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INTERNATIONAL STANDARD

colour inside

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

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

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

This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

a) The requirement on water oxygen content is specified in 6.1.
b) Former recommendations in 6.2 have been changed to become requirements.
c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.
d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.
e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

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

Draft	Report on voting
87/784/FDIS	87/789/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

NOTE The following print types are used:

- Requirements: in Arial 10 point
- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: *Times New Roman + Italic*
- Compliance clauses: in *Arial Italic*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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- withdrawn,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

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INTRODUCTION

Ultrasound at low megahertz frequencies is widely used in medicine for the purposes of physiotherapy. Such equipment consists of a generator of high frequency electrical energy and usually a hand-held **treatment head**, often referred to as an applicator. The **treatment head** contains a transducer, usually a disc 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 document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document only relates to **ultrasonic physiotherapy equipment** employing a single plane non-focusing circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head**.

This document 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 within the scope of this document.

Ultrasonic physiotherapy equipment using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

IEC 61161~~:2013~~, *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*~~
~~Amendment 1:2013~~

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

~~NOTE SI units (see ISO/IEC Directives – Part 2:2011, Annex I b) are used in the Notes to entry below certain parameter definitions for defining certain parameters, such as beam areas and intensities. It may be convenient to use decimal multiples or submultiples in practice but care should be taken in using decimal prefixes in combination with units when using and calculating numerical data. For example, beam area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2.~~

3.1
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 to entry: 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 Clause A.2 for further guidance.

Note 2 to entry: **Absolute maximum rated output power** is expressed in watts (W).

3.2
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 cm)

Note 1 to entry: **Active area coefficient** is expressed in units of one per metre (m^{-1}).

3.3
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~~

ratio of the difference of the **beam cross-sectional area** at z_N, $A_{BCS}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, A_{BCS}(0,3 cm), divided by the difference of the respective distances

$$m = \frac{A_{BCS}(z_N) - A_{BCS}(0{,}3\ \text{cm})}{z_N - 0{,}3\ \text{cm}} \quad (1)$$

where

A_{BCS} is the **beam cross-sectional area**;

z_N is the distance from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**

Note 1 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – The calculation scheme of the gradient was added to the definition, and the formula was added.]

3.4
absolute maximum beam non-uniformity ratio
beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio**

3.5
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**

3.6
absolute minimum effective radiating area
effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.7
acoustic-working frequency
acoustic frequency
f_{awf}
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 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.7.1 and 3.7.2.

Note 2 to entry: 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 to entry: **Acoustic frequency** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.3]

3.7.1
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 to entry: This frequency definition usually is intended for ~~pulse-wave~~ systems that produce short pulses containing only a few cycles, but it could be used for tone bursts.

Note 2 to entry: It is assumed that $f_1 < f_2$.

Note 3 to entry: If f_2 is not found within the range < $3f_1$, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is 3 dB below the peak magnitude.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.3.2, modified – Note ~~3~~ 1 to entry has been ~~added~~ modified.]

3.7.2
zero-crossing acoustic-working frequency
f_{awf}
number, n, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n-th half-cycle

Note 1 to entry: None of the n consecutive half-cycles should show evidence of phase change.

Note 2 to entry: The measurement should be performed at terminals in the receiver that are as close as possible to the receiving transducer (**hydrophone**) and, in all cases, before rectification.

Note 3 to entry: This frequency is determined in accordance with the procedure specified in IEC TR 60854.

Note 4 to entry: This frequency is intended for **continuous wave** or quasi-continuous-wave (e.g. tone-burst) systems only.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.3.1, modified – In Note 4 to entry, "or quasi-continuous-wave (e.g. tone-burst)" has been added.]

3.8
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 to entry: Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.1, ~~modified – deletion of NOTE 2~~]

3.9
acoustic repetition period
arp
pulse repetition period equal to the time interval between corresponding points of consecutive cycles for **continuous wave** systems

Note 1 to entry: **Acoustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.2, modified – The definition ~~cited above is~~ has been made more specific for non-scanning systems.]

3.10
amplitude modulated wave
wave in which the ratio ~~$p_p / \sqrt{2} p_{rms}$~~ $p_{tp}/(\sqrt{2}p_{RMS})$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where ~~p_p~~ p_{tp} is the **temporal-peak acoustic pressure** and ~~p_{rms}~~ p_{RMS} is the **RMS acoustic pressure**

3.11
attachment head
accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

[SOURCE: IEC 60601-2-5:2009, 201-3-202]

3.12
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 to entry: 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**.~~

straight line joining two points of **maximum RMS acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head** at specific distances

Note 1 to entry: One plane is at a distance of approximately a^2/λ where a is the geometrical radius of the active element of the **treatment head**. The second plane surface is at a distance of either $2a^2/\lambda$ or $a^2/(3\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**.

Note 2 to entry: 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 ~~$A_{ERN}/(\pi\lambda)$~~ a^2/λ 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 7.3.

3.13
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 1 to entry: **Beam cross-sectional area** is expressed in units of square metre (m^2).

Note 2 to entry: The rationale supporting the definition is described in Annex D.

3.14
beam maximum intensity
product of the **beam non-uniformity ratio** and **effective intensity**

Note 1 to entry: **Beam maximum intensity** is expressed in units of watt per square metre (W/m^2).

3.15
beam non-uniformity ratio
R_{BN}
ratio of the square of the **maximum RMS acoustic pressure** to the spatial average of the square of the **RMS acoustic pressure**, where the spatial average is taken over the **effective radiating area**~~. **Beam non-uniformity ratio** is given by:~~

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

$$R_{BN} = \frac{p_{max,RMS}^2 A_{ER}}{pms_t A_0} \quad (2)$$

where

$p_{max,RMS}$ is the **maximum RMS acoustic pressure**;

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

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

A_0 is the unit area for the raster scan.

3.16
beam type
descriptive classification of the ultrasonic beam

Note 1 to entry: There are three beam types: **collimated** (3.18), **convergent** (3.19) and **divergent** (3.20).

3.17
continuous wave
wave in which the ratio ~~$p_p/\sqrt{2}p_{rms}$~~ $p_{tp}/(\sqrt{2}\,p_{RMS})$, at any point in the **far field** on the **beam alignment axis**, is less than or equal to 1,05, where ~~p_p~~ p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

3.18
collimated
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.19
convergent
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.20
divergent
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.21
duty factor
ratio of the **pulse duration** to the **pulse repetition period**

3.22
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 1 to entry: **Effective intensity** is expressed in units of watt per square metre (W/m^2).

3.23
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 cm), multiplied by a dimensionless factor F_{ac} equal to 1,333

Note 1 to entry: 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, ~~in references [1] and [2] in Annex K~~.

Note 2 to entry: **Effective radiating area** is expressed in units of square metre (m^2).

3.24
end-of-cable loaded sensitivity
~~end-of-cable loaded sensitivity of a hydrophone~~
~~end-of-cable loaded sensitivity of a 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 to entry: **End-of-cable loaded sensitivity** is expressed in volt per pascal (V/Pa).~~

~~[SOURCE: IEC 62127-3:2007, definition 3.5]~~

$\underline{M}_{\mathrm{L}}(f)$

<of a **hydrophone** or hydrophone assembly> quotient of the Fourier transformed **hydrophone** voltage-time signal $\mathcal{F}(u_{\mathrm{L}}(t))$ 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 Fourier transformed **acoustic pulse waveform** $\mathcal{F}(p(t))$ in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

$$\underline{M}_{\mathrm{L}}(f) = \frac{\mathcal{F}(u_{\mathrm{L}}(t))}{\mathcal{F}(p(t))} \tag{3}$$

Note 1 to entry: The **end-of-cable loaded sensitivity** is a complex-valued parameter. Its modulus is expressed in units of volt per pascal (V/Pa), its phase angle is expressed in degrees, and represents the phase difference between the electrical voltage and the sound pressure.

[SOURCE: IEC 61828:2020, 3.50]

3.25
far field

region of the field where $z > z_{\mathrm{T}}$ aligned along the beam axis for planar non-focusing transducers where z is the distance from the face of the **treatment head** to a specified point on the **beam alignment axis**

Note 1 to entry: In the **far field**, the sound pressure appears to be spherically **divergent** from a point on or near the radiating surface. Hence the pressure produced by the sound source is approximately inversely proportional to the distance from the source.

Note 2 to entry: The term "**far field**" is used in this document only in connection with non-focusing source transducers. For focusing transducers a different terminology for the various parts of the transmitted field applies (see IEC 61828).

Note 3 to entry: For the purposes of this document, the **far field** starts at a distance where $z_{\mathrm{T}} = A_{\mathrm{ERN}}/(\pi\lambda)$, 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 the NOTE in IEC 62127-1 Amendment 1:2013.~~

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.28, modified – ~~The above definition has replaced the Note 3 to entry~~ In the definition, specification of z has been added and Note 3 to entry has been replaced to provide specific information on z_{T}]

3.26
hydrophone

transducer that produces electrical signals in response to ~~waterborne acoustic signals~~ pressure fluctuations in water

Note 1 to entry: A **hydrophone** is principally a passive device designed and built to respond to sound pressure.

Note 2 to entry: In some applications, a **hydrophone** is used as an active device to transmit sound.

[SOURCE: IEC 60050-801:~~1994~~2021, 801-32-26]

3.27
instantaneous acoustic pressure
$p(t)$
pressure at a particular instant in time and at a particular point in an acoustic field, minus the ambient pressure

Note 1 to entry: **Instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03~~, modified – only grammatical, plus addition of the Note 1 to entry~~]

3.28
maximum RMS acoustic pressure
$p_{max,RMS}$
maximum value ~~of the **rms acoustic pressure** detected by a **hydrophone**~~ over the entire acoustic field of the **RMS acoustic pressure**

Note 1 to entry: **Maximum RMS acoustic pressure** is expressed in pascals (Pa).

3.29
mean square acoustic pressure
mean square of the **instantaneous acoustic pressure** at a particular point in the acoustic field, taken over an integral number of **acoustic repetition periods**

Note 1 to entry: In practice, the mean value is often derived from RMS measurements.

Note 2 to entry: **Mean square acoustic pressure** is expressed in units of pascal squared (Pa^2).

3.30
modulation waveform
temporal envelope waveform of the **amplitude modulated wave** at the point of **peak RMS 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**

Note 1 to entry: See Annex K for examples.

3.31
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 to entry: **Output power** is expressed in watts (W).

[SOURCE: IEC 61161:2013, 3.3, modified – In the definition, "**ultrasonic transducer**" has been replaced by "**treatment head** of **ultrasonic physiotherapy equipment**".]

3.32
peak RMS acoustic pressure
maximum value of the **RMS acoustic pressure** over a specified region, line or plane in an acoustic field

Note 1 to entry: **Peak RMS acoustic pressure** is expressed in pascals (Pa).

3.33
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 value of the pressure amplitude and 10 % of the difference between the maximum and minimum value of the pressure amplitude~~

time interval beginning when the **modulation waveform** exceeds a reference value and ending at the next time the **modulation waveform** returns to that value

Note 1 to entry: The reference value is equal to the sum of the minimum value of the **modulation waveform** and 10 % of the difference between the maximum and minimum value of the **modulation waveform**.

Note 2 to entry: This definition differs from that in IEC 62127-1:2007 ~~Amendment 1:2013, from which it is derived, to account for incomplete modulation~~ to be applicable to **amplitude modulated waves**.

Note 3 to entry: See Annex K for examples.

Note 4 to entry: **Pulse duration** is expressed in seconds (s).

3.34
pulse repetition period
prp
time interval between equivalent points on ~~successive pulses or tone-bursts~~ the **modulation waveform** for an **amplitude modulated wave**

Note 1 to entry: See Annex K for examples.

Note 2 to entry: **Pulse repetition period** is expressed in seconds (s).

~~[SOURCE: IEC 62127-1:2007 Amendment 1:2013, definition 3.51, modified – NOTE 1 from IEC 62127-1 Amendment 1:2013 not copied]~~

3.35
pulse repetition rate
prr
reciprocal of the **pulse repetition period**

Note 1 to entry: The **pulse repetition rate** is equal to the repetition frequency of the modulated waveform.

Note 2 to entry: The **pulse repetition rate** is expressed in hertz (Hz)

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.52, modified – Note 1 to entry differs from the original NOTE 1.]

3.36
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 1 to entry: **Rated output power** is expressed in watts (W).

3.37
RMS acoustic pressure
$p_{\mathbf{RMS}}$
root-mean-square (RMS) of the **instantaneous acoustic pressure** at a particular point in an acoustic field

Note 1 to entry: The mean should be taken over an integral number of **acoustic repetition periods** unless otherwise specified.

Note 2 to entry: **RMS acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.53]

3.38
spatial-peak temporal-peak acoustic pressure
p_{sptp}
larger of the peak-compressional acoustic pressure or the peak-rarefactional acoustic pressure

Note 1 to entry: **Spatial-peak temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.63]

3.39
temporal-maximum output power
P_{tm}
<for an **amplitude modulated wave**> ~~the **temporal-maximum output power** is given by~~ actual **output power** scaled by half of the squared ratio of the **temporal-peak acoustic pressure** and the **RMS acoustic pressure**

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

$$P_{tm} = \frac{1}{2}\left(\frac{p_{tp}}{p_{RMS}}\right)^2 \times P \qquad (4)$$

where

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

~~p_p~~ p_{tp} is the **temporal-peak acoustic pressure**;

p_{RMS} is the ~~true~~ **RMS acoustic pressure**.

Note 1 to entry: Both ~~p_p~~ p_{tp} and p_{RMS} are measured ~~under **amplitude modulated wave** conditions and~~ at a specified point on the **beam alignment axis.**

Note 2 to entry: **Temporal-maximum output power** is expressed in watts (W).

