p, the position of the **hydrophone** shall be adjusted in the plane perpendicular to the **beam alignment axis** to determine the **maximum r.m.s. acoustic pressure,** p_{max}, in the field.

This may be done by carrying out a raster scan over a limited region of the acoustic field or it may be done by manual translation.

7.4.3

The **beam cross-sectional area** shall be determined at 0,3 cm from the output face of the **treatment head**, and at the position of the last axial maximum, z_N. The analysis of the raster scans shall be carried out in accordance with B.3. The analysis yields the **beam cross-sectional areas**, $A_{BCS}(0,3)$ and $A_{BCS}(z_N)$ and the **total mean square acoustic pressure**, pms_t, at each measurement plane.

7.4.4

The **active area gradient**, m, and the **active area coefficient**, Q, [$Q = mA_{BCS}(0,3)$] shall be determined.

7.4.5

The **beam type** shall be determined from:

$$\begin{aligned} Q &> 0{,}1\ \text{cm}^{-1} && \textbf{divergent} \\ -0{,}05\ \text{cm}^{-1} \le Q &\le 0{,}1\ \text{cm}^{-1} && \textbf{collimated} \\ Q &< -0{,}05\ \text{cm}^{-1} && \textbf{convergent} \end{aligned} \qquad (8)$$

7.4.6

The **effective radiating area**, A_{ER}, of the **treatment head** shall be determined as follows:

$$A_{ER} = F_{ac}\, A_{BCS}(0,3) = 1{,}354\, A_{BCS}(0,3) \qquad (9)$$

NOTE Studies have shown that physically unrealistic values for treatment head **effective radiating area** can occur when applying linear extrapolation procedures to scans carried out in four planes on small *ka* **treatment heads**. The analysis described above, in which the **effective radiating area** is determined from measurements made in a plane at a distance of 0,3 cm from the output face of the treatment head, produces physically realistic data.

7.4.7

The **beam non-uniformity ratio**, R_{BN}, shall be calculated from:

$$R_{BN} = \frac{p_{max}^2 A_{ER}}{\overline{pms_t s^2}} \qquad (10)$$

where

$$\overline{pms_t s^2} = \frac{1}{2}\left\{\left[pms_t(0,3)s^2(0,3)\right] + \left[pms_t(z_N)s^2(z_N)\right]\right\} \qquad (11)$$

NOTE Although p_{max} and pms_t are referred to as acoustic pressure or pressure-squared parameters, only their ratio is required for the determination of R_{BN}, hence the **end-of-cable loaded sensitivity of the hydrophone** is not required.

The product $pms_t \cdot s^2$ is related to the acoustic power and is calculated by summation of the pressure-squared values over the area of the raster scans in the plane at 0,3 cm from the treatment head, and also the plane at z_N. It should ideally be invariant with the distance from the **treatment head**.

7.4.8

The procedures given in 7.4.2 to 7.4.7 refer to measurements made on one **treatment head**. After measurements have been completed on the group of **treatment heads** in accordance with the sampling requirements of 9.1, mean values of the various parameters specified in 7.5 shall be determined.

7.5 Reference type testing parameters

For the purposes of reference type testing, values for the following parameters shall be determined and recorded:

- rated output power;
- effective radiating area (A_{ER}) of the treatment head;
- effective intensity (I_e) at the same equipment settings as the rated output power;
- acoustic working frequency (f);
- the distance of the peak r.m.s acoustic pressure from the front face of the treatment head, (z_p);
- beam non-uniformity ratio (R_{BN});
- beam type;
- pulse duration, pulse repetition period and duty factor for each modulation setting;
- modulation waveform for each modulation setting.

NOTE This set of parameters could be used for the purposes of recording the performance of a single piece of **ultrasonic physiotherapy equipment**.

The values shall be the mean values based on sampling specified in 9.1. The overall uncertainty at the 95 % confidence level shall also be determined based on the methods specified in Annex J.

In addition, absolute maximum or absolute minimum values for certain parameters shall be determined as follows:

The **absolute minimum effective radiating area** shall be determined by subtracting the 95 % confidence overall uncertainty in the **effective radiating area** from the mean value of the **effective radiating area**.

The **absolute maximum beam non-uniformity ratio** shall be determined by adding the 95 % confidence overall uncertainty in the determination of the **beam non-uniformity ratio** to the mean value of the **beam non-uniformity ratio**.

7.6 Acceptance criteria for reference type testing

For the parameters listed below, the acceptance criteria for each **treatment head** shall be that the measured values plus and minus the 95 % confidence overall uncertainty in the measured values shall be entirely within the range defined by the nominal values and their tolerances specified in Clause 5. The parameters are:

- rated output power;
- effective radiating area (A_{ER}) of the treatment head;
- acoustic working frequency;
- pulse duration, pulse repetition period and duty factor for each modulation setting.

For **beam type**, the acceptance criterion shall be that the **beam type** shall be the same as the nominal **beam type** specified in Clause 5.

For **effective intensity** and **beam non-uniformity ratio**, acceptance criteria are specified in IEC 60601-2-5. Guidance on these parameters can be found in Annex A.

Compliance is checked by measurement in accordance with 7.2 to 7.4.

8 Routine measurement procedure

8.1 General

These procedures shall be used as the basis of tests that may be undertaken on a routine basis, possibly for each unit of **ultrasonic physiotherapy equipment,** but more typically for a certain percentage of the production. This could form the basis of good manufacturing practice or quality assurance procedures.

The routine tests specified here involve the determination of the values of certain acoustical parameters, which shall then be compared with the manufacturer's declared values (nominal values) and their tolerances, where appropriate, given in Clause 5.

8.2 Rated output power

The **rated output power** of the **equipment** shall be determined in accordance with 7.2.

NOTE Although not a requirement of this document, ascertaining accuracy of indicated power is an integral part of calibration: see IEC 60601-2-5.

8.3 Effective radiating area

8.3.1 The **treatment head** is set up in the test vessel in accordance with Clause 6. However, alignment of the **treatment head** may be achieved by using a mount designed to hold the **treatment head** under test in an orientation similar to that used for the reference type testing. It is anticipated that an appropriate mechanical alignment device may be used that accepts the **treatment head** and always defines the orientation of the front face in relation to the translational axes of the **hydrophone**.

NOTE The aim here is to allow all **treatment heads** to be set up using a jig or alignment method in such a way that the orientation of each **treatment head** is the same as that used for the reference measurements.

8.3.2 A full axial plot of the acoustic pressure distribution shall be completed to locate the positions of z_p and z_N for each treatment head, such that p_{max} may be determined.

8.3.3 The **beam cross-sectional area** shall be determined in the plane at a distance of 0,3 cm from the face of the **treatment head** by carrying out a raster scan as described in 7.4. The **beam cross-sectional area** at z_N shall also be determined, and may be derived from a raster scan in accordance with the requirements of Annex B, or by using four line or diametrical scans. The measurement and analysis procedures used for determination of **beam cross-sectional area** using diametrical scans shall be in accordance with Annex C.

Depending on whether a raster scan or line/diametrical scans are used, the procedures given in Annexes B or C shall be used to derive values for $A_{BCS}(0,3)$, $A_{BCS}(z_N)$ and the **total mean square acoustic pressure**, pms_t.

The **effective radiating area**, A_{ER}, in centimetres squared, shall be determined according to 7.4.6.

8.3.4 The **effective radiating area,** A_{ER}, may also be estimated on a routine evaluation basis through an alternative experimental method that uses a radiation force balance in conjunction with circular apertures, formed by an ultrasound attenuating material. An example of such an implementation, and a worked example of the calculations required to derive the **effective radiating area** from the measurements made using a range of aperture diameters, is described in detail in Annex I.

NOTE The value derived for the **effective radiating area** using the aperture technique should be considered as an approximation to the true effective radiating area that would be derived when carrying out the procedures described in 7.4.

8.4 Beam non-uniformity ratio

The **beam non-uniformity ratio**, R_{BN} shall be determined according to 7.4.7.

8.5 Effective intensity

The **effective intensity** shall be determined according to 3.17.

8.6 Acceptance criteria for routine testing

The range of **rated output power** defined by the measured **rated output power** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **rated output power** (see 9.3), shall be entirely within the range of values defined by the manufacturer's nominal value for the **rated output power** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.2.

The range of **effective radiating area** defined by the measured **effective radiating area** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **effective radiating area**, shall be entirely within the range of values defined by the manufacturer's nominal value of the **effective radiating area** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 8.3.

The range of **effective intensity** defined by the measured **effective intensity** plus and minus the 95 % confidence overall uncertainty for the routine measurement of **effective intensity**, shall be entirely within the range of values defined by the manufacturer's nominal value of the **effective intensity** and its tolerances specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.2 and 8.3.

The value of the **beam non-uniformity ratio** plus the 95 % confidence overall uncertainty in the routine measurement of **beam non-uniformity ratio** shall be less than or equal to the nominal value of the **beam non-uniformity ratio** specified in accordance with Clause 5.

Compliance is checked by measurement in accordance with 7.4.7.

9 Sampling and uncertainty determination

9.1 Reference type testing measurements

The mean values for reference type testing specified in 7.5 shall be based on a sample batch of at least 10 nominally identical units of the **ultrasonic physiotherapy equipment**.

9.2 Routine measurements

The routine measurements are to be undertaken as the basis of good manufacturing practice. Normally, they would be undertaken as the basis for testing batch production or at any time when there may be reason to suspect changes may have occurred. Typically, they would be undertaken on a certain percentage of production but, exceptionally, could be undertaken on each manufactured unit of **ultrasonic physiotherapy equipment**.

For the purpose of carrying out the Type A uncertainty evaluation (see Annex J) for routine measurements when full repeat measurements are impractical, partial repeat measurements may be carried out (by repeating those aspects of the measurement process which can be undertaken simply and quickly) and a prior knowledge for the type of measurement being undertaken then used to carry out an estimated Type A uncertainty evaluation.

NOTE An example of this would be to carry out two line scan measurements on a type of **treatment head**, and to use the outcome from a Type A uncertainty evaluation carried out previously on a raster scan on a **treatment head** of the same type to produce an overall uncertainty in **effective radiating area.**

9.3 Uncertainty determination

Where it is necessary to determine the 95 % confidence overall uncertainty of the measurement or any parameter for the purposes of this standard, normal uncertainty analysis and estimation methods shall be used (see Annex J for guidance).

Annex A
(informative)

Guidance for performance and safety

A.1 General

The clauses in this annex reflect the established approach on acceptable values of a few safety related parameters.

A.2 Rated output power

The **rated output power** should 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 should be checked by measurement of the **rated output power** in accordance with 7.2 at 90 %, 100 % and 110 % of the rated value of the mains voltage. For example, if the physiotherapy unit has a rated mains voltage* of 230 V, the **rated output power** should be checked at mains voltages of 230 V ± 10%.

NOTE The term 'rated' is defined in IEC 60601-1 as "value assigned by the manufacturer to a quantity characteristic of the equipment". This means that when a manufacturer specifies a useable voltage on the back of a therapy unit, this is a 'rated' value, and so from IEC 60601-2-5, the power output must be checked for variation at 90 %, 100 % and 110 % of the declared value even when there is a range.

A.3 Effective intensity

The **absolute maximum effective intensity** should be less than or equal to 3,0 W/cm^2 [1].

*Compliance is checked by determination of the **absolute maximum rated output power** in accordance with 7.2 and **absolute minimum effective radiating area** in accordance with 7.4.*

A.4 Beam non-uniformity ratio

A.4.1 General

The **absolute maximum beam non-uniformity ratio** should be less than or equal to 8,0.

Compliance is checked by measurement in accordance with 7.4.

A.4.2 Rationale behind using a limiting value for the beam non-uniformity ratio (R_{BN})

The ultrasonic beam distribution produced by a therapeutic **treatment head** is non-uniform by nature. Besides this natural character, details of the construction and operation of the **treatment head** can produce regions of very high local pressure, also referred to as "hot spots". These may result in excessive heating in small regions of the tissue being treated, arising in potential harmful effects to the patient.

At the present time, therapeutic transducers are not designed to provide highly localized tissue treatment. Consequently, the transducers addressed in this standard are planar. The characterization of focused transducers capable of generating high intensity beams which are being used in therapeutic applications will be the subject of future standards.

Alongside the safety aspects and the increased possibility of thermal injury, localized peaking of the pressure distribution resulting in a "hot spot" may also be considered as an adverse indicator of transducer quality. For these reasons, the therapist should have knowledge of the sound field distribution in order to apply therapeutic ultrasound judiciously. A measure of this non-uniformity is provided by the **beam non-uniformity ratio** (R_{BN}). The R_{BN} parameter represents the ratio of the highest intensity in the field to the average intensity, as indicated on the physiotherapy device.

From theoretical calculations, using an ideal plane piston source, the R_{BN} can be estimated. For a plane wave approximation, pressure and velocity are in phase, the ratio between the time-average intensity distribution (I_p) in a field and average intensity of the piston source if there were no acoustic interferences (I_o) is given in Figure A.1 [2]. Following on from the previous discussion, this relation also represents the R_{BN}, and it follows that, on theoretical grounds, the maximum value will be 4. Even when the pressure and the velocity are not in phase, represented by the true intensity (I), the maximum is 4 and will be found at one near-field length (s = 1 in Figure A.1). From the distance of about one transducer element radius, (x/a = 1), back to the element itself the maximum ratio will decrease typically to a value of the order of 2.

The actual determination of the R_{BN} may be performed using a **hydrophone**. In the following it will be shown that a calibrated **hydrophone** is not needed, which will simplify the method of determination.

In a plane wave approximation the relation between intensity and pressure (p) is given by: $I = p^2/\rho c$, where ρc is the specific acoustic impedance. This equation cannot strictly be used within the near field, in particular at distances closer than one transducer element radius of the **treatment head**. In most cases the maximum pressure is found at greater distances than the **treatment head** radius and the error in using the expression, $I = p^2/\rho c$, results in relatively small inaccuracies as illustrated in Figure A.1.

As it may be assumed that the **hydrophone** output voltage is linearly related to the received acoustic pressure, the equation of the R_{BN} can be simplified as stated in this standard as follows:

The highest intensity in the beam, spatial-peak temporal-average, I_{spta}, is given by:

$$I_{spta} = \frac{U_p^2}{M_L^2 \rho c} \tag{A.1}$$

The quantity pms_t, used in the main body of this standard, is given by

$$pms_t = \sum_{i=1}^{N} \frac{U_i^2}{M_L^2} \tag{A.2}$$

and is known as the **total mean square acoustic pressure**. It represents a summation of the acquired voltages squared during the raster scan. Using pms_t, the spatial-average temporal-average intensity is given by:

$$I_{sata} = \frac{\text{acoustic power}}{A_{ER}} = \frac{A_o \; pms_t}{\rho c \; A_{ER}} \tag{A.3}$$

The expression for the R_{BN}, given as the ratio I_{spta}/I_{sata}, may then be derived as:

$$R_{BN} = \frac{U_p^2 A_{ER}}{A_o(z_j) \sum_{i=1}^{N} U_i^2(z_j)} \quad \text{(A.4)}$$

The denominator is related to the total **output power**, derived by a summation of the intensities over the acoustic beam.

In the above equations, the parameters are as follows:

U_p is the maximum value of the **hydrophone** voltage;

U_i is the **hydrophone** voltage at the *i*th point of measurement;

M_L is the **end-of-cable loaded sensitivity of the hydrophone**;

pms_t is the **total mean square acoustic pressure**;

ρ is the density of water;

c is the velocity of sound in water;

A_o is the unit area of the scan ($A_o = s^2$ for a raster scan where s is the step size);

N is the total number of measurement points in the scan;

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

z_j is the distance from the **treatment head** to the measurement plane of interest.

Figure A.2 illustrates a histogram in which the R_{BN} values calculated using the above equation are presented for 37 different **treatment heads**, along with the frequency that these values occurred when the values of R_{BN} are separated into bands of 0,5. Normally, the R_{BN} appears to be in the range 3 to 7, but some transducers having a $R_{BN} > 8$ are shown and these may be considered to have a high R_{BN}.