3.40
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 1 to entry: **Total mean square acoustic pressure** is expressed in units of pascal squared (Pa^2).

3.41
temporal-maximum intensity
I_m
<for an **amplitude modulated wave**> ~~the **temporal-maximum intensity** is given by~~ quotient of the **temporal-maximum output power** and the **effective radiating area**

$$I_m = \frac{P_{tm}}{A_{ER}} \qquad (5)$$

where

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

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

Note 1 to entry: **Temporal-maximum intensity** is expressed in units of watt per square metre (W/m^2).

3.42
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 to entry: **Temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.67]

3.43
treatment head
assembly comprising one **ultrasonic transducer** and associated parts for local application of **ultrasound** to the patient

[SOURCE: IEC 60601-2-5:2009, 201.3.214, modified – The NOTE has not been included.]

3.44
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

[SOURCE: IEC 62127-1:2007 ~~Amendment 1:2013~~, 3.73]

3.45
ultrasound
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

3.46
ultrasonic physiotherapy equipment
equipment
equipment for the generation and application of **ultrasound** to a patient for therapeutic purposes

Note 1 to entry: Excluded equipment includes, but is not limited to:

– equipment in which **ultrasound** waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;
– equipment in which a tool is driven by **ultrasound** (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);
– equipment in which **ultrasound** waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);
– equipment in which **ultrasound** waves are intended to treat cancerous (i.e. malignant) or pre-cancerous tissue, or benign masses, such as high intensity focused ultrasound (HIFU) or high intensity therapeutic ultrasound (HITU).

[SOURCE: IEC 60601-2-5:2009, 201.3.216, modified – The NOTE has been ~~omitted~~ modified to give some examples of excluded equipment.]

4 Symbols

a	geometrical radius of the active element of a **treatment head**
A_{BCS}	**beam cross-sectional area**
$A_{BCS}(0{,}3\ cm)$	**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~~ maximum effective **hydrophone** size, defined in IEC 62127-1
A_o	unit area for a raster scan
arp	**acoustic repetition period**
b	minimum radius of a target for a radiation force balance
c	speed of sound in water
ERD	echo reduction
f_{awf}	**acoustic working frequency**
F_{ac}	conversion factor to convert $A_{BCS}(0{,}3\ cm)$ 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~~ M_L	**end-of-cable loaded sensitivity** of a **hydrophone**
P	**output power** of a **treatment head**
P_{tm}	**temporal-maximum output power**
$p(t)$	**instantaneous acoustic pressure**
~~p_p~~ p_{tp}	**temporal-peak acoustic pressure**
p_{sptp}	**spatial-peak temporal-peak acoustic pressure**
$p_{max,RMS}$	**maximum RMS 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~~
prp	**pulse repetition period**
prr	**pulse repetition rate**
Q	**active area coefficient**
R	ratio of the **peak RMS acoustic pressure** to the **RMS 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~~
s_n	normalized distance from the face of the transducer to a specified point on the **beam alignment axis**
~~U~~ u	end-of-cable voltage for a **hydrophone**
~~U_i~~ u_i	**hydrophone** signal for the i-th scan point
~~U_p~~	~~maximum value of the **hydrophone** voltage~~
u_n	RMS noise 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** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**
z_p	distance ~~of the **peak rms acoustic pressure**~~ from the ~~front~~ face of the **treatment head** to the **peak RMS acoustic pressure** on the **beam alignment axis**
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** (I_e) at the same equipment settings as the nominal value of the **rated output power** (±30 %);
– **acoustic working frequency** (f_{awf}) (±10 %);
– **beam non-uniformity ratio** (R_{BN}) (±30 %);
– **beam maximum intensity** (±30 %);
– **beam type**;
– **pulse duration**, **pulse repetition period** (prp), **duty factor** and the ratio of the **temporal maximum output power** to the **output power** for each modulation setting (±5 %);
– **modulation waveform** for each modulation setting.

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

6 Conditions of measurement and test equipment used

6.1 General

All measurements undertaken in water shall be 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 8.6, are not dependent on the temperature at which the tests were undertaken.

Degassed water shall be used for the measurement of ultrasonic power, see Clause 7. ~~Degassed water is not essential for the **hydrophone** measurements, see 7.3.~~ The amount of dissolved oxygen in the degassed water shall be < 4 mg/l during all measurements.

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~~ can be found in IEC 61161, IEC TR 62781 and in [1][1].

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~~ shall 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~~ shall possess three independent degrees of translational movement. The measurements ~~should~~ shall 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.~~

1 Numbers in square brackets refer to the Bibliography.

*Compliance for overall echo reduction of an acoustic absorber may be checked using the ~~following~~ procedure from IEC TS 63081. If echo reduction ~~should~~ is determined it shall 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 (ERD, in dB) is calculated using:~~*

$$ERD = -20 \log_{10} \left[\frac{U_{\text{absorber}}}{U_{\text{reflector}}} \right]$$

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

*The pressure amplitude of the reflection from the front surface of the acoustic absorber, $p_{absorber}$, is compared to that from a perfect planar reflector, $p_{reflector}$. The acoustic absorber and the reference reflector shall be aligned near normal to the **beam alignment axis** but angled so that the reflected signal can be intercepted by the **hydrophone**. Given that the amplitude reflection coefficient of a reference reflector $R_{p,reflector}$, such as a stainless-steel reflector ($R_{p,reflector}$ = 0,938 9) is slightly less than that of a perfect reflector ($R_{p,reflector}$ = 1), the measured reflection pressure amplitude $p_{absorber}$ can be adjusted to account for the imperfect reflection in accordance with*

$$\hat{p}_{\text{absorber}}(f) = p_{\text{absorber}}(f) \cdot R_{p,\text{reflector}} \tag{6}$$

The echo reduction ERD in decibels (dB) is then calculated using

$$ERD = -20 \log_{10} \left[\frac{\hat{p}_{\text{absorber}}}{p_{\text{reflector}}} \right] \text{dB} \tag{7}$$

When a reference reflector is used, its thickness shall be sufficient that reflections from its rear surface do not introduce unwanted measurement artefacts.

Compliance of the test vessel to free-field conditions is checked by noting the invariance of the product $pms_t \cdot s^2$ (see ~~7.4.6~~ 7.4.7) after completing the measurements specified in Clause 7.

NOTE For some **treatment heads**, **ultrasound** reflected back to the **treatment head** ~~may~~ can 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~~ can 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).~~ All pressure measurements shall be made with a **hydrophone**, for example, with either a piezoelectric polymer or ceramic active element. 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:

$$a_{max} / \lambda \leq 0{,}4 \quad (8)$$

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

NOTE 2 The influence of effective **hydrophone** radius on measurement is described in Annex H.

NOTE 3 Information on the frequency-dependent effective **hydrophone** radius or size and its derivation from directional response measurements can be found in IEC 62127-3.

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:~~

$$~~p = U/M_L~~$$

~~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 **rms acoustic pressure** for convenience. In fact, measurements may be based on either **rms** or **temporal-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**.*~~

The measured end-of-cable voltage $u_L(t)$ at the **hydrophone** shall be related to the **instantaneous acoustic pressure** p applying the **end-of-cable loaded sensitivity** $\underline{M}_L$ of the **hydrophone** in accordance with IEC 62127-1. If distortion caused by nonlinear propagation effects is negligible, the narrow-band approximation can be applied, and the **instantaneous acoustic pressure** can be determined from

$$p(t) = u_L(t) / |\underline{M}_L(f_{awf})| \quad (9)$$

where $|\underline{M}_L(f_{awf})|$ is the modulus of the **end-of-cable loaded sensitivity** of the **hydrophone** at the **acoustic-working frequency**. However, in practice, the absolute values of the acoustic pressure are not required as the analysis of measured data throughout this document is based on relative **hydrophone** measurements.

NOTE 1 For more information on criteria for the narrow-band approximation, and alternatives for broadband measurements using the frequency-dependent sensitivity of the **hydrophone**, see IEC 62127-1.

NOTE 2 For more information on the determination of the **hydrophone** sensitivities see IEC 62127-2.

Subsequent reference to acoustic pressure will refer to the **RMS acoustic pressure** for convenience. In fact, if distortion caused by nonlinear propagation effects is negligible, in which case the **temporal-peak acoustic pressure** is proportional to the **RMS acoustic pressure** as the excitation voltage to the **ultrasonic transducer** is increased, **temporal-peak acoustic pressure** may as well be chosen. All measurements need to be based on the same method.

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 shall be checked using a well-characterized linear **ultrasonic transducer** 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.

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

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. The amount of dissolved oxygen in the degassed water shall be < 4 mg/l during all measurements. Overall uncertainty of measurement expressed at the 95 % confidence level shall be determined (see 9.3) and ~~should~~ shall be better than ±15 %. Measurements ~~should~~ shall 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 7.4.2).~~

~~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. For treatment heads with $ka \leq 20$ this intensity should be less than 0,2 W/cm^2. 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**.~~

All measurements of **effective radiating area** shall be undertaken with the equipment set in **continuous wave** mode at intensities low enough to avoid cavitation. Using degassed water in the measurement system is good practice to ensure that 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 needle **hydrophones** used. The validity of extrapolating these values to higher power levels more typical of therapeutic treatment is demonstrated in Annex G.

NOTE 2 **Treatment heads** with $a \leq 10$ mm, when compared with **treatment heads** of larger dimensions operating at similar **equipment** output settings, have been observed to produce higher **temporal-peak acoustic pressure** levels. For **treatment heads** with an **acoustic-working frequency** of 1 MHz or less, this increases the risk of cavitation occurring. The lower limit of 0,2 W/cm^2 for these small ka **treatment heads** minimizes this likelihood.

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~~ shall 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 by **hydrophone** scanning in accordance with IEC 62127-1. The second plane surface (see 3.12) ~~should~~ shall initially be chosen as $A_{\mathrm{ERN}}/(3\pi\lambda)$. If it is not possible to locate a single peak at or close to this distance, the larger distance of $2A_{\mathrm{ERN}}/(\pi\lambda)$ ~~should~~ shall 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 RMS acoustic pressure**, z_{p}, and the position of the last axial maximum, z_N, shall be determined. It may occur that z_{p} and z_N are equal.

The step size of the axial plot ~~should~~ shall 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 Effective radiating area measurements

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~~ shall be derived from the **beam cross-sectional area**, A_{BCS}. The general requirements for raster scans are given in Clauses B.1 and B.2. The actual procedure for the reference measurements and the analysis of the results are given in 7.4.2 to 7.4.7. Under normal test conditions, the results using the test methods described ~~should~~ shall 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~~ shall achieve a measurement uncertainty (at the 95 % confidence level) of less than ±15 %.

7.4.2 Hydrophone positioning

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 RMS acoustic pressure**, $p_{max,RMS}$, in the field.

This ~~may~~ shall be done either 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 Beam cross-sectional area determination

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 Clause B.3. The analysis yields the **beam cross-sectional areas**, A_{BCS}(0,3 cm) and $A_{BCS}(z_N)$ and the **total mean square acoustic pressure**, pms_t, at each measurement plane.

7.4.4 Active area gradient determination

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

7.4.5 Beam type determination

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

$Q \geq 0{,}1$ cm^{-1}	**divergent**	
$-0{,}05$ cm$^{-1} \leq Q \leq 0{,}1$ cm^{-1}	**collimated**	(10)
$Q < -0{,}05$ cm^{-1}	**convergent**	

7.4.6 Effective radiating area calculation

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

$$A_{ER} = F_{ac}A_{BCS}(0{,}3 \text{ cm}) = 1{,}333A_{BCS}\ (0{,}3 \text{ cm}) \quad (11)$$

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 Beam non-uniformity ratio calculation

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

$$R_{\mathrm{BN}} = \frac{p_{\mathrm{max}}^2 \cdot A_{\mathrm{ER}}}{\overline{pms_{\mathrm{t}} \cdot s^2}} \tag{12}$$

where

$$\overline{pms_{\mathrm{t}} \cdot s^2} = \frac{1}{2}\left\{\left[pms_{\mathrm{t}}(0{,}3) \cdot s^2(0{,}3)\right] + \left[pms_{\mathrm{t}}(z_N) \cdot s^2(z_N)\right]\right\} \tag{13}$$

NOTE 1 Although $p_{\mathrm{max,RMS}}$ and pms_{t} are referred to as acoustic pressure or pressure-squared parameters, only their ratio is ~~required~~ used for the determination of R_{BN}, hence the **end-of-cable loaded sensitivity** of the **hydrophone** is not ~~required~~ needed.

NOTE 2 The product $pms_{\mathrm{t}} \cdot s^2$ 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~~ In ideal cases, it is invariant with distance from the **treatment head**.

7.4.8 Testing requirements

The procedures given in 7.4.1 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_{awf});
- the distance ~~of the **peak r.m.s acoustic pressure**~~ from the ~~front~~ face of the **treatment head** to the **peak RMS acoustic pressure** on the **beam alignment axis** (z_{p});
- **beam non-uniformity ratio** (R_{BN});
- **beam type**;
- **pulse duration**, **pulse repetition period** (prp) 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 as follows:

– **rated output power**;

– **effective radiating area** (A_{ER}) of the **treatment head**;

– **acoustic-working frequency** (f_{awf});

– **pulse duration**, **pulse repetition period** (prp) 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~~ shall be set up in the test vessel in accordance with Clause 6. However, alignment of the **treatment head** ~~may~~ shall 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}~~ $p_{RMS,max}$ may be determined. It may occur that z_p and z_N are equal.

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}, shall be determined according to 7.4.~~

8.3.4 The **effective radiating area**, A_{ER}, ~~may also~~ can 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~~ absorbing material with low reflection loss. 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~~ is considered 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 in accordance with ~~7.4.6.~~ 7.4.7.

8.5 Effective intensity

The **effective intensity** shall be determined in accordance with 3.22.

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 7.4 and 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 nominally identical units of the **ultrasonic physiotherapy equipment**.

9.2 Routine measurements

The routine measurements shall be undertaken as the basis of good manufacturing practice. Normally, they shall 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 shall 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 document, normal uncertainty analysis and estimation methods shall be used (see Annex J for guidance).

Annex A
(~~informative~~ normative)

Guidance for performance and safety

A.1 General

Clauses A.2 to A.4 reflect the established approach on acceptable values of a few safety related parameters.

A.2 Rated output power

According to IEC 60601-2-5, the **rated output power** ~~should~~ shall not vary by more than ±20 % for variations of the mains voltage of ±10 %. Manual readjustment of the equipment for compliance with this requirement is not permitted.

*Compliance ~~should be~~ is 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~~ shall be checked at mains voltages of 230 (±10 %) V.*

The term "rated" is defined in IEC 60601-1 as the "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; so, from IEC 60601-2-5, the power output ~~has~~ needs to be checked for variation at 90 %, 100 % and 110 % of the declared value even when there is a range.

A.3 Effective intensity

According to IEC 60601-2-5, the **absolute maximum effective intensity** ~~should~~ shall be less than or equal to 3,0 W /cm^2.

*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

According to IEC 60601-2-5, the **absolute maximum beam non-uniformity ratio** ~~should~~ shall 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~~ can result in excessive heating in small regions of the tissue being treated, ~~arising~~ resulting in potential harmful effects to the patient.

~~At the present time, therapeutic~~ Transducers of **ultrasonic physiotherapy equipment** are not designed to provide highly localized tissue treatment. Consequently, the transducers addressed in this document are planar. The characterization of focusing transducers capable of generating high intensity beams which are being used in therapeutic applications is the subject of other documents (see IEC 62555 and IEC TS 62556).

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.

If, as in a plane wave, the intensity is derived from the acoustic pressure alone, the ratio between the time-average intensity distribution (I_p) in a field and average intensity of the piston source (I_0) 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 four. Even in the correct treatment where the true intensity (I) is given by the product of acoustic pressure and particle velocity, the maximum is four and will be found at one near-field length (s_n = 1 in Figure A.1). From the distance of about one transducer element radius, (z/a = 1), back to the element itself, the maximum ratio will decrease typically to a value of the order of two.

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 characteristic acoustic impedance. This formula cannot strictly be used 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 formula of the R_{BN} can be simplified as stated in this document as follows.

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

$$I_{spta} = \frac{U_p^2}{M_L^2 \rho c}$$

$$I_{spta} = \frac{u_p^2}{|\underline{M}_L|^2 \rho c} \qquad \text{(A.1)}$$

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

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

$$pms_{\mathrm{t}} = \sum_{i=1}^{N} \frac{u_i^{\,2}}{\left|\underline{M}_{\mathrm{L}}\right|^2} \tag{A.2}$$

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:

$$I_{\mathrm{sata}} = \frac{P}{A_{\mathrm{ER}}} = \frac{A_0 \cdot pms_{\mathrm{t}}}{\rho \cdot c \cdot A_{\mathrm{ER}}} \tag{A.3}$$

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

$$R_{\mathrm{BN}} = \frac{u_{\mathrm{p}}^2 \, A_{\mathrm{ER}}}{A_0 (z_j) \sum_{i=1}^{N} u_i^2 (z_j)} \tag{A.4}$$

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

In the above formulae, the parameters are as follows:

~~U_{p}~~ u_{p} is the maximum value of ~~the **hydrophone** voltage~~ u_i;

~~U_i~~ u_i is the RMS **hydrophone** voltage at the i-th point of measurement;

$\underline{M}_{\mathrm{L}}$ is the **end-of-cable loaded sensitivity** of the **hydrophone**;

P is the acoustic power;

pms_{t} is the **total mean square acoustic pressure**;

ρ is the density of water;

c is the speed of sound in water;

A_0 is the unit area of the scan ($A_0 = s^2$ 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 Formula (A.4) are presented for 37 different **treatment heads**, along with the frequency with which 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 three to seven, but some transducers having a R_{BN} greater than eight are shown and these may be considered to have a high R_{BN}.

The limiting value of eight has been identified in this document for the following reasons.

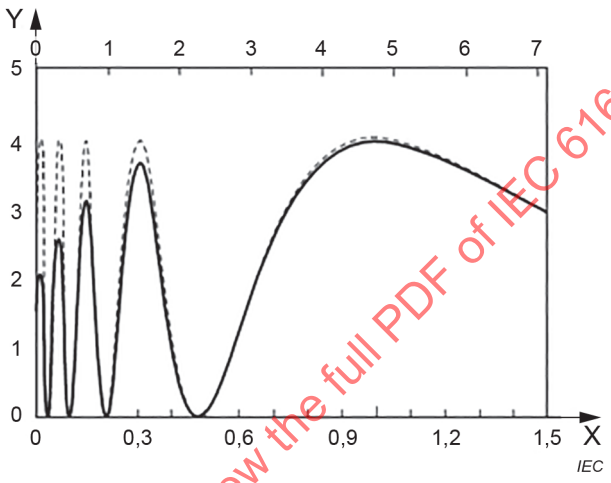
– In **ultrasound** physiotherapy the treatment protocol (output, duration and frequency) used is based on an ultrasonic beam behaving normally, following theoretical expectations. Evaluating the dose for a treatment is currently difficult to define. Accordingly, a relaxation of the ideal R_{BN} value of four is appropriate. Relaxing the theoretical value of R_{BN} by a factor

of two seems to be quite reasonable. As can be seen in Figure A.2, for normal behaving practical transducers, R_{BN} values less than eight can readily be attained.

– Physiotherapists have no current requirement for a focusing transducer. If a transducer is focusing, 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 in 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.



Key

X bottom axis: s_n

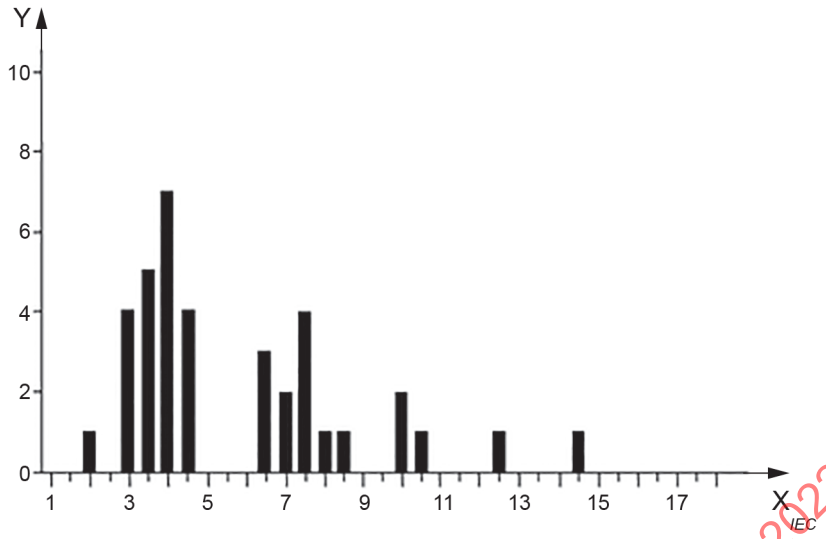
X top axis: z/a

Y solid line: I/I

Y broken line: I_p/I_p

NOTE In [2], the symbol "s" is used to describe the normalized distance. To avoid confusion with the raster scan step size definition used in this document, the normalized distance symbol here has been changed to s_n.

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



Key

X R_{BN}

Y Number of transducers

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

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

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 RMS 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 that 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~~ voltage u_n shall be subtracted from the measured signals in the following manner. If the **hydrophone** signal at each measurement point is ~~U_i~~ u_i, then the **hydrophone** signal after correcting for the contribution from noise, ~~U_i'~~ u_i' is:

$$U_i' = (U_i^2 - U_n^2)^{1/2}$$

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

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

B.3.1 General

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

B.3.2 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:

$$pms_t = \sum_{i=1}^{N} (U_i')^2 / M_L^2$$

$$pms_t = \sum_{i=1}^{N} u_i'^2 \Big/ |\underline{M}_L|^2 \qquad \text{(B.2)}$$

where

N is the total number of points in the scan;

~~U_i'~~ u_i' is the noise-corrected voltage (either peak or RMS) of the i-th point in the scan;

$\underline{M}_L$ 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)~~ (B.2) to convert the measured voltage to acoustic pressure. However, due to cancellation, when pms_t is introduced into Equation ~~(B.2)~~ (B.3), its absolute value is not ~~required~~ needed.

B.3.3 Calculation of the beam cross-sectional area, A_{BCS}

The values ~~U_i'~~ 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:

$$\frac{1}{M_L^2} \sum_{i=1}^{n} (U_i')^2 \leq 0{,}75\ pms_t$$

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

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^{n} u_i'^2 \leq 0{,}75\ pms_t \qquad \text{(B.3)}$$

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^{n+1} u_i'^2 > 0{,}75\ pms_t$$

The value of A_{BCS} is then given by $A_0 \cdot n$, where A_0 is the unit area of the raster scan ($A_0 = s^2$ where s is the distance 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~~ 8 may be performed using diametrical or line scans. The term line scan is used within Annex C. If line scans are used, then the procedures and analysis methods specified in Clauses C.2 and C.3 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 RMS 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~~ can be of different step size. Here, for ease of analysis, they ~~will be~~ are 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~~ is 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

C.3.1 The individual line scans will be analysed in the following way.

NOTE In the steps described in Clause C.3, the symbols [A] and [B] refer to data arrays and ~~should~~ are not ~~be interpreted as~~ references to publications in the bibliography.

C.3.2 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.3.3 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.3.4 For the measurement point which lies on the **beam alignment axis** (designated the j = 0 point) the contribution to such an area will be A_0, given in centimetres squared, by:

$$A_0 = \frac{\pi \cdot s^2}{4} \tag{C.1}$$

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

C.3.5 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 by the expression:

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

$$A_j = 2\pi \cdot j \cdot s^2 \tag{C.2}$$

C.3.6 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_0. By dividing A_j given in Equation (C.2) by A_0 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:

$$n_j = 8j \tag{C.3}$$

C.3.7 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 u_j^2	Number of elements in array [B] of value U_j^2 u_j^2
j = 0 (point on **beam alignment axis**)	U_0^2 u_0^2	1
j = 1 (first point off-axis)	U_1^2 u_1^2	8
j = 2 (second point off-axis)	U_2^2 u_2^2	16
•	•	•
•	•	•
•	•	•
$j = (N_1 - 1)/2$ (last point in scan)	$u^2_{(N_1-1)/2}$	$4(N_1 - 1)$
NOTE The j-th ($j > 0$) 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.3.8 In a similar manner to the analysis undertaken using the raster scan data in B.2.4, the RMS noise level U_n u_n shall be subtracted from each line-scan data point, to account for the contribution of noise. If the **hydrophone** signal at each point in the line scan is U_j u_j, then the **hydrophone** signal after correcting for the contribution from noise, U_j' u_j' is:

$$U_j' = (U_j^2 - U_n^2)^{1/2}$$

$$u_j' = \left(u_j^2 - u_n^2\right)^{1/2} \tag{C.4}$$

C.3.9 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:

$$pms_t = \frac{1}{M_L^2}(U_0')^2 + \frac{1}{M_L^2}\sum_{j=1}^{(\frac{N_1-1}{2})} 8\, j\, (U_j')^2$$

$$pms_t = \frac{1}{|M_L|^2}u_0'^2 + \frac{1}{|M_L|^2}\sum_{j=1}^{(\frac{N_1-1}{2})} 8j\, u_j'^2 \tag{C.5}$$

C.3.10 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.3.11 The **beam cross-sectional area**, A_{BCS}, of the half-line scan is given by $A_{BCS}=\frac{n \cdot \pi \cdot s^2}{4}$, where s is the step size.

C.3.12 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:

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

$$\sigma^2 = \frac{1}{7}\sum_{j=1}^{8}\left(A_{BCSj}(z) - \bar{A}_{BCS}(z)\right)^2 \quad \text{(C.6)}$$

where

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

$\overline{A_{BCS}(z)}$ $\bar{A}_{BCS}(z)$ 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~~ need 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~~ is part of a plane located at or close to the ~~applicator~~ **treatment head**, through which almost all of the **ultrasound** power passes. It is defined in this document 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 (7.4). It also may be estimated by using circular absorbing apertures (8.3.4).

The parameter, **beam cross-sectional area**, as defined in 3.13, 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 document represents the outcome of studies, based on actual measurements and theoretical calculations, to provide a useful definition and a reliable measurement method [1], [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** [9] 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) [10] 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 [10], 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~~

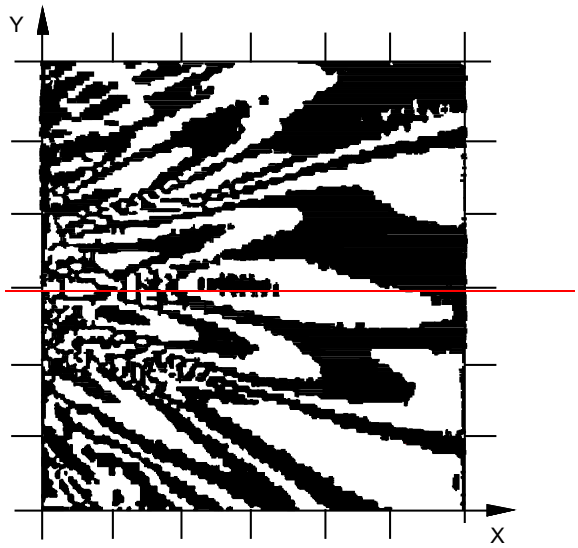
greater than those for the IEC definition. The smooth character of the curves for the IEC definition is also evident from Figure D.2.