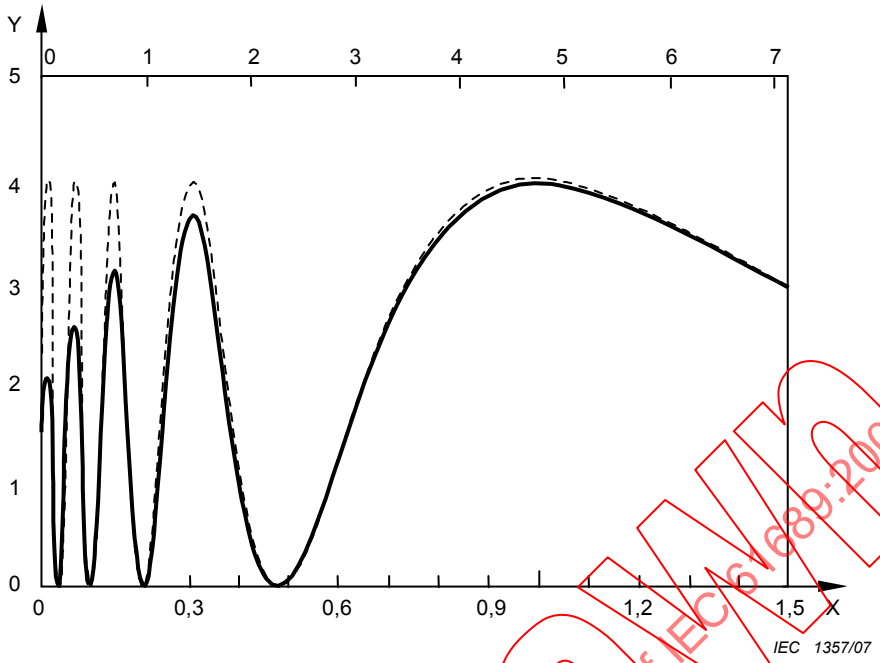
The limiting value of eight has been identified in this International Standard for the following reasons:

– 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. As can be seen in Figure F.2, for normal behaving practical transducers, R_{BN} values less than eight can readily be attained;

– 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 having a R_{BN} greater than eight;

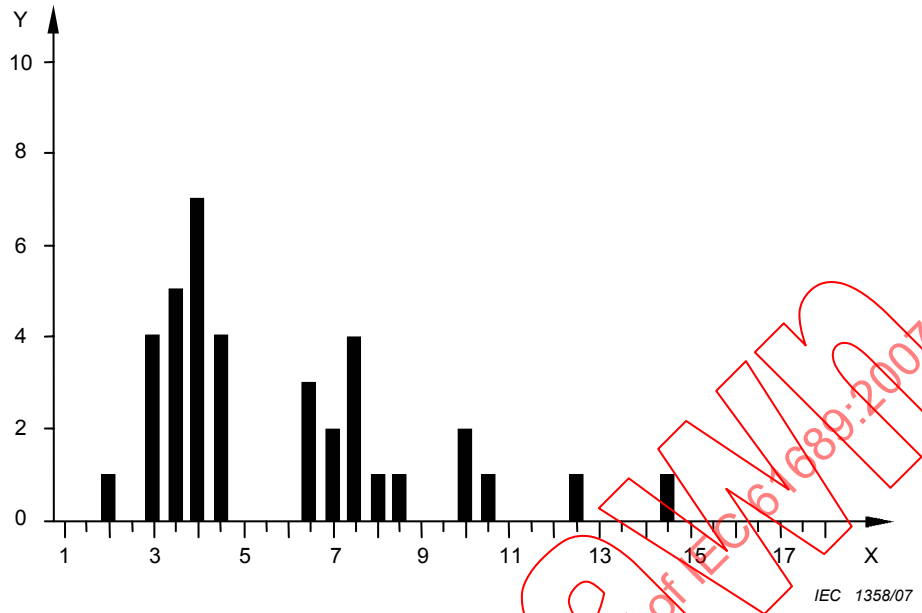
– it can be calculated that a R_{BN} value of 8,0 (limiting value) results in a maximum pressure at the maximum allowed output setting (3 W/cm^2) in the range of 1 MPa, a spatial-peak temporal-peak intensity (I_{sptp}) of 48 W/cm^2 and a spatial-peak temporal-average intensity (I_{spta}) of 24 W/cm^2. It can be expected that higher values cause unwanted biological effects.



X: bottom axis: *s*,
X: top axis: *x* / *a*

Y: $\bar{I}/I_o$ ———— ; $\bar{I}_p/I_o$ – – – – –

Figure A.1 – The normalized, time-averaged values of the acoustic intensity (unbroken line) and of one of its plane-wave approximations (broken line), existing on the axis of a circular piston source of ka = 30, versus the normalized distance s, where $s = \lambda z/a^2$



X: R_{BN}
Y: Number of transducers

Figure A.2 – Histogram of R_{BN} values for 37 treatment heads of various diameter and frequency

NOTE The R_{BN} value (in bands of 0,5) has been displayed against its frequency of occurrence.

Annex B
(normative)

Raster scan measurement and analysis procedures

B.1 General

The determination of the **effective radiating area** of the **treatment head** for the purposes of reference measurements shall be performed using raster scans at 0,3 cm from the face of the **treatment head**. These procedures may also be used for routine measurements in accordance with Clause 8.

B.2 Requirements for raster scans

B.2.1 All raster scans shall be square grids with the central point on the **beam alignment axis** and in a plane perpendicular to the **beam alignment axis**. The scan shall not be a continuous motion but shall be performed in discrete steps with the values of r.m.s. or peak voltage measured at each point.

NOTE With the central point being on the **beam alignment axis**, there are necessarily an odd number of measured points on each line.

B.2.2 The boundaries of the raster scan shall be large enough to ensure that the signal level at any part outside the scanned boundary is at least 26 dB below the peak signal. However, for **treatment heads** having $z_N \leq 13$ cm, the level beyond the limits of the raster scan should be at least 32 dB below the peak signal.

NOTE Initial measurements are usually necessary to identify the size of the raster scan, and care needs to be taken to ensure that local diffraction minima do not lead to spuriously small scan areas.

B.2.3 The spacing between measurement points (step size) should be small enough such there are at least 31 measurements across the full width of the raster scan (the raster scan will therefore constitute a square grid of at least 31×31 points). See also B.3.2.

B.2.4 During the raster scan, the **hydrophone** may be scanned to a distance from the centre of the ultrasonic beam where no signal is obtained above the noise. To apply a correction to the integral of the square of the **hydrophone** signal to account for the contribution from the noise, the rms noise level U_n shall be subtracted from the measured signals in the following manner. If the **hydrophone** signal at each measurement point is U_i, then the **hydrophone** signal after correcting for the contribution from noise, U_i' is:

$$U_i' = (U_i^2 - U_n^2)^{1/2} \quad \text{(B.1)}$$

The noise level shall be determined, as in IEC 62127-1, by moving the **hydrophone** to a position sufficiently far from the ultrasonic field that no direct acoustic signal is detected. In general, this shall be at a distance in the direction perpendicular to the **beam alignment axis** equal to at least twice the distance from the beam centre to the limit used for the raster scanning process.

B.3 Requirements for analysis of raster scan data

The two-dimensional array of data values obtained from the raster scan shall be analysed in the following way.

B.3.1 Total mean square acoustic pressure

The summation of the squares of the voltages obtained over the raster scan is related to the **total mean square acoustic pressure**, pms_t, given by:

$$pms_t = \sum_{i=1}^{N} U_i^2 / M_L^2 \qquad \text{(B.2)}$$

where

N is the total number of points in the scan;

U_i is the voltage (either peak or r.m.s.) of the i-th point in the scan;

M_L is the **end-of-cable loaded sensitivity of the hydrophone**.

NOTE The **end-of-cable loaded sensitivity of the hydrophone** has been introduced for convenience in Equation B.1 to convert the measured voltage to acoustic pressure. However, due to cancellation, when pms_t is introduced into Equation B.2, its absolute value is not required.

B.3.2 Calculation of the beam cross-sectional area, A_{BCS}

The values U_i are sorted into a set in descending order (either rms or temporal peak) in the scan. A second summation shall be performed to find the value of n that satisfies the following two relationships:

$$\frac{1}{M_L^2}\sum_{i=1}^{n} U_i^2 \leq 0{,}75\ pms_t \qquad \text{(B.3)}$$

$$\frac{1}{M_L^2}\sum_{i=1}^{n+1} U_i^2 > 0{,}75\ pms_t$$

The value of A_{BCS}, in centimetres squared, is then given by $A_o \times n$ where A_o is the unit area of the raster scan ($A_o = s^2$ where s is the distance, in centimetres, between successive points in the scan, i.e. the step size). This procedure provides a value for the **beam cross-sectional area** in the measurement plane of interest.

For reliable determination of A_{BCS}, the number of points, n, included in the determination of A_{BCS}, should be at least 100.