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 [10].

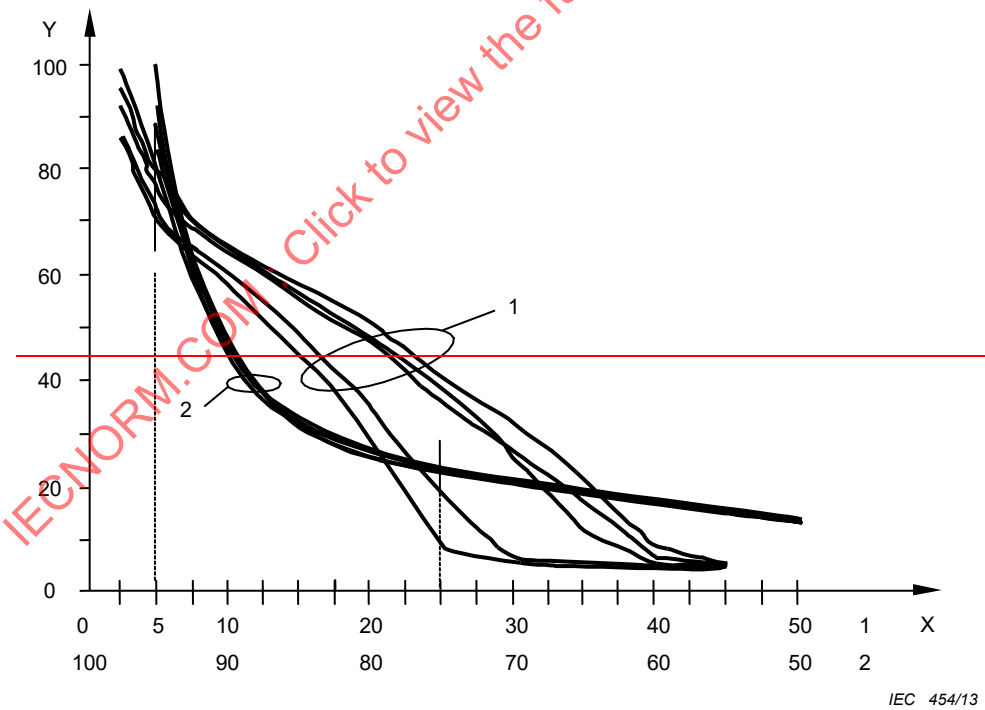
In other calculations presented in Figure D.5, the normalized **beam cross-sectional area** is calculated as a function of ka. The range of ka values used covers the whole range of sizes of **ultrasonic transducers** used in the **treatment heads** of **ultrasonic physiotherapy equipment**. Although 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 [10].



IEC 453/13

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

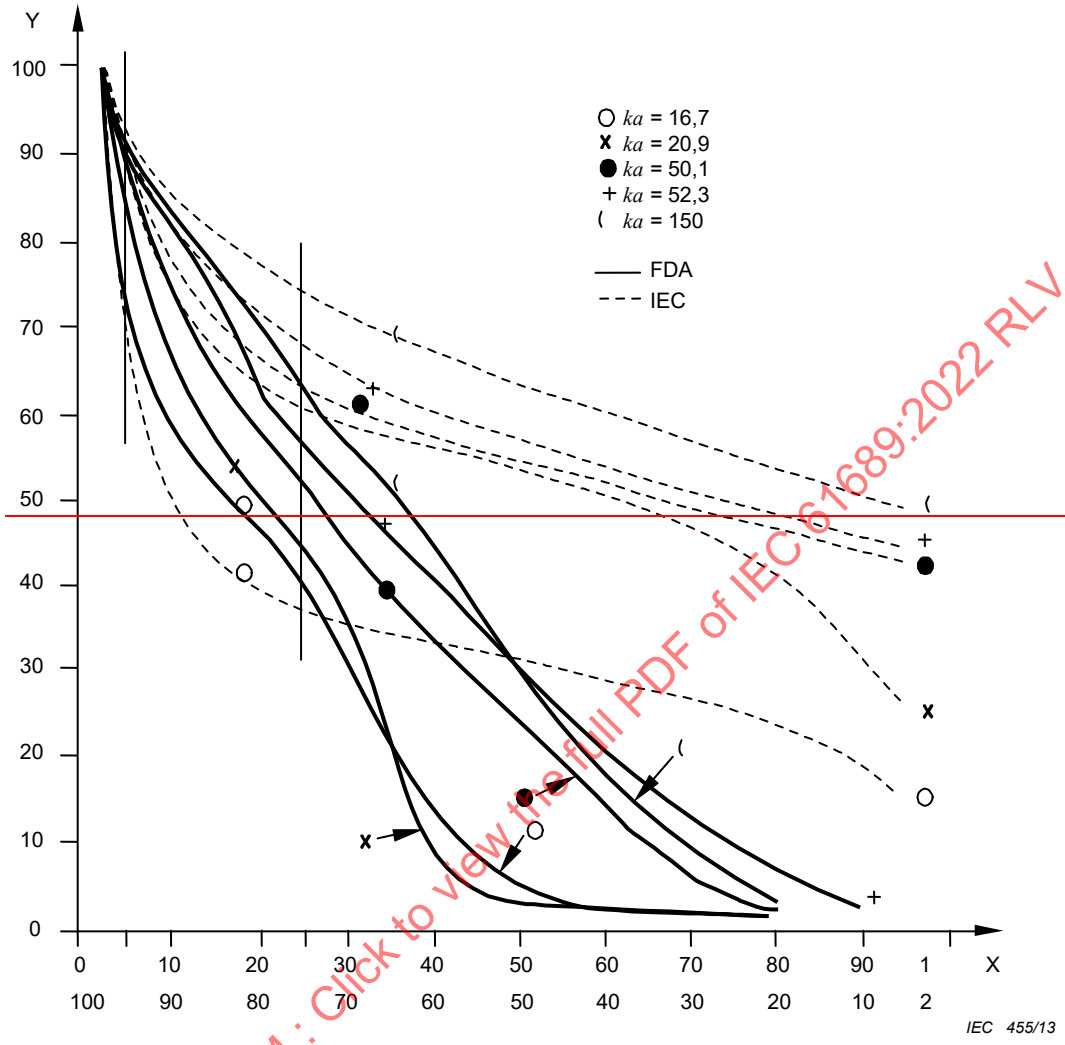
Figure D.1 – Iso-pressure lines of a typical physiotherapy treatment head of small geometrical area (k_a = 17)



IEC 454/13

Key
X limit %, 1 following FDA standard
2 following IEC standard
Y relative value of A_{BCS}
z = 4,50 mm, 4,75 mm, 5,00 mm, 5,25 mm, 5,50 mm

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



Key

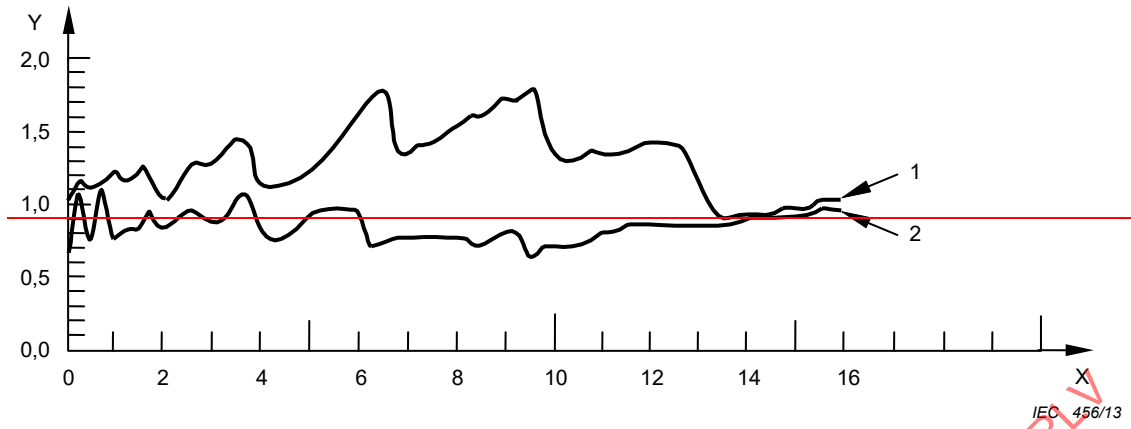
X limit %, 1 following FDA standard

2 following IEC standard

Y relative value of A_{BCS}

z = 0,5 cm

Figure D.3 – Normalized values of beam cross-sectional area for IEC and FDA limit values for five transducers of different ka values

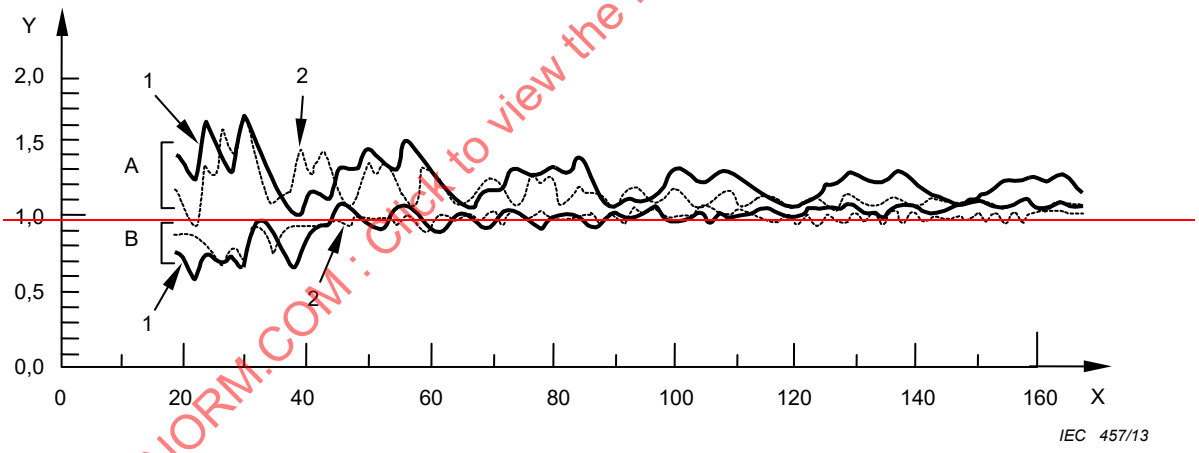


Key
X z/λ

Y normalized beam cross-sectional area A_{BCS}, 1 following FDA standard, 2 following IEC standard

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

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



Key
X ka

Y normalized beam cross-sectional area A_{BCS}

A following FDA standard

B following IEC standard

1 at z = 5 mm

2 at $z = 2a$, where a is the geometrical radius of the active element of the **ultrasonic transducer**

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

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

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 document requires the **effective radiating area**, A_{ER}, to be derived from the **beam cross-sectional area** close to the face of the **treatment head**, $A_{BCS}(0{,}3\ cm)$. 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:

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

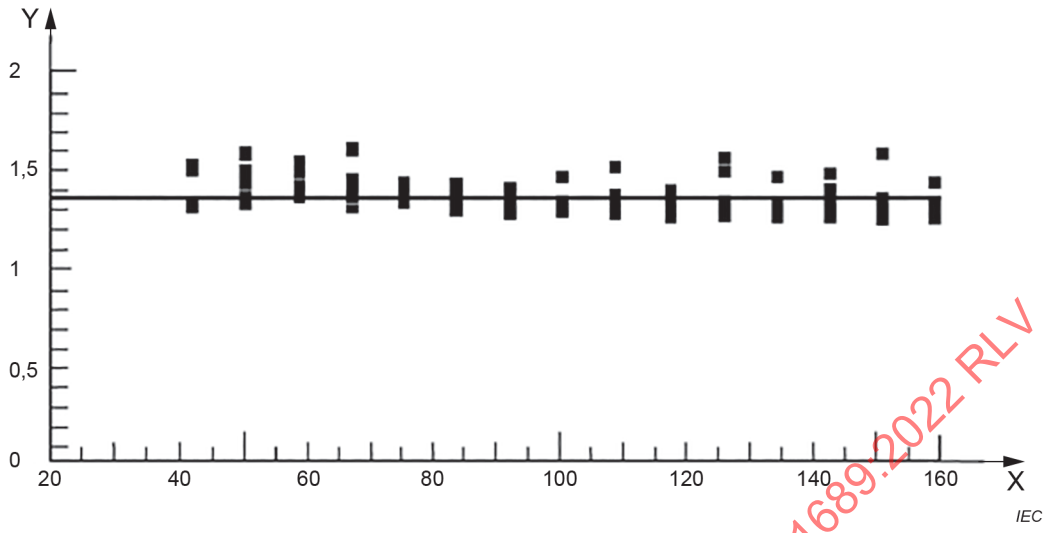
From the physical point of view, it can be expected that the simplified model is useful for values of ka that are not too small ($k = 2\pi/\lambda$ is the circular wavenumber; a is the geometrical radius of the active element of the **treatment head**). With smaller values of ka, diffraction effects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

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 (from [3]) 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.

A study has been carried out on a large sample of small ka physiotherapy **treatment heads** [4] and has defined the approach described in 7.3 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 $A_{BCS}(0{,}3\ cm)$ 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**.