Annex C
(normative)

Diametrical or line scan measurement and analysis procedures

C.1 General

The determination of the **beam cross-sectional area** at a specified distance from the **treatment head** for the purposes of routine measurements in accordance with Clause 9 may be performed using diametrical or line scans. The term line scan will be used within this annex. If line scans are used then the procedures and analysis methods described below shall be used.

C.2 Requirements for line scans

C.2.1 The central or common point of the four line scans shall lie on the **beam alignment axis**. The relative angle of the scans shall be 45°, and the four line scans shall divide the plane perpendicular to the **beam alignment axis** into eight equal areas.

C.2.2 The scan shall not be a continuous motion but shall consist of a series of discrete steps perpendicular to the **beam alignment axis** with the r.m.s. or peak voltage generated by the hydrophone being measured at each position.

C.2.3 The boundaries of each full-line scan shall be sufficiently large such that the **hydrophone** signal level at the edge of the line scan, relative to the peak level obtained, shall be at least 32 dB below the peak level.

C.2.4 The step size used during the line scan shall be sufficiently small such that the line scan consists of at least 50 points.

NOTE Each of the four line scans may be of different step size. Here, for ease of analysis, they will be assumed to be identical.

C.2.5 The noise level shall be determined, and measurements corrected for the influence of noise in accordance with B.2.4.

C.2.6 For simplicity, it will be assumed that the four line scans are of identical size, each containing N_1 measurements. This will be true for analysis of raster scan data but not generally true for line scan measurements.

C.3 Analysis of line scans

The individual line scans will be analysed in the following way.

C.3.1 The four line scans shall be further sub-divided into a pair of radial scans (half-line scans). Each of these half-line scans consists of one-dimensional arrays, $[A]$, of data points sharing a common point on the **beam alignment axis** and having $(N_1 - 1)/2$ other points.

C.3.2 To calculate the **beam cross-sectional area** for each of the half-line scans, the one-dimensional sampling of the acoustic beam profile is transformed into a two-dimensional description of the beam assuming cylindrical symmetry.

C.3.3 For the measurement point which lies on the **beam alignment axis** (designated the i=0 point) the contribution to such an area will be A_0, given in centimetres squared, by:

$$A_o = \frac{\pi s^2}{4} \quad \text{(C.1)}$$

where s is the step size in centimetres (for diagonal radial scans derived from raster scan measurements the step size will be $s\sqrt{2}$).

C.3.4 For all of the other elements of the half-line scan, from $j = 1$ to $(N_1 - 1)/2$, the contribution to the scan area will be annuli of thickness s. For the j-th measurement the corresponding annulus area, A_j, will be given in centimetres squared by the expression:

$$A_j = \pi s^2 \left[\left(j + \frac{1}{2} \right)^2 - \left(j - \frac{1}{2} \right)^2 \right]$$

$$A_j = 2\pi j s^2 \quad \text{(C.2)}$$

C.3.5 To calculate the **beam cross-sectional area**, the area of each of the annuli from $j = 1$ to $(N_1 - 1)/2$ shall be broken down into multiples of the smallest unit area A_o. By dividing A_j given in equation (C.2) by A_o given in equation (C.1), it may be seen that the j-th annulus is comprised of n_j units of the smaller area, such that:

$$n_j = 8j \quad \text{(C.3)}$$

C.3.6 Using this expression, the original one-dimensional array representing the line scan shall be transformed into a new one-dimensional array $[B]$ the elements of which are shown in Table C.1.

Table C.1 – Constitution of the transformed array [*B*] used for the analysis of half-line scans

Measurement point	Voltage squared U_j^2	Number of elements in array [*B*] of value U_j^2
$J = 0$ (point on **beam alignment axis**)	U_o^2	1
$J = 1$ (first point off-axis)	U_1^2	8
$J = 2$ (second point off-axis)	U_2^2	16
•	•	•
•	•	•
•	•	•
$J = (N_1 - 1)/2$ (last point in scan)	$U^2_{[(N1-1)/2]}$	$4(N_1-1)$

NOTE The jth ($j > 0$) point in the half-line scan array $[A]$ is represented in the new array by $8j$ elements of the original voltage-squared values. The new array will contain N_1^2 elements.

C.3.7 To evaluate the **beam cross-sectional area** the **total mean square acoustic pressure**, pms_t, of the half-line scan is required. This is given by:

$$pms_t = \frac{1}{M_L^2} U_o^2 + \frac{1}{M_L^2} \sum_{j=1}^{\left(\frac{N_1-1}{2}\right)} 8\, j\, U_j^2 \quad \text{(C.4)}$$

C.3.8 The new array [B] is sorted into descending order and a second summation performed as described in equations (B.3), leading to the determination of the value of n.

NOTE Performing the sorting process on the original n values will lead to the same result if the correct weighting is applied during the summation process.

C.3.9 The **beam cross-sectional area**, A_{BCS}, of the half-line scan in centimetres squared is given by $A_{BCS} = \frac{n\pi s^2}{4}$ where s is the step size in centimetres.

C.3.10 The analysis shall be completed for all eight half-line scans and the results averaged to determine the mean value along with the standard deviation.

In the measurement plane z, the standard deviation, σ, of the distribution of **beam cross-sectional areas** for the eight half-line scans shall be determined from:

$$\sigma^2 = \frac{1}{7}\sum_{j=1}^{8}\left(A_{BCSj}(z) - \overline{A_{BCS}(z)}\right)^2 \qquad \text{(C.5)}$$

where

$A_{BCSj}(z)$ is the **beam cross-sectional area** derived from the j-th line scan in the plane at distance z;

$\overline{A_{BCS}(z)}$ is the mean value calculated from the eight line scans.

Annex D
(informative)

Rationale concerning the beam cross-sectional area definition

In physiotherapy, the ultrasonic intensity levels used are relatively high. They are in the range where adverse biological effects have been observed in addition to those which are intended to be beneficial. It is therefore important that the operator knows the particular ultrasonic intensities being delivered by the **ultrasonic physiotherapy equipment**. In principle, this is achieved by the **ultrasonic physiotherapy equipment** having a front-panel indication of output power and intensity and these indications have to be reliable and accurate.

Since the most appropriate indication of effective intensity is a spatial average value derived by dividing the **output power** by an area, the use of an intensity indication implies the need for a well defined area. This area should be seen as that part of a plane - at or close to - the applicator, through which almost all of the ultrasound power passes and is defined in this standard as the **effective radiating area**.

A **treatment head** used in **ultrasonic physiotherapy equipment** contains an **ultrasonic transducer** consisting of a piezoelectric active element which is often mounted on a metal face plate. Since this piezoelectric element does not vibrate with the same amplitude over its entire surface, it is not sufficient to specify beam area as the geometric area of the piezoelectric element. The actual **effective radiating area** is determined directly from **hydrophone** measurements.

The parameter **beam cross-sectional area**, as defined in this standard, is the area determined using the **hydrophone** and represents an intermediate step in the process of deriving the **effective radiating area**. The method specified in this standard represents the outcome of studies, based on actual measurements and theoretical calculations, to provide a useful definition and a reliable measurement method [3, 4, 5, 6, 7].

Any method used to determine the **beam cross-sectional area** should not be too sensitive to local inhomogeneities within the ultrasonic beam. During an evaluation of **ultrasonic physiotherapy equipment** [8] it was demonstrated that measuring the **beam cross-sectional area** in accordance with the definition used in the US FDA standard (which takes the contribution at a distance of 5 mm of all areas where the intensity is greater than 5 % of the maximum intensity in the plane) [9] produces, for certain ultrasonic beams, very inaccurate results.

The pressure distribution of a typical **treatment head** with a small geometric radiating area, having a ka of approximately 17, where k is equal to $2\pi/\lambda$ and a is the geometrical radius of the active element of the **ultrasonic transducer** used in the **treatment head**, is given in Figure D.1. In this distribution the maximum pressure decreases rapidly with distance from the face of the **treatment head**.

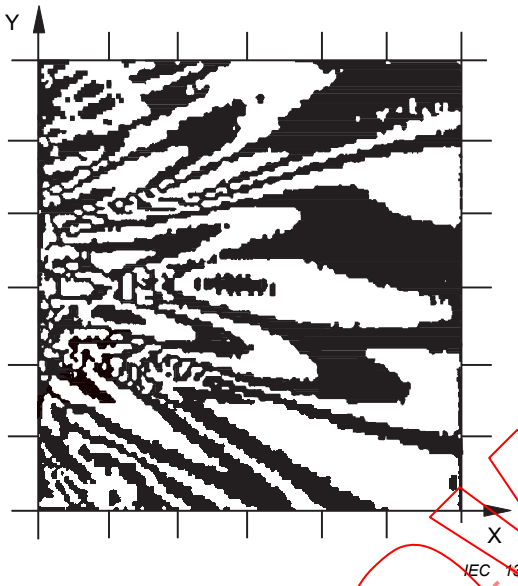
To investigate the effect of the beam characteristics on the defined areas, the limit levels, 5 % of the maximum intensity for the FDA definition and 75 % of the sum of the **total mean square acoustic pressure** for the IEC definition, are explored more widely. Figure D.2 shows the variation of **beam cross-sectional area** measurements (IEC) and **effective radiating area** measurements (FDA) with the limit levels for a set of measurement planes close to 5 mm from the face of the **treatment head**. Results for five measurement planes are shown, the total separation from the 5 mm plane being ±0,5 mm with a spacing of 0,25 mm between measurement planes. Figure D.2 shows that the **effective radiating area**, following the FDA definition, is very sensitive to the measurement position. It also shows that if another limiting level is taken, greater than the 5 % required in the FDA definition [9], this results in an increased sensitivity of the **effective radiating area** to small errors in the position of the measurement plane, i.e. the slopes of the curves shown in Figure D.2 for the FDA definition are greater than those for the IEC definition. The smooth character of the curves for the IEC definition is also evident from Figure D.2.

Treatment heads used in physiotherapy are of various frequencies and diameters and may typically have ka values in the range between 17 and 150. In Figure D.3, the typical behaviour of the **beam cross-sectional area** as a function of different limit levels is plotted for some **treatment heads** with ka values in this range. Although the ka values for the different **treatment heads** differ considerably, the shape of the curves seems to be similar.

Instabilities in the pressure measurement, e.g. caused by thermal drift or inhomogeneities in the water path, can be seen as instabilities in the limit level. The effect of this instability in the pressure measurement on the calculated **beam cross-sectional area** is complex and depends strongly on the beam shape. The **effective radiating area** derived from the FDA analysis is very sensitive to these instabilities as it depends critically on the reliable evaluation of a single maximum level. This is not the case using the IEC definition, which exhibits a relative insensitivity to the peak value acquired in the scan. This is demonstrated in Figure D.3 from the 75 % limit used in this standard.

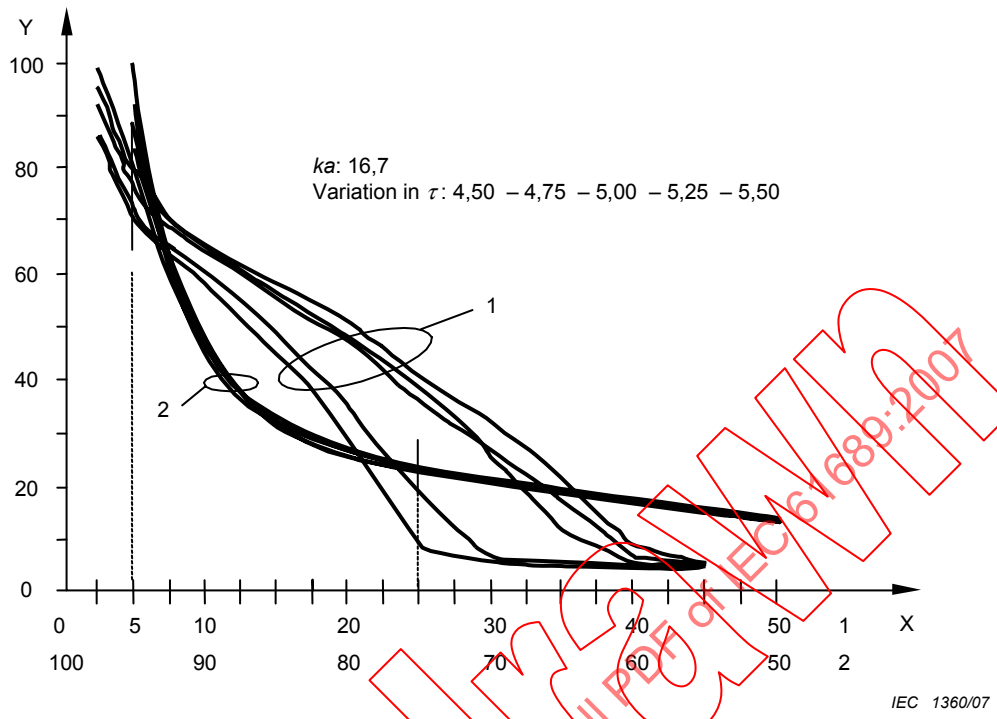
These experimental conclusions are confirmed by theoretical calculations. Calculations carried out using a circular piston source with radius $a = 4\lambda$, which represents a relatively small transducer, and a point receiver, are presented in the series of curves making up Figure D.4. These depict the variation of **effective radiating area** and **beam cross-sectional area** for increasing distances away from the **treatment head**. The **hydrophone** - **treatment head** separation has been normalized to the acoustic wavelength which means that the whole range of frequencies currently used in physiotherapy is presented. The **beam cross-sectional area** value (**effective radiating area** for the FDA definition) has been normalized relative to the actual element size. Although the **beam cross-sectional area** following the new definition shows some variation with normalized distance, it is clearly less dependent on the beam characteristics than the **effective radiating area** calculated from the FDA definition [9].

In other calculations presented in Figure D.5, the normalized **beam cross-sectional area** is calculated as a function of ka. The range of ka values used covers the whole range of sizes of **ultrasonic transducers** used in the **treatment heads** of **ultrasonic physiotherapy equipment**. Although the curves shown in Figure D.5 only present results obtained at distances of 5 mm and $2a$ from the face of the **ultrasonic transducer**, the behaviour is representative of calculations performed at other distances. From Figure D.5 the same general conclusion can be drawn as from Figure D.4: the **beam cross-sectional area** definition as specified in this standard is less dependent on details of the ultrasound beam profile than the definition used in the FDA standard [9].



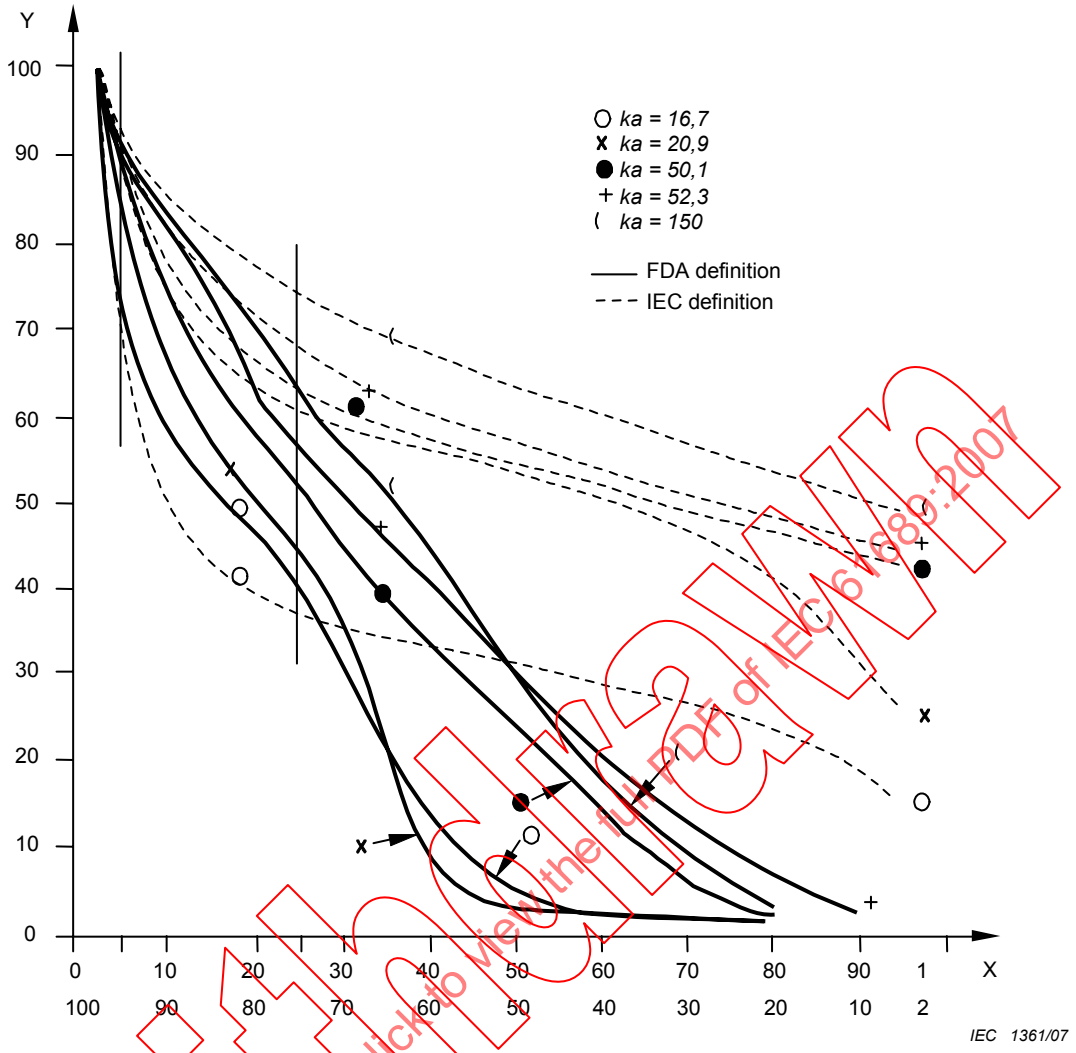
X: z direction, along the beam axis
Y: x direction, parallel to transducer front
X, Y, scale: 5 mm / division