The numerical investigations performed in the above studies did confirm agreement, within the uncertainty achieved, with the value obtained using the simplified sound field model. For the sample size studied (66 points), the standard deviation of the mean value is approximately 0,09. The deviation of the mean value ($F_{ac} = 1{,}354$) from the value obtained using the simplified sound field model ($F_{ac} = 1{,}333$) was less than this standard deviation. To avoid that, possibly large, uncertainties need to be taken into account in the determination of the **effective radiating area**, it has been agreed to use $F_{ac} = 1{,}333$ without the need to consider an uncertainty contribution for this fixed ~~value~~ conversion factor.



Key

X ka

Y F_{ac}

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

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

Annex F
(informative)

Determining acoustic power through radiation force measurements

This document 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~~ needs to be large enough to cover the whole ultrasonic field. Subclause A.5.3 of IEC 61161:2013 gives formulae for calculating the minimum value of the target radius b as a function of the target distance z, the wavelength and a_1, the effective radius of the active element of the **treatment head**. The formulae given in IEC 61161:2013 are based on theoretical calculations using a piston field approach [8]. 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**, $A_{BCS}(z)$. An equivalent radius b_{eq} can be determined from:

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

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 measurement. 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, IEC TR 62781 and [1]). The amount of dissolved oxygen in the degassed water should be < 4 mg/l during all measurements.

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 document, 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 61161:2013).

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 in accordance with A.5.3.1 of IEC 61161:2013 (see [8])

Effective radius of the treatment head a_1 cm	Ultrasonic frequency f MHz	Target distance z cm	Minimum target radius b 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)

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 (from [3]) presents the verification that values of **beam cross-sectional area** obtained at low powers are valid at higher operating powers employed for physiotherapy treatments. Table G.1 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 operated 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 B 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 [a] $A_{BCS}(z)$ cm^2	Transducer B [b] $A_{BCS}(z)$ 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

[a] 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 4,0 cm.

[b] 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 2,9 cm, the distance of the **maximum RMS 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 document to accurately determine the **effective radiating area** of a **treatment head** require 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 because 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 $A_{BCS}(z)$ between 1 % and 3 %.

With currently utilized physiotherapy **treatment head** frequencies and diameters, the most stringent test of 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 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 mm	**Measurement**	**Treatment head-hydrophone separation, z** cm			
		1,0	2,0	4,0	8,0
A ceramic a_g = 0,3	$A_{BCS}(z)$ cm^2	2,00	1,97	2,01	2,07
	R[a]	1,55	1,57	1,68	2,69
C ceramic a_g = 0,5	$A_{BCS}(z)$ cm^2	1,93	1,96	1,99	2,08
	R[a]	1,68	1,69	1,60	2,26
PVDF bilaminar membrane a_g = 2	$A_{BCS}(z)$ cm^2	2,01	2,00	2,02	2,10
	R[a]	1,95	1,91	2,04	2,33

NOTE Measurements were made on a 3 MHz **treatment head** at four distances.

[a] The R values have been derived using the averaged p^2 value evaluated in the specified measurement plane.

Annex I
(informative)

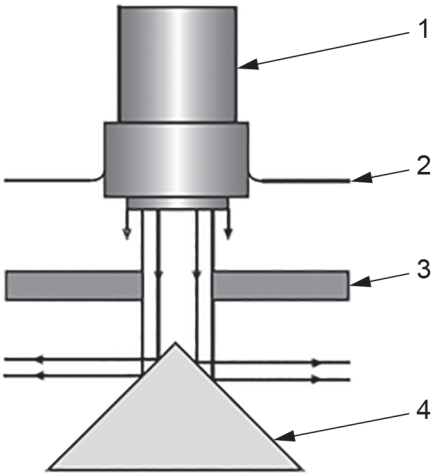
Effective radiating area measurements using a radiation force balance and absorbing apertures

I.1 General

This Annex I provides details of a method for determining the **effective radiating area** (A_{ER}) of physiotherapy **treatment heads** that utilizes a radiation force balance and a series of masks for measuring its ultrasonic **output power**. Such approaches are described in [9] and [10]. Radiation force balances are widely available within hospitals, and it is anticipated that this method could be applied as a simple method of "in-service" checking of the **effective radiating area**. The method described in this Annex I is not intended as a replacement for the procedures described in Clause 7, which represent 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 Clause I.5, is to compute the area through 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 I, the term "aperture" will be used to represent the mask and the circular hole cut therein.



Key

1 treatment head

2 water surface

3 aperture mask (I.3.2)

4 radiation force balance target

NOTE Figure I.1 portrays a "vertical" arrangement of radiation force balance with a reflecting target, although alternative arrangements ~~may~~ can also be used (IEC 61161).

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

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 is ~~better~~ less than −30 dB, and

– the transmission loss of **ultrasound** through the material is ~~less~~ greater than ~~–~~25 dB.

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

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

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

I.3.2.2 Aperture diameter

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, 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 ~~shall be~~ is reset to a nominally identical power value, to ensure that it is operating under nominally identical conditions.

I.4.3 A power setting of 5 W is recommended for large **treatment heads** (effective diameter greater than 2,0 cm) as this represents a compromise between measurement sensitivity and restricting the extent of heating of any aperture mask material, which may be important.

NOTE The effective diameter is equal to twice the effective radius of the **treatment head** radius, a_1. The effective radius ~~may~~ can be derived from the manufacturer's value of the **effective radiating area**, using the expression $a_1 = (A_{ER}/\pi)^{½}$. If the A_{ER} is not available, then the nominal **effective radiating area** (A_{ERN}) ~~should~~ can be used to derive a value for a_1.

I.4.4 For small **treatment heads** (effective diameters less than 1,5 cm), the maximum power output should be used, and this may typically lie in the range 0,9 W to 1,8 W. In addition, to restrict the irradiation time used, the switch ON time shall be limited to 5 s for each aperture to minimize any heating of the aperture surface.

I.4.5 In setting up, the **treatment head** shall be positioned as close to the aperture surface as possible but not touching – separations in the range 0,2 cm to 0,4 cm are acceptable. The surface of the **treatment head** and the front face of the aperture should be as parallel as possible.

I.4.6 It is important that the axis of symmetry of the reflecting target (if used) and the aperture axis are co-axial. The sensitivity of the results obtained using the aperture technique to alignment has been assessed [11], and it is sufficient to align the system by eye. The **treatment head** is then positioned centrally over the aperture, again purely by eye, such that the acoustic axis of the beam is assumed to be nominally coincident with that of the aperture and target. No re-positioning of the **treatment head** in the plane of the aperture is carried out for subsequent apertures.

NOTE 1 In order to aid alignment of the aperture below the surface of the **treatment head**, alignment cross-hairs can be marked on the surfaces of the aperture mask.

NOTE 2 Alignment of the target relative to the aperture ~~may not be as~~ is expected to be less critical for radiation force balances which employ an absorbing target.

NOTE 3 The co-axiality of the aperture and **treatment head** assumes that the spatial distribution of the intensity within the ultrasonic beam is broadly symmetrical and centred on the geometrical axis of the transducer. In situations where crystal damage has occurred, this ~~may not~~ is unlikely to be the case and scanning the **treatment head** in the plane of a small diameter aperture (0,4 cm to 0,6 cm) will provide some guidance on how the power is distributed.

I.4.7 As in the case of power measurements, care should be taken to ensure there are no bubbles in the intervening path or on the surfaces of the aperture masks. These can normally be wiped clear using a paint-brush.

NOTE It ~~may~~ can be found that small bubbles adhere to parts of the aperture. If these are generally positioned well away from the acoustic beam, they ~~should not~~ are unlikely to influence the transmitted power. Pre-soaking of the apertures in water containing a small amount of detergent ~~may~~ can also reduce this effect.

I.4.8 For each aperture, typically three or four switches OFF to ON and ON to OFF should be carried out and an average power taken in order to improve the statistics. Using the minimal irradiation time identified in I.4.4, this process should take around 30 s to 40 s in total.

I.4.9 In-between the aperture measurements, and certainly at the beginning and end of the run, a number of checks of the "free" or "unapertured"' power should be made with no aperture in place.

I.4.10 A set of aperture measurements will typically comprise the results of around 12 apertures, along with three or four "unapertured" power measurements.

I.4.11 For small **treatment heads** whose effective diameter is less than 1,5 cm, these could typically cover aperture diameters in the range 0,4 cm to 1,8 cm.

I.4.12 For larger **treatment heads** whose effective diameter is greater than 2,0 cm, these could typically cover aperture diameters in the range 0,6 cm to 3,0 cm.

I.4.13 In either case, a reasonably even distribution of aperture sizes should be used.

NOTE With care in the experimental technique, values of power produced by a particular aperture ~~should~~ are expected to be reproducible to within ±3 % to ±4 %.

I.4.14 In some situations, a "blank" aperture (essentially a layer of the mask material with no hole present, so it represents a continuous piece of absorber) might be useful. When this is placed in front of the **treatment head**, the power balance should read zero. If it does not, then there may be other signals affecting the balance reading (for example, radio-frequency electrical signals emitted by the transducer).

I.5 Analysis of raw data to derive the effective radiating area

I.5.1 This Clause I.5 provides a step-by-step breakdown of the data analysis procedure, taking a typical set of raw data. These have been derived from measurements made on a commercially available 1 MHz **treatment head** of effective diameter 2,2 cm, with the data having been acquired using nominal aperture diameters in the range 0,8 cm to 3,0 cm, using the method described in [9]. Table I.1 represents the raw data derived from a typical measurement run, showing transmitted power as a function of aperture diameter.

Table I.1 – Aperture measurement check sheet

Date: **/**/**

Operator: **

Treatment head: *****-*** ***

Serial number: ********

Drive unit setting: 5,4 W

Frequency: 1 MHz

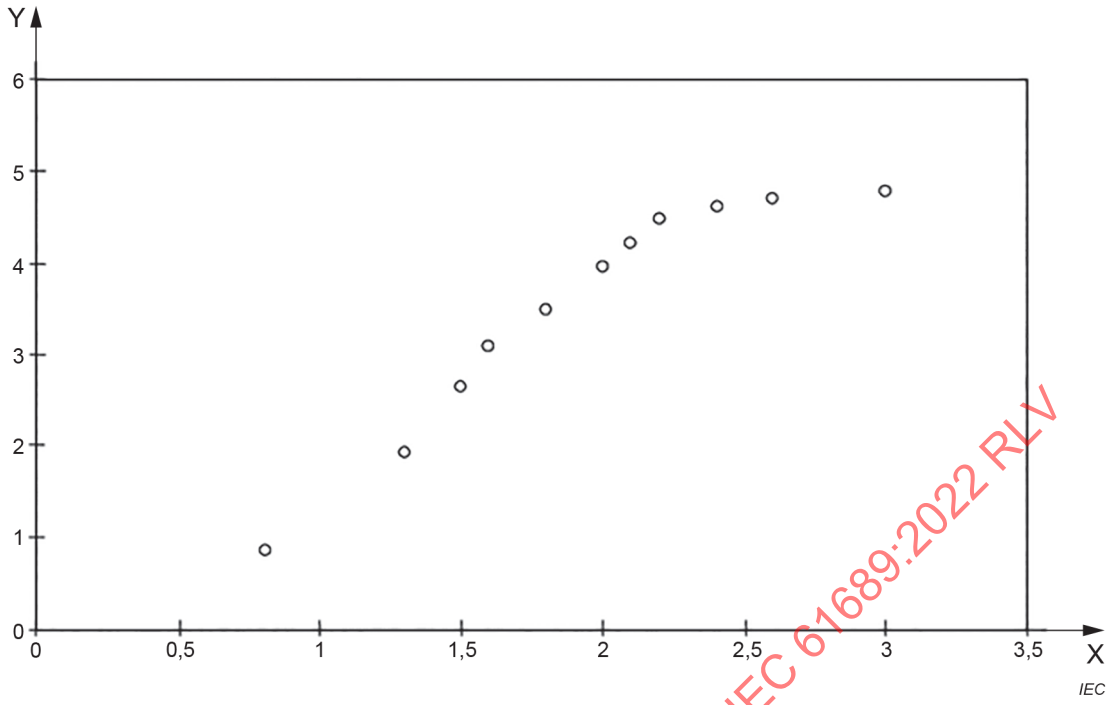
Aperture diameter cm	Radiation force balance readings (W)				
	OFF 1	ON 1	OFF 2	ON 2	Mean reading
No aperture	0,00	4,98	0,02	4,97	4,965
2,0	0,00	3,92	0,04	4,00	3,93
2,4	0,00	4,59	0,02	4,64	4,593
3,0	0,00	4,76	0,01	4,80	4,767
No aperture	0,00	4,88	0,01	4,90	4,88
2,6	0,00	4,70	0,03	4,74	4,693
2,0	0,00	3,96	0,02	3,92	3,933
2,1	0,00	4,26	0,01	4,34	4,28
2,2	0,00	4,52	0,02	4,49	4,497
1,6	0,00	3,07	0,00	3,12	3,087
No aperture	0,00	4,97	0,00	4,99	4,98
1,8	0,00	3,47	0,01	3,54	3,487
1,5	0,00	2,65	0,01	2,72	2,653
1,3	0,00	1,93	0,00	1,95	1,937
0,8	0,00	0,89	0,01	0,83	0,86
2,4	0,00	4,64	0,01	4,66	4,64
No aperture	0,00	4,87	0,01	4,94	4,887
2,0	0,00	4,00	0,01	4,02	4,00
1,8	0,00	3,49	0,00	3,52	3,5
2,1	0,00	4,16	0,00	4,17	4,163
2,2	0,00	4,55	0,01	4,58	4,553
1,6	0,00	3,13	0,02	3,10	3,107
2,6	0,00	4,75	0,01	4,72	4,733
3,0	0,00	4,86	0,00	4,80	4,84
No aperture	0,00	5,01	0,03	4,99	4,98

The data have been derived by switching the **treatment head** ON and OFF in the sequence indicated, the mean reading being calculated from:

$$[(ON1 - OFF1) + (ON1 - OFF2) + (ON2 - OFF2)]/3.$$

NOTE The data set has been derived using eleven apertures. Repeats have been carried out on several apertures to check on the reproducibility of the measurements. The "no aperture" power measurement has been repeated five times to improve statistics.