Figure D.1 – Iso-pressure lines of a typical physiotherapy treatment head of small geometrical area (ka = 17)



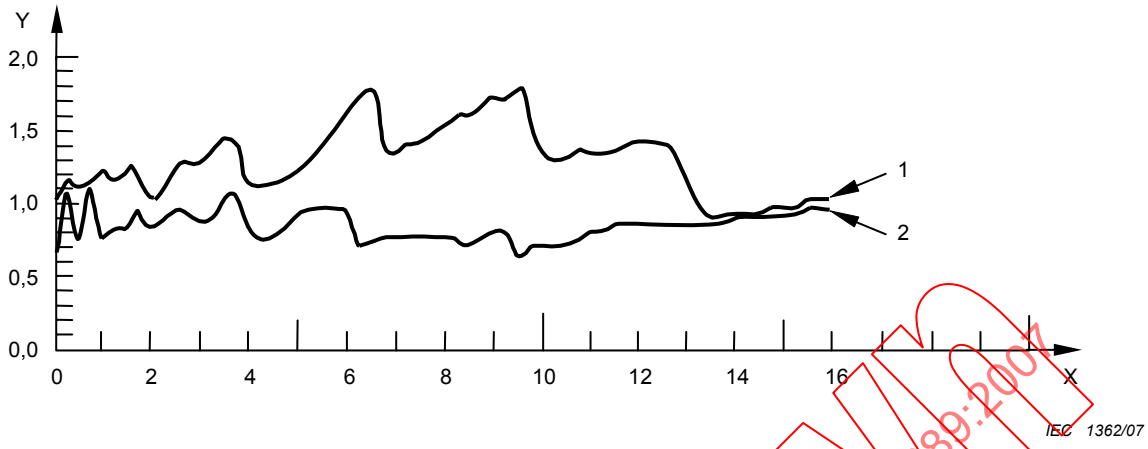
X: Limit %, 1 following FDA standard
2 following IEC standard
Y: Relative value of A_{BCS} (mm^2)

Figure D.2 – Plot of beam cross-sectional area against different limit values for a small variation in distance along the beam alignment axis, z



X: Limit %, 1 following FDA standard
2 following IEC standard
Y: Relative value of A_{BCS} (mm^2)

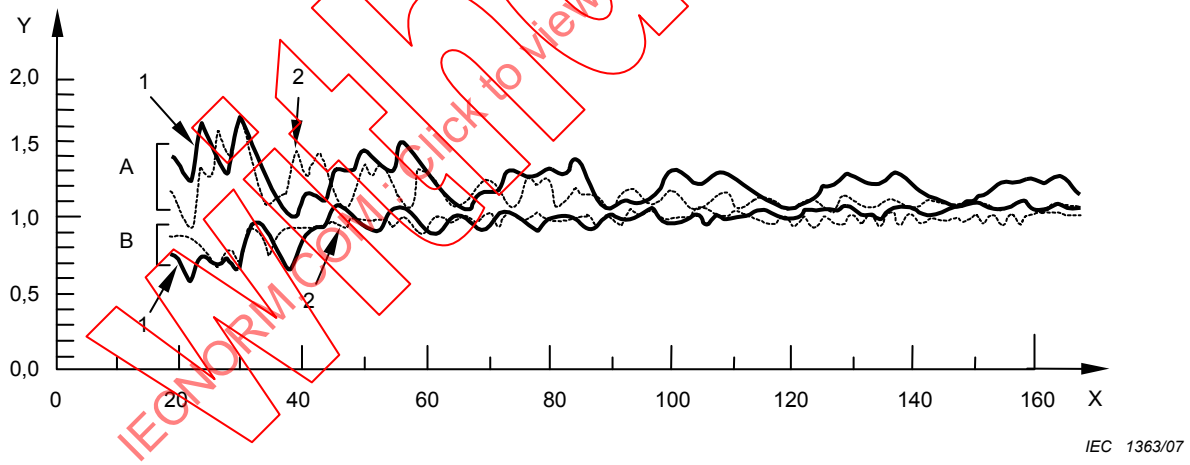
Figure D.3 – Normalized values of beam cross-sectional area for IEC and FDA limit values for five transducers of different *ka* values, *z* = 0,5 cm



X: z/λ,
Y: A_{BCS} (mm^2) 1 following FDA standard
2 following IEC standard

Figure D.4 – Variation of the beam cross-sectional area (A_{BCS}) with distance from the face of the treatment head

NOTE The distance, z, and the **beam cross-sectional area** have been normalized to the acoustic wavelength and true element area, respectively.



X: ka
Y: Normalised beam cross-sectional area A_{BCS}
A: following FDA standard
B: following IEC standard
1: at z = 5 mm
2: at $z = d$ mm

Figure D.5 – Variation of the normalized beam cross-sectional area (A_{BCS}) with transducer ka

NOTE Calculations have been carried out at distances of 5 mm and 2a from the **treatment head**.

Annex E
(informative)

Factor used to convert the beam cross-sectional area (A_{BCS}) at the face of the treatment head to the effective radiating area (A_{ER})

This standard requires the **effective radiating area**, A_{ER}, to be derived from the **beam cross-sectional area** close to the face of the **treatment head**, $A_{BCS}(0.3)$. The **beam cross-sectional area**, $A_{BCS}(z)$, is defined as the smallest area contributing 75 % of the total **mean square acoustic pressure.**

When a simplified sound field model with a collimated beam and constant pressure distribution over its cross-section perpendicular to the sound field axis is used, the definitions lead to the following relation:

$$A_{ER} = 1{,}333\ A_{BCS}(0) = 1{,}333\ A_{BCS}(z) \qquad \text{(E.1)}$$

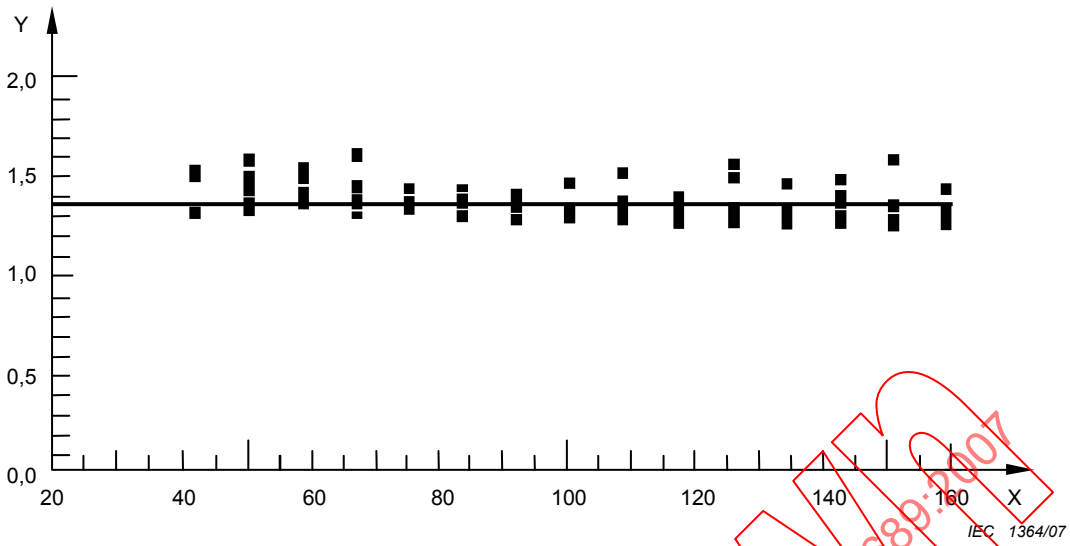
From the physical point of view, it can be expected that the simplified model is useful for values ka that are not too small ($k = 2\pi/\lambda$ = circular wavenumber, a = geometrical radius of the active element of the **treatment head**). With smaller values of ka product assumed, diffraction effects will cause the sound beam to spread and consequently the simplified model will fail.

In order to obtain a realistic estimate of the conversion factor needed (termed F_{ac} in what follows), numerical simulations were performed using a circular piston source, finite size receivers of radius 0,25 mm and 0,5 mm at frequencies of 1 MHz, 2 MHz and 3 MHz. For transducers of small effective radii (<4 mm), and particularly at low frequencies, the beam will diverge to such an extent that no realistic estimate of the **effective radiating area** may be made. In practice, because no physiotherapy **treatment heads** exhibit effective radii smaller than 4 mm, the calculations have been limited to radii ≥4 mm. In the computer simulations, the *ka* product covers the range from approximately 16 to 160. The calculations follow exactly the definitions mentioned above.

Figure E.1 shows the distribution of F_{ac} in the range $ka \approx 40$ to $ka \approx 160$. The mean value calculated is F_{ac} = 1,354, which is very close to F_{ac} = 1,333, valid for the simplified sound field model.

NOTE For the sample size studied (66 points), the standard deviation in the mean value is approximately 0,09. This value may be used in a Type B evaluation of the uncertainty in effective radiating area.

A study has been carried out on a large sample of small ka **physiotherapy treatment heads** [8], and have defined the approach described in Subclause 7.4 for determining the **effective radiating area,** whereby raster scans are carried out in a plane at a distance of 0,3 cm from the treatment head. Results from the study show that this approach produces $A_{BCS}(0,3)$ values which may be multiplied by the same F_{ac} value (1,354) to derive the A_{ER}, independent of the ka value of the **treatment head**.



X: *ka*
Y: F_{ac}

Figure E.1 – Conversion factor F_{ac} as a function of the *ka* product for *ka* product between 40 and 160

NOTE The solid line represents the mean value, F_{ac} = 1,354.

Annex F
(informative)

Determining acoustic power through radiation force measurements

This standard requires the declaration of the **rated output power**. As stated in 7.2, the measurement of the **output power** of the **ultrasonic physiotherapy equipment** is to be carried out in accordance with IEC 61161, where the use of a radiation force balance is recommended. Radiation force measuring devices are easy to handle and to calibrate.

The most important part of a radiation force device is the target. It must be large enough to cover the whole ultrasonic field. Subclause 5.3 of IEC 61161 gives formulas for calculating the minimum value of the target radius b as a function of the target distance z (referred to as x in IEC 61161), the wavelength and a_1, the effective radius of the active element of the **treatment head**. The formulas given in IEC 61161 are based on theoretical calculations using a piston field approach [5]. Table F.1 shows some typical results. The target radius should be understood as the radius of the largest cross-section of the target, and the target distance as the distance of that cross-section from the **treatment head**.

It should be noted that the results given apply to a piston field. It may be that the **treatment head** under test does not behave like a piston. It is therefore recommended to also make use of the information contained in the measurement results of the **beam cross-sectional area**, $A_{\mathrm{BCS}}(z)$. An equivalent radius b_{eq} can be determined from:

$$b_{\mathrm{eq}}(z) = (A_{\mathrm{BCS}}(z)/\pi)^{1/2} \qquad \text{(F.1)}$$

NOTE If A_{BCS} is given in centimetres squared, b_{eq} is obtained in centimetres.

If 2 b_{eq} is larger than the value of b determined in accordance with IEC 61161 and Table F.1, then 2 b_{eq} is used as the minimum value for the target radius.

Bubbles in water act as scatterers of ultrasonic waves and can lead to errors in measurements. It is therefore important to use only degassed water in measurements on physiotherapy devices, and always to make sure that (a) no bubbles are present on the transducer and target surfaces and (b) no bubbles appear during the measurement as a consequence of the degassing potential of high-intensity ultrasound (see IEC 61161 and bibliographic reference [10]).

Although **output power** values are often in the watt range for **ultrasonic physiotherapy equipment**, in order to cover the full range of **output power** measurements for compliance with this standard, a balance with a sensitivity as low as 15 mW may be required. One problem for measurements at higher power ranges may be the stability of the target position during the measurement. While an absorbing target is not affected by lateral radiation force components and a concave reflector is self-centring, a convex reflector may be de-centred by the radiation force. This effect depends mainly on the magnitude of the ultrasonic **output power**, on the target weight and the kind of target suspension (see 5.6 of IEC 61161).

Table F.1 – Necessary target size, expressed as the minimum target radius b, as a function of the ultrasonic frequency, f, the effective radius of the treatment head, a_1, and the target distance, z, calculated according to 5.3 of IEC 61161 (see [5])

Effective radius a_1 of the treatment head	Ultrasonic frequency f	Target distance	Minimum target radius
cm	MHz	cm	cm
0,5	1	0,5	0,77
		2,0	1,89
		4,0	3,54
		6,0	5,23
1,5	1	0,5	2,25
		2,0	2,25
		4,0	2,46
		6,0	3,05
0,5	3	0,5	0,75
		2,0	1,02
		4,0	1,67
		6,0	2,36
1,5	3	0,5	2,25
		2,0	2,25
		4,0	2,25
		6,0	2,25

Annex G
(informative)

The validity of low-power measurements of the beam cross-sectional area (A_{BCS})

Measurements of the **beam cross-sectional area** made using **hydrophones** require the **treatment head** to be operated in **continuous wave** mode at intensities of 0,5 W cm^{-2} or less (see 7.3). Measurements at low powers are required to prevent damaging the probe **hydrophones** used. Table G.1 presents the verification that values of **beam cross-sectional area** obtained at low powers are valid at higher operating powers employed for physiotherapy treatments. The table illustrates measurements made using a polyvinylidene fluoride (PVDF) membrane **hydrophone** of the differential output type for various powers indicated by the physiotherapy unit used. The **treatment heads** were both 1,5 MHz transducers of diameter 2,8 cm; A was operating normally whilst B was characterized as a "hot spot" transducer exhibiting a large axial peak at 2,9 cm. The measurements for the second transducer were made in this plane.

Table G.1 – Variation of the beam cross-sectional area ($A_{BCS}(z)$) with the indicated output power from two transducers

Indicated power W	**Transducer A**[1] $A_{BCS}(z)$ cm^2	**Transducer B**[2] $A_{BCS}(z)$ cm^2
1,25	3,54	2,99
5,00	3,50	2,92
7,50	3,52	2,80
10,0	3,48	2,79
12,5	3,51	2,80
15,0	3,49	2,87

1) 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 4,0 cm

2) 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 2,9 cm; the distance of **the maximum r.m.s. acoustic pressure** for this "hot spot" transducer

The results presented in Table G.1 show that the variation of $A_{BCS}(z)$ with power is small, no more than a few per cent.

This invariance of the **beam cross-sectional area** with **output power** may not be valid for some defective **treatment heads**, particularly those where heating occurs, although it is anticipated that such cases will be rare.

Annex H
(informative)

Influence of hydrophone effective diameter

Most **hydrophones** currently available commercially have active elements of diameter in the range 0,2 mm to 1,0 mm. At megahertz frequencies the accuracy of ultrasonic field measurements may be compromised by spatial averaging of the acoustic pressure over the active element. IEC 62127-1 provides the following criterion for the maximum permissible **hydrophone** radius, a_{max}, which may be used in any measurement situation:

$$a_{max} = \frac{\lambda}{8}\left(1+\frac{z^2}{a_1^2}\right)^{1/2} \quad \text{(H.1)}$$

where

λ is the acoustic wavelength;

z is the distance from the **treatment head** to the measurement plane;

a_1 is the effective radius of the active element of the **treatment head**.