I.5.2 The data listed in Table I.1 are used to produce a graph, shown in Figure I.2. This demonstrates the expected variation in power as a function of aperture diameter.



Key

X aperture diameter (cm)

Y measured power (W)

Figure I.2 – Measured power as a function of aperture diameter for commercially available 1 MHz physiotherapy treatment heads

To derive a value for **effective radiating area**, further data manipulation is required: the reason for this lies in the spatial distribution of **ultrasound** in the field produced by the physiotherapy **treatment head**, and in the fact that the **effective radiating area** is itself defined via a secondary parameter, the **beam cross-sectional area** (A_{BCS}), which describes the minimum area through which the majority of the ultrasonic power is distributed. The raw data are actually analysed and "sorted" in a manner analogous to that described in Annex B. This procedure is described below in a step-by-step format.

I.5.3 From the raw data (power as a function of aperture diameter), the nominal aperture diameters are converted to areas.

I.5.4 Considering the 0,8 cm diameter aperture, it transmits a power of 0,86 W (see Table I.1). By increasing the aperture size to 1,3 cm, the transmitted power is 1,94 W, and so the power difference of 1,08 W is assumed to be distributed evenly over an area equal to the annulus formed by the two apertures. By then taking the 1,5 cm aperture and identifying its power contribution relative to the 1,3 cm aperture (0,72 W), a representation of the power distribution may be built up. This is done for all adjacent aperture pairs and the data obtained is illustrated in Table I.2.

NOTE For the 0,8 cm diameter aperture, the power is clearly distributed over a circle of radius 0,4 cm, and not an annulus.

Table I.2 – Annular power contributions

Aperture pair	Power contribution W
0 to 0,8	0,86
0,8 to 1,3	1,08
1,3 to 1,5	0,72
1,5 to 1,6	0,44
1,6 to 1,8	0,40
1,8 to 2,0	0,47
2,0 to 2,1	0,26
2,1 to 2,2	0,27
2,2 to 2,4	0,12
2,4 to 2,6	0,097
2,6 to 3,0	0,091

I.5.5 The power contributions from each annulus are converted into intensity contributions, by dividing the power contained in a particular annulus by the area of that annulus. This produces a data set of intensity contributions from each pair of successive apertures and is shown in Table I.3.

Table I.3 – Annular intensity contributions

Aperture pair	Area of larger aperture cm^2	Annulus area cm^2	Power contribution W	Intensity contribution $W\ cm^{-2}$
0 to 0,8	0,503	0,503	0,86	1,71
0,8 to 1,3	1,327	0,825	1,08	1,31
1,3 to 1,5	1,767	0,440	0,72	1,64
1,5 to 1,6	2,011	0,243	0,44	1,81
1,6 to 1,8	2,545	0,534	0,40	0,75
1,8 to 2,0	3,142	0,597	0,47	0,79
2,0 to 2,1	3,464	0,322	0,26	0,81
2,1 to 2,2	3,801	0,338	0,27	0,80
2,2 to 2,4	4,524	0,723	0,12	0,17
2,4 to 2,6	5,309	0,785	0,097	0,12
2,6 to 3,0	7,069	1,759	0,091	0,05

I.5.6 The intensity contributions are then sorted in descending order, ensuring that the association is kept of the annulus area (aperture pair) that produced each contribution. This is shown in Table I.4.

Table I.4 – Annular intensity contributions, sorted in descending order

Aperture pair	Intensity contribution W cm^{-2}	Annulus area cm^2
1,5 to 1,6	1,81	0,243
0 to 0,8	1,71	0,503
1,3 to 1,5	1,64	0,44
0,8 to 1,3	1,31	0,825
2,0 to 2,1	0,81	0,322
2,1 to 2,2	0,8	0,338
1,8 to 2,0	0,79	0,597
1,6 to 1,8	0,75	0,534
2,2 to 2,4	0,17	0,723
2,4 to 2,6	0,12	0,785
2,6 to 3,0	0,05	1,759

NOTE From this data set, it is clear that most of the intensity lies centred about the acoustic beam axis between apertures 0 and 1,6 cm.

I.5.7 Each intensity value is converted back to a power value by multiplying by the corresponding annular area. This produces a data set of power contributions and annular areas, which have actually been sorted in order of descending intensity. This is shown in Table I.5.

Table I.5 – Annular power contributions, sorted in descending order of intensity contribution

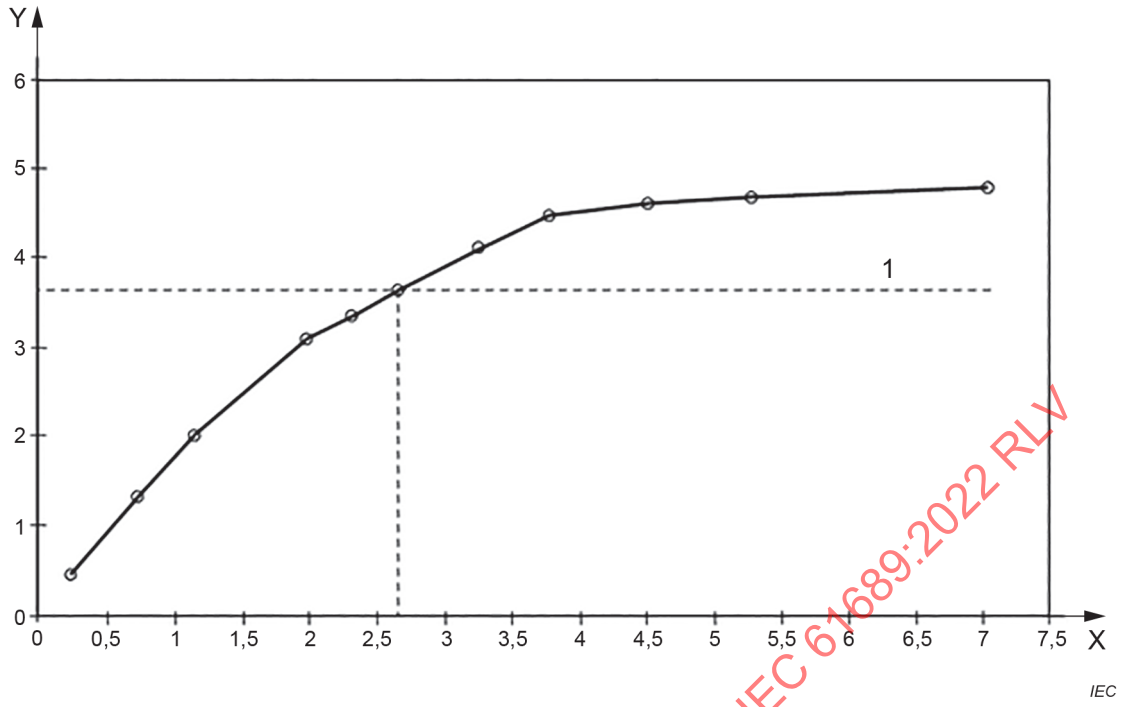
Aperture pair	Intensity contribution W cm^{-2}	Annulus area cm^2	Power contribution W
1,5 to 1,6	1,81	0,243	0,44
0 to 0,8	1,71	0,503	0,86
1,3 to 1,5	1,64	0,44	0,72
0,8 to 1,3	1,31	0,825	1,08
2,0 to 2,1	0,81	0,322	0,26
2,1 to 2,2	0,8	0,338	0,27
1,8 to 2,0	0,79	0,597	0,47
1,6 to 1,8	0,75	0,534	0,40
2,2 to 2,4	0,17	0,723	0,12
2,4 to 2,6	0,12	0,785	0,09
2,6 to 3,0	0,05	1,759	0,09

I.5.8 A running sum is then produced of cumulative power against cumulative area, by summing the values down the table (the cumulative power total should be equal to the power transmitted through the largest aperture). This is shown in Table I.6.

Table I.6 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contribution, and the cumulative sum of their respective annular areas

Intensity contribution W cm^{-2}	Annulus area cm^2	Power contribution W	Cumulative area cm^2	Cumulative power W
1,81	0,243	0,44	0,24	0,44
1,71	0,503	0,86	0,75	1,30
1,64	0,44	0,72	1,19	2,02
1,31	0,825	1,08	2,01	3,10
0,81	0,322	0,26	2,33	3,36
0,8	0,338	0,27	2,67	3,63
0,79	0,597	0,47	3,27	4,11
0,75	0,534	0,40	3,80	4,51
0,17	0,723	0,12	4,53	4,63
0,12	0,785	0,09	5,31	4,72
0,05	1,759	0,09	7,07	4,81

I.5.9 A figure should then be plotted, of cumulative power as a function of cumulative area, as in Figure I.3. From the value of power measured for the "unapertured" case (4,89 W), calculate the 75 % transmitted power (3,67 W), and read off the cumulative area at this power level. The cumulative area value is finally divided by 0,75 to derive an estimate of the **effective radiating area** of the **treatment head**.



Key

X cumulative area (cm^2)

Y cumulative power (W)

1 75 % level of power

Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contributions, plotted against the cumulative sum of their respective annular areas

NOTE The **treatment head** analysed in this case has an **effective radiating area** of 3,5 cm^2, given by the quotient of 2,65 cm^2 to 0,75.

I.6 Implementation of the aperture technique

It is envisaged that the aperture method will be applied in a number of different ways, for example:

– as a means of acceptance testing prior to a **treatment head** being placed into clinical service, a full characterization could be carried out using many apertures (> 12). This would then produce a reference curve for that **treatment head**;

– as a means of routine evaluation, on an annual basis, using only two or three apertures to compare with the reference curve;

– as a means of verifying continual reliable performance, if a **treatment head** has been dropped or damaged: again, this could be done using a limited number of apertures, followed by more extensive tests if differences are noted.

I.7 Relationship of results to reference testing method

Bibliographic reference [9] represents a comparison of the aperture method with **hydrophone** measurements carried out using the test procedures given in Clause 7 for seventeen **treatment heads** commonly used in clinical practice. Although differences for some **treatment heads** were noticed of up to ±20 %, the typical level of agreement was ±11 %. Reference [11] contains details of measurements made using the apertures with implementations of a radiation force balance which utilizes absorbing and reflecting targets.

NOTE In general, the aperture technique gives best agreement (typically ±11 %) with results for the A_{ER} determined through **hydrophone** scanning for large ka transducers (ka > 50). For transducers with ka < 30, the agreement with the reference technique is typically ±20 %.

Annex J
(informative)

Guidance on uncertainty determination

To be truly meaningful, the result of a measurement ~~must~~ needs to be accompanied by its associated uncertainty. In evaluating and expressing the uncertainty in the measurement, the guidance provided by [12] should be followed.

In general, uncertainty components are grouped in accordance with how the values are estimated.

– Type A: evaluated by statistical means.

– Type B: evaluated by other means.

The following is a list of common sources of uncertainty in the measurement of **ultrasonic physiotherapy equipment** that may be evaluated on a Type B basis. The list is not exhaustive but may be used as a guide when assessing uncertainties for a particular measurement system or method. Depending on the parameter under consideration, the measurement system and method chosen and its implementation, some (though possibly not all) of these sources will need assessing. For example, the errors from measuring instruments may be minimized by the use of the same measuring channel (amplifier, filter, voltmeter, etc.) for all signals. However, since this may not be the case in all implementations, components for these sources of error have been included in the list.

Sources of uncertainty applicable to **hydrophone** measurements in general:

- interference from acoustic reflections, leading to a lack of free-field conditions;
- lack of acoustic **far-field** conditions;
- spatial averaging effects of the **hydrophones** used due to their finite size and the lack of perfect plane-wave conditions;
- misalignment, particularly at higher frequencies where the **hydrophone** response may be far from omnidirectional;
- acoustic scattering from the **hydrophone** mount (or vibrations picked up and conducted by the mount);
- errors in measurement of the received voltage (including the accuracy of the measuring instrumentation – voltmeter, digitizers, etc.);
- inaccuracy of the gains of any amplifiers, filters and digitizers used;
- errors in the measurement of the drive current or voltage;
- errors due to the lack of linearity in the measurement system (the use of a calibrated attenuator to equalize the measured signals may significantly reduce this contribution);
- inaccuracy of any electrical signal attenuators used;
- electrical noise including RF pick-up;
- inaccuracy of any electrical loading corrections made to account for loading by extension cables and preamplifiers;
- bubbles or air clinging to transducers (this should be minimized by adequate wetting and soaking of transducers);
- errors in the values for acoustic frequency.

Sources of uncertainty specific to determination of **effective radiating area** and **total mean square acoustic pressure**:

- errors in the measurement of the separation distance;
- spatial resolution of the beam scans carried out (local structure which may be undersampled).

More details about uncertainty calculation of **effective radiating area**, **total mean square acoustic pressure** and **beam non-uniformity ratio** can be found in [13] and [14].

Annex K
(informative)

Examples of pulse duration and pulse repetition period of amplitude modulated waves

In Figure K.1, Figure K.2, Figure K.3, Figure K.4 and Figure K.5, the **pulse duration** and the **pulse repetition period** (prp) are illustrated for five simple **modulation waveforms**, shown as solid lines in each figure. For simplicity, the **acoustic pulse waveforms** are not shown in the figures. The **modulation waveforms** are considered to be represented by voltages $U(t)$ within this Annex K. Each figure contains two dots where the **modulation waveform** crosses the dashed reference line, which has value U_{ref}. The time between these two dots defines the **pulse duration** (3.33).

In the first three examples, the minimum value of the **modulation waveform** is zero. The reference value (U_{ref}) (see Note 1 to entry in 3.33) is equal to 10 % of the maximum value of the **modulation waveform** ($U_{ref} = 0{,}1 \cdot U_{max}$).

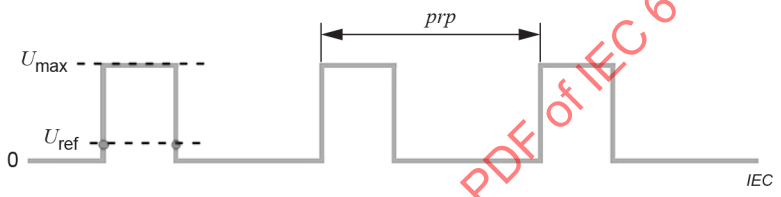


Figure K.1 – Example 1: Tone-burst (i.e. rectangular modulation waveform)

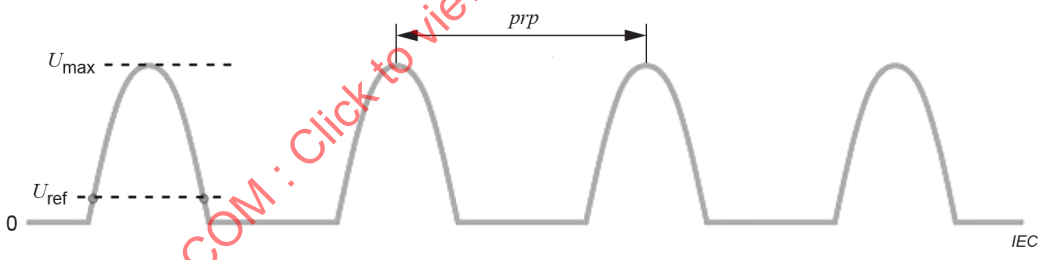


Figure K.2 – Example 2: Half-wave modulation with no filtering of the AC mains voltage

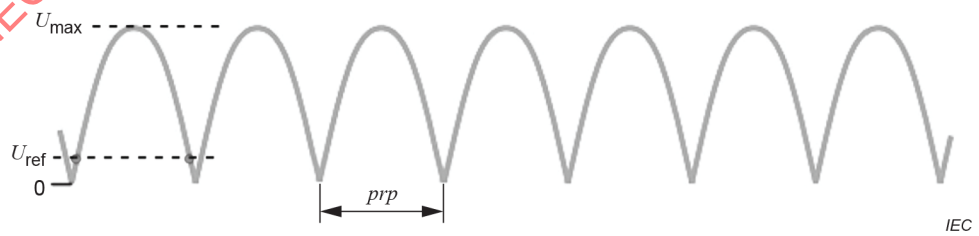


Figure K.3 – Example 3: Full-wave modulation with no filtering of the AC mains voltage

In the next two examples, the minimum value of the **modulation waveform** is greater than zero. The reference value (U_{ref}) is equal to the sum of the minimum value of the **modulation waveform** and 10 % of the difference between the maximum and minimum value of the **modulation waveform** [$U_{ref} = U_{min} + 0{,}1 \cdot (U_{max} - U_{min})$].

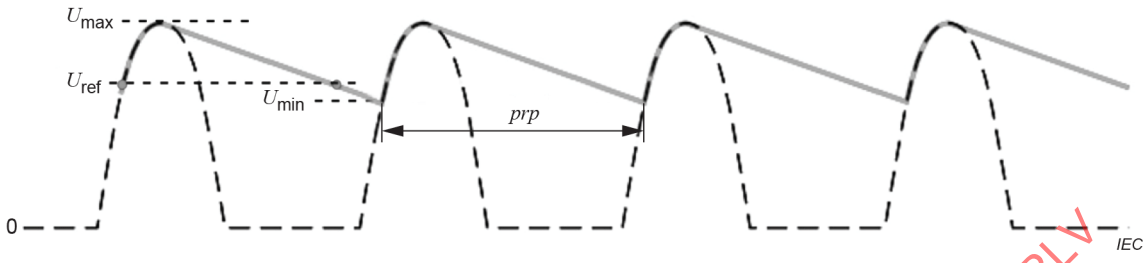


Figure K.4 – Example 4: Half-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)

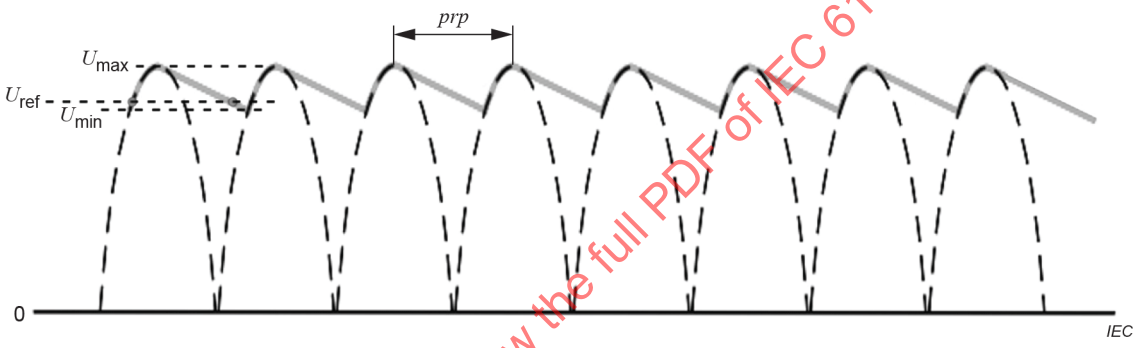


Figure K.5 – Example 5: Full-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)

In Examples 2 and 4 the **pulse repetition rate** ($prr = 1/prp$) is equal to the mains frequency; for example, prr = 50 Hz or prr = 60 Hz. In Examples 3 and 5 the **pulse repetition rate** ($prr = 1/prp$) is equal to twice the mains frequency; for example, prr = 100 Hz or prr = 120 Hz.

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IEC 61689

Edition 4.0 2022-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Ultrasons – Systèmes de physiothérapie – Spécifications des champs et méthodes de mesure dans la plage de fréquences de 0,5 MHz à 5 MHz

IEC 61689:2022-03(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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This fourth edition cancels and replaces the third edition published in 2013. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition.

a) The requirement on water oxygen content is specified in 6.1.
b) Former recommendations in 6.2 have been changed to become requirements.
c) Several definitions in Clause 3 have been updated in line with other TC 87 documents.
d) The formerly informative Annex A has been changed to become normative, and now contains details on how conformance with IEC 60601-2-5 requirements is checked.
e) Annex D has been considerably shortened and reference to a now withdrawn regulatory document has been removed.

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

Draft	Report on voting
87/784/FDIS	87/789/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

NOTE The following print types are used:

- Requirements: in Arial 10 point
- Notes: in Arial 8 point
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: *Times New Roman + Italic*
- Compliance clauses: in *Arial Italic*

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

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** contains a transducer, usually a disc 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 document is applicable to ultrasonic equipment designed for physiotherapy containing an **ultrasonic transducer** generating continuous or quasi-continuous (e.g. tone burst) wave **ultrasound** in the frequency range 0,5 MHz to 5 MHz. This document only relates to **ultrasonic physiotherapy equipment** employing a single plane non-focusing circular transducer per **treatment head**, producing static beams perpendicular to the face of the **treatment head**.

This document 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 within the scope of this document.

Ultrasonic physiotherapy equipment using **ultrasound** in the frequency range from 20 kHz to 500 kHz is dealt with in IEC 63009.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

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

IEC 62127-1, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
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 to entry: 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 Clause A.2 for further guidance.

Note 2 to entry: **Absolute maximum rated output power** is expressed in watts (W).

3.2
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**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$

Note 1 to entry: **Active area coefficient** is expressed in units of one per metre (m^{-1}).

3.3
active area gradient
m
ratio of the difference of the **beam cross-sectional area** at z_N, $A_{\mathrm{BCS}}(z_N)$, and the **beam cross-sectional area** at 0,3 cm from the face of the **treatment head**, $A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})$, divided by the difference of the respective distances

$$m = \frac{A_{\mathrm{BCS}}(z_N) - A_{\mathrm{BCS}}(0{,}3\ \mathrm{cm})}{z_N - 0{,}3\ \mathrm{cm}} \tag{1}$$

where

A_{BCS} is the **beam cross-sectional area**;

z_N is the distance from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**

Note 1 to entry: **Active area gradient** is expressed in metres (m).

[SOURCE: IEC 61689:2013, 3.3, modified – The calculation scheme of the gradient was added to the definition, and the formula was added.]

3.4
absolute maximum beam non-uniformity ratio
beam non-uniformity ratio plus the 95 % confidence overall uncertainty in the **beam non-uniformity ratio**

3.5
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**

3.6
absolute minimum effective radiating area
effective radiating area minus the 95 % confidence overall uncertainty in the **effective radiating area**

3.7
acoustic-working frequency
acoustic frequency
f_{awf}
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 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.7.1 and 3.7.2.

Note 2 to entry: 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 to entry: **Acoustic frequency** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.3]

3.7.1
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 to entry: This frequency definition usually is intended for systems that produce short pulses containing only a few cycles, but it could be used for tone bursts.

Note 2 to entry: It is assumed that $f_1 < f_2$.

Note 3 to entry: If f_2 is not found within the range < $3f_1$, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is 3 dB below the peak magnitude.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.3.2, modified – Note 1 to entry has been modified.]

3.7.2
zero-crossing acoustic-working frequency
f_{awf}
number, n, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n-th half-cycle

Note 1 to entry: None of the n consecutive half-cycles should show evidence of phase change.

Note 2 to entry: The measurement should be performed at terminals in the receiver that are as close as possible to the receiving transducer (**hydrophone**) and, in all cases, before rectification.

Note 3 to entry: This frequency is determined in accordance with the procedure specified in IEC TR 60854.

Note 4 to entry: This frequency is intended for **continuous wave** or quasi-continuous-wave (e.g. tone-burst) systems only.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.3.1, modified – In Note 4 to entry, "or quasi-continuous-wave (e.g. tone-burst)" has been added.]

3.8
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 to entry: Temporal waveform is a representation (e.g. oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.1]

3.9
acoustic repetition period
arp
pulse repetition period equal to the time interval between corresponding points of consecutive cycles for **continuous wave** systems

Note 1 to entry: **Acoustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2007, 3.2, modified – The definition has been made more specific for non-scanning systems.]

3.10
amplitude modulated wave
wave in which the ratio $p_{tp}/(\sqrt{2}p_{RMS})$ at any point in the **far field** on the **beam alignment axis** is greater than 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

3.11
attachment head
accessory intended to be attached to the **treatment head** for the purpose of modifying the ultrasonic beam characteristics

[SOURCE: IEC 60601-2-5:2009, 201-3-202]

3.12
beam alignment axis
straight line joining two points of **maximum RMS acoustic pressure** on two plane surfaces parallel to the faces of the **treatment head** at specific distances

Note 1 to entry: One plane is at a distance of approximately a^2/λ where a is the geometrical radius of the active element of the **treatment head**. The second plane surface is at a distance of either $2a^2/\lambda$ or $a^2/(3\lambda)$, whichever is the more appropriate. For the purposes of alignment, this line may be projected to the face of the **treatment head**.

Note 2 to entry: 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^2/λ 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 7.3.

3.13
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 1 to entry: **Beam cross-sectional area** is expressed in units of square metre (m^2).

Note 2 to entry: The rationale supporting the definition is described in Annex D.

3.14
beam maximum intensity
product of the **beam non-uniformity ratio** and **effective intensity**

Note 1 to entry: **Beam maximum intensity** is expressed in units of watt per square metre (W/m^2).

3.15
beam non-uniformity ratio
R_{BN}
ratio of the square of the **maximum RMS acoustic pressure** to the spatial average of the square of the **RMS acoustic pressure**, where the spatial average is taken over the **effective radiating area**

$$R_{BN} = \frac{p^2_{max,RMS} A_{ER}}{pms_t A_0} \quad (2)$$

where

$p_{max,RMS}$ is the **maximum RMS acoustic pressure**;

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

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

A_0 is the unit area for the raster scan.

3.16
beam type
descriptive classification of the ultrasonic beam

Note 1 to entry: There are three beam types: **collimated** (3.18), **convergent** (3.19) and **divergent** (3.20).

3.17
continuous wave
wave in which the ratio $p_{tp}/(\sqrt{2}\, p_{RMS})$, at any point in the **far field** on the **beam alignment axis**, is less than or equal to 1,05, where p_{tp} is the **temporal-peak acoustic pressure** and p_{RMS} is the **RMS acoustic pressure**

3.18
collimated
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.19
convergent
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.20
divergent
<beam> having an **active area coefficient**, Q, that obeys the following inequality

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

3.21
duty factor
ratio of the **pulse duration** to the **pulse repetition period**

3.22
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 1 to entry: **Effective intensity** is expressed in units of watt per square metre (W/m^2).

3.23
effective radiating area
A_{ER}
beam cross-sectional area determined at a distance of 0,3 cm from the front of the **treatment head**, $A_{BCS}(0{,}3\ \text{cm})$, multiplied by a dimensionless factor F_{ac} equal to 1,333

Note 1 to entry: 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.