The procedures specified in this standard to accurately determine the **effective radiating area** of a **treatment head** requires measurements close to the face of the **treatment head** and will result in the frequent violation of this criterion. Equation H.1 relates strictly to the measurement of peak pressures and is of relevance for reliably determining the **beam non-uniformity ratio** (R_{BN}). Due to the greater accuracy required of measurements of the **effective radiating area**, it is important to establish the effect of violation on measurements of $A_{BCS}(z)$ and A_{ER}.

Measurements made on a 3 MHz **treatment head** of diameter 2,4 cm using various **hydrophones** of different active element radius are presented in Table H.1. Measurements were made using ceramic **hydrophones** of active diameter 0,6 mm and 1,0 mm, and a 4 mm diameter PVDF **hydrophone** of the membrane type (the latter was used as a ceramic hydrophone with 4 mm active element was not available). For measurements at z = 1,0 cm, according to Equation H.1, these **hydrophones** are strictly too large by factors of 4, 6,5 and 26 respectively. The results displayed in Table H.1 indicate agreement between measurements of $A_{BCS}(z)$ of between 1 % and 3 %.

With currently utilized physiotherapy **treatment head** frequencies and diameters, the most stringent test of the IEC 62127-1 criterion is for measurements close (z = 1,0 cm) to large diameter, 3 MHz **treatment heads**. Even in this case violation will be by no more than a factor of six to seven for a 1 mm active element diameter **hydrophone**.

Table H.1 also presents values of the ratio of the peak pressure squared to the average pressure squared over the **beam cross-sectional area** in the plane at distance z, where z varies from 1,0 cm to 8,0 cm (this ratio is denoted by R in Table H.1), which indicates that even in the presence of strong violation for measurements using the 4 mm diameter **hydrophone**, differences are no more than 20 %. These results can be directly related to the choice of the diameter of the active element of the **hydrophone** for the purposes of determining R_{BN}. However, these findings should be treated with some caution. Certain **treatment heads** exhibit "hot spots" characterized by beam widths (–6 dB) of the main peak as small as 2 mm to 3 mm. Use of a **hydrophone** as large as 4 mm would underestimate the true value of the R_{BN}.

Due to the concern over R_{BN} measurement accuracy, the criterion used in 6.2 of this standard will allow valid measurements of the **beam cross-sectional area** to be made with a 1,0 mm **hydrophone** on currently available **ultrasonic physiotherapy equipment** operating up to

3 MHz. For **ultrasonic physiotherapy equipment** operating above 3 MHz, a **hydrophone** of diameter less than 0,6 mm is specified. These **hydrophones** will, in most practical circumstances, allow measurements of **effective radiating area** and **beam non-uniformity ratio** to be made reliably.

Table H.1 – Comparison of measurements of the beam cross-sectional area ($A_{BCS}(z)$) made using hydrophones of geometrical active element radii 0,3 mm, 0,5 mm and 2,0 mm

Hydrophone	Measurement	Treatment head-hydrophone separation, z cm			
		1,0	2,0	4,0	8,0
A ceramic a_g = 0,3 mm	$A_{BCS}(z)$ (cm^2)	2,00	1,97	2,01	2,07
	R [1)]	1,55	1,57	1,68	2,69
C ceramic a_g = 0,5 mm	$A_{BCS}(z)$ (cm^2)	1,93	1,96	1,99	2,08
	R [1)]	1,68	1,69	1,60	2,26
PVDF bilaminar membrane a_g = 2 mm	$A_{BCS}(z)$ (cm^2)	2,01	2,00	2,02	2,10
	R [1)]	1,95	1,91	2,04	2,33
1) The R values have been derived using the averaged p^2 value evaluated in the specified measurement plane.					
NOTE Measurements were made on a 3 MHz **treatment head** at four distances.					

Annex I
(informative)

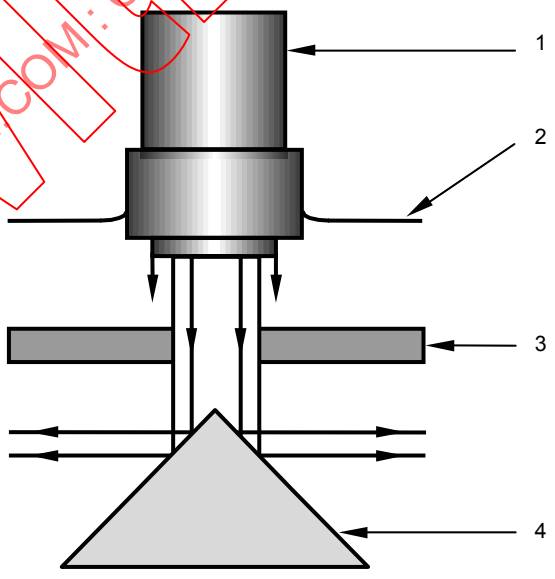
Effective radiating area measurement using a radiation force balance and absorbing apertures

I.1 General

This Annex provides details of a method of determining the effective radiating area (AER) of physiotherapy treatment heads that utilizes a radiation force balance for measuring its ultrasonic output power. Radiation force balances are widely available within hospitals and it is anticipated that this method could be applied as simple method of 'in-service' checking of the effective radiating area. The method described in this annex is not intended as a replacement for the procedures described in Clause 7, which represents the reference method for determining effective radiating area.

I.2 Concept of aperture method

The concept behind the aperture method is illustrated schematically in Figure I.1, where an absorbing aperture is shown interposed between the **treatment head** and the target of the radiation force balance, which in this case is of the convex conical reflecting type (an absorbing target could also be used). The apertures are circular holes cut within an acoustically absorbing material, which, when placed in front of a **treatment head**, allow the effective radiating surface of the **treatment head** to be selectively reduced. The resulting reduction in power is measured using the radiation force balance. By masking off areas of the ultrasound beam using a range of apertures, the spatial distribution of the transmitted power can be sampled. The aim of the measurements, in combination with the data analysis presented in I.5, is to compute the area though which the majority of power is transmitted, thus deriving a value for the **effective radiating area** or A_{ER}. In the remainder of this annex, the term 'aperture' will be used to represent the mask and the circular hole cut therein.



1: Treatment head
2: Water surface
3: Aperture mask (I.3.2)
4: Radiation force balance target

Figure I.1 – Schematic representation of aperture measurement set-up

NOTE The diagram portrays a 'vertical' arrangement of radiation force balance with a reflecting target, although alternative arrangements may be used (IEC 61161).

I.3 Requirements for the aperture method

I.3.1 Radiation force balance

Aside from the geometrical considerations of the need to be able to interpose the absorber layer forming the aperture between the **treatment head** and the radiation force balance target, the key aspect of the radiation force balance relating to its performance in measuring **effective radiating area** lies in its reproducibility and resolution, which should ideally be ±0,01 W.

I.3.2 Apertures

I.3.2.1 Acoustic properties of aperture material

It is important that any material used to fabricate the apertures minimally perturbs the **output power** generated by the **treatment head** under test. Its acoustic properties should be such that the:

- reflection loss of ultrasound from the surface of the apertures must be better than –30 dB;
- transmission loss of ultrasound through the material must be less than –25 dB;

both of these properties refer to the particular frequency of operation of the **treatment head**.

NOTE 1 Compliance can be checked using techniques similar to those described in 6.2.

NOTE 2 The aperture mask materials may be made from single or multi-layers and can be manufactured from absorbing rubbers.

I.3.2.2 Aperture diameters

Nominal aperture diameters in the range 0,4 cm to 3,0 cm allow measurements of **effective radiating area** to be made on the majority of commercially-available physiotherapy **treatment heads**. The actual diameters should be uniformly cylindrical to, and known to ±0,01 cm.

I.3.2.3 Lateral extent of aperture mask material

It is important that, apart from the power transmitted through the circular aperture, all other power is absorbed within the mask material, so that unwanted power does not impinge on the radiation force balance target. The width of the aperture in the plane parallel to the **treatment head** should be greater than or equal to 4,5 cm. The aperture mask can be held with a holder appropriate for use with the particular radiation force balance, although it is important that no acoustically reflecting components are positioned within the ultrasonic field.

I.4 Measurement procedure for determining the effective radiating area

I.4.1 Power measurements made using the radiation force balance are carried out in the usual way, by switching the drive to the **treatment head** ON and OFF in a predefined manner (see IEC 61161).

I.4.2 For each of the individual aperture measurements, the output of the physiotherapy **treatment head** device under test must be reset to a nominally identical power value, to ensure that it is operating under nominally identical conditions.