Note 2 to entry: **Effective radiating area** is expressed in units of square metre (m^2).

3.24
end-of-cable loaded sensitivity
$\underline{M}_L(f)$
<of a **hydrophone** or hydrophone assembly> quotient of the Fourier transformed **hydrophone** voltage-time signal $\mathcal{F}(u_L(t))$ 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 Fourier transformed **acoustic pulse waveform** $\mathcal{F}(p(t))$ in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

$$\underline{M}_L(f) = \frac{\mathcal{F}(u_L(t))}{\mathcal{F}(p(t))} \tag{3}$$

Note 1 to entry: The **end-of-cable loaded sensitivity** is a complex-valued parameter. Its modulus is expressed in units of volt per pascal (V/Pa), its phase angle is expressed in degrees, and represents the phase difference between the electrical voltage and the sound pressure.

[SOURCE: IEC 61828:2020, 3.50]

3.25
far field
region of the field where $z > z_T$ aligned along the beam axis for planar non-focusing transducers where z is the distance from the face of the **treatment head** to a specified point on the **beam alignment axis**

Note 1 to entry: In the **far field**, the sound pressure appears to be spherically **divergent** from a point on or near the radiating surface. Hence the pressure produced by the sound source is approximately inversely proportional to the distance from the source.

Note 2 to entry: The term "**far field**" is used in this document only in connection with non-focusing source transducers. For focusing transducers a different terminology for the various parts of the transmitted field applies (see IEC 61828).

Note 3 to entry: For the purposes of this document, the **far field** starts at a distance where $z_T = A_{ERN}/(\pi\lambda)$, 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**.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.28, modified – In the definition, specification of z has been added and Note 3 to entry has been replaced to provide specific information on z_T]

3.26
hydrophone
transducer that produces electrical signals in response to pressure fluctuations in water

Note 1 to entry: A **hydrophone** is principally a passive device designed and built to respond to sound pressure.

Note 2 to entry: In some applications, a **hydrophone** is used as an active device to transmit sound.

[SOURCE: IEC 60050-801:2021, 801-32-26]

3.27
instantaneous acoustic pressure
$p(t)$
pressure at a particular instant in time and at a particular point in an acoustic field, minus the ambient pressure

Note 1 to entry: **Instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03]

3.28
maximum RMS acoustic pressure
$p_{max,RMS}$
maximum value over the entire acoustic field of the **RMS acoustic pressure**

Note 1 to entry: **Maximum RMS acoustic pressure** is expressed in pascals (Pa).

3.29
mean square acoustic pressure
mean square of the **instantaneous acoustic pressure** at a particular point in the acoustic field, taken over an integral number of **acoustic repetition periods**

Note 1 to entry: In practice, the mean value is often derived from RMS measurements.

Note 2 to entry: **Mean square acoustic pressure** is expressed in units of pascal squared (Pa^2).

3.30
modulation waveform
temporal envelope waveform of the **amplitude modulated wave** at the point of **peak RMS 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**

Note 1 to entry: See Annex K for examples.

3.31
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 to entry: **Output power** is expressed in watts (W).

[SOURCE: IEC 61161:2013, 3.3, modified – In the definition, "**ultrasonic transducer**" has been replaced by "**treatment head** of **ultrasonic physiotherapy equipment**".]

3.32
peak RMS acoustic pressure
maximum value of the **RMS acoustic pressure** over a specified region, line or plane in an acoustic field

Note 1 to entry: **Peak RMS acoustic pressure** is expressed in pascals (Pa).

3.33
pulse duration
time interval beginning when the **modulation waveform** exceeds a reference value and ending at the next time the **modulation waveform** returns to that value

Note 1 to entry: The reference value is equal to the sum of the minimum value of the **modulation waveform** and 10 % of the difference between the maximum and minimum value of the **modulation waveform**.

Note 2 to entry: This definition differs from that in IEC 62127-1:2007 to be applicable to **amplitude modulated waves**.

Note 3 to entry: See Annex K for examples.

Note 4 to entry: **Pulse duration** is expressed in seconds (s).

3.34
pulse repetition period
prp
time interval between equivalent points on the **modulation waveform** for an **amplitude modulated wave**

Note 1 to entry: See Annex K for examples.

Note 2 to entry: **Pulse repetition period** is expressed in seconds (s).

3.35
pulse repetition rate
prr
reciprocal of the **pulse repetition period**

Note 1 to entry: The **pulse repetition rate** is equal to the repetition frequency of the modulated waveform.

Note 2 to entry: The **pulse repetition rate** is expressed in hertz (Hz)

[SOURCE: IEC 62127-1:2007, 3.52, modified – Note 1 to entry differs from the original NOTE 1.]

3.36
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 1 to entry: **Rated output power** is expressed in watts (W).

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 to entry: The mean should be taken over an integral number of **acoustic repetition periods** unless otherwise specified.

Note 2 to entry: **RMS acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.53]

3.38
spatial-peak temporal-peak acoustic pressure
p_{sptp}
larger of the peak-compressional acoustic pressure or the peak-rarefactional acoustic pressure

Note 1 to entry: **Spatial-peak temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.63]

3.39
temporal-maximum output power
P_{tm}
<for an **amplitude modulated wave**> actual **output power** scaled by half of the squared ratio of the **temporal-peak acoustic pressure** and the **RMS acoustic pressure**

$$P_{tm} = \frac{1}{2}\left(\frac{p_{tp}}{p_{RMS}}\right)^2 \times P \qquad (4)$$

where

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

p_{tp} is the **temporal-peak acoustic pressure**;

p_{RMS} is the **RMS acoustic pressure**.

Note 1 to entry: Both p_{tp} and p_{RMS} are measured at a specified point on the **beam alignment axis**.

Note 2 to entry: **Temporal-maximum output power** is expressed in watts (W).

3.40
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 1 to entry: **Total mean square acoustic pressure** is expressed in units of pascal squared (Pa^2).

3.41
temporal-maximum intensity
I_m
<for an **amplitude modulated wave**> quotient of the **temporal-maximum output power** and the **effective radiating area**

$$I_m = \frac{P_{tm}}{A_{ER}} \quad (5)$$

where

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

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

Note 1 to entry: **Temporal-maximum intensity** is expressed in units of watt per square metre (W/m^2).

3.42
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 to entry: **Temporal-peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.67]

3.43
treatment head
assembly comprising one **ultrasonic transducer** and associated parts for local application of **ultrasound** to the patient

[SOURCE: IEC 60601-2-5:2009, 201.3.214, modified – The NOTE has not been included.]

3.44
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

[SOURCE: IEC 62127-1:2007, 3.73]

3.45
ultrasound
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

3.46
ultrasonic physiotherapy equipment
equipment
equipment for the generation and application of **ultrasound** to a patient for therapeutic purposes

Note 1 to entry: Excluded equipment includes, but is not limited to:

– equipment in which **ultrasound** waves are intended to destroy conglomerates (for example stones in the kidneys or the bladder) or tissue of any type;

– equipment in which a tool is driven by **ultrasound** (for example surgical scalpels, phacoemulsifiers, dental scalers or intracorporeal lithotripters);

– equipment in which **ultrasound** waves are intended to sensitize tissue to further therapies (for example radiation or chemotherapy);

– equipment in which **ultrasound** waves are intended to treat cancerous (i.e. malignant) or pre-cancerous tissue, or benign masses, such as high intensity focused ultrasound (HIFU) or high intensity therapeutic ultrasound (HITU).

[SOURCE: IEC 60601-2-5:2009, 201.3.216, modified – The NOTE has been modified to give some examples of excluded equipment.]

4 Symbols

a	geometrical radius of the active element of a **treatment head**
A_{BCS}	**beam cross-sectional area**
$A_{BCS}(0,3\ cm)$	**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_g	geometrical radius of the active element of a **hydrophone**
a_{max}	maximum effective **hydrophone** size, defined in IEC 62127-1
A_o	unit area for a raster scan
arp	**acoustic repetition period**
b	minimum radius of a target for a radiation force balance
c	speed of sound in water
ERD	echo reduction
f_{awf}	**acoustic working frequency**
F_{ac}	conversion factor to convert $A_{BCS}(0,3\ cm)$ 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**
$p(t)$	**instantaneous acoustic pressure**
p_{tp}	**temporal-peak acoustic pressure**
p_{sptp}	**spatial-peak temporal-peak acoustic pressure**
$p_{max,RMS}$	**maximum RMS acoustic pressure**
p_{RMS}	**RMS acoustic pressure**
pms_t	**total mean square acoustic pressure**
prp	**pulse repetition period**
prr	**pulse repetition rate**
Q	**active area coefficient**

R	ratio of the **peak RMS acoustic pressure** to the **RMS 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_n	normalized distance from the face of the transducer to a specified point on the **beam alignment axis**
u	end-of-cable voltage for a **hydrophone**
u_i	**hydrophone** signal for the i-th scan point
u_n	RMS noise 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 from the face of the **treatment head** to the last maximum of the **RMS acoustic pressure** on the **beam alignment axis**
z_p	distance from the face of the **treatment head** to the **peak RMS acoustic pressure** on the **beam alignment axis**
λ	ultrasonic wavelength
ρ	density of water

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** (I_e) at the same equipment settings as the nominal value of the **rated output power** (±30 %);
– **acoustic working frequency** (f_{awf}) (±10 %);
– **beam non-uniformity ratio** (R_{BN}) (±30 %);
– **beam maximum intensity** (±30 %);
– **beam type**;
– **pulse duration**, **pulse repetition period** (prp), **duty factor** and the ratio of the **temporal maximum output power** to the **output power** for each modulation setting (±5 %);
– **modulation waveform** for each modulation setting.

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

6 Conditions of measurement and test equipment used

6.1 General

All measurements undertaken in water shall be 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 8.6, are not dependent on the temperature at which the tests were undertaken.

Degassed water shall be used for the measurement of ultrasonic power, see Clause 7. The amount of dissolved oxygen in the degassed water shall be < 4 mg/l during all measurements.

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 can be found in IEC 61161, IEC TR 62781 and in [1][1].

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** shall 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** shall possess three independent degrees of translational movement. The measurements shall 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.

1 Numbers in square brackets refer to the Bibliography.

Compliance for overall echo reduction of an acoustic absorber may be checked using the procedure from IEC TS 63081. If echo reduction is determined it shall 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 pressure amplitude of the reflection from the front surface of the acoustic absorber,* $p_{absorber}$*, is compared to that from a perfect planar reflector,* $p_{reflector}$*. The acoustic absorber and the reference reflector shall be aligned near normal to the* ***beam alignment axis*** *but angled so that the reflected signal can be intercepted by the* ***hydrophone****. Given that the amplitude reflection coefficient of a reference reflector* $R_{p,reflector}$*, such as a stainless-steel reflector (*$R_{p,reflector}$ *= 0,938 9) is slightly less than that of a perfect reflector (*$R_{p,reflector}$ *= 1), the measured reflection pressure amplitude* $p_{absorber}$ *can be adjusted to account for the imperfect reflection in accordance with*

$$\hat{p}_{\text{absorber}}(f) = p_{\text{absorber}}(f) \cdot R_{p,\text{reflector}} \tag{6}$$

The echo reduction ERD *in decibels (dB) is then calculated using*

$$ERD = -20 \log_{10}\left[\frac{\hat{p}_{\text{absorber}}}{p_{\text{reflector}}}\right] \text{dB} \tag{7}$$

When a reference reflector is used, its thickness shall be sufficient that reflections from its rear surface do not introduce unwanted measurement artefacts.

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

NOTE For some **treatment heads**, **ultrasound** reflected back to the **treatment head** can 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 can be obtained by using acoustic absorbers with textured surfaces.

6.3 Hydrophone

All pressure measurements shall be made with a **hydrophone**, for example, with either a piezoelectric polymer or ceramic active element. 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:

$$a_{max} / \lambda \leq 0{,}4 \tag{8}$$

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

NOTE 2 The influence of effective **hydrophone** radius on measurement is described in Annex H.

NOTE 3 Information on the frequency-dependent effective **hydrophone** radius or size and its derivation from directional response measurements can be found in IEC 62127-3.

6.4 RMS peak signal measurement

The measured end-of-cable voltage $u_L(t)$ at the **hydrophone** shall be related to the **instantaneous acoustic pressure** p applying the **end-of-cable loaded sensitivity** $\underline{M}_L$ of the **hydrophone** in accordance with IEC 62127-1. If distortion caused by nonlinear propagation effects is negligible, the narrow-band approximation can be applied, and the **instantaneous acoustic pressure** can be determined from

$$p(t) = u_L(t) / |\underline{M}_L(f_{awf})| \quad (9)$$

where $|\underline{M}_L(f_{awf})|$ is the modulus of the **end-of-cable loaded sensitivity** of the **hydrophone** at the **acoustic-working frequency**. However, in practice, the absolute values of the acoustic pressure are not required as the analysis of measured data throughout this document is based on relative **hydrophone** measurements.

NOTE 1 For more information on criteria for the narrow-band approximation, and alternatives for broadband measurements using the frequency-dependent sensitivity of the **hydrophone**, see IEC 62127-1.

NOTE 2 For more information on the determination of the **hydrophone** sensitivities see IEC 62127-2.

Subsequent reference to acoustic pressure will refer to the **RMS acoustic pressure** for convenience. In fact, if distortion caused by nonlinear propagation effects is negligible, in which case the **temporal-peak acoustic pressure** is proportional to the **RMS acoustic pressure** as the excitation voltage to the **ultrasonic transducer** is increased, **temporal-peak acoustic pressure** may as well be chosen. All measurements need to be based on the same method.

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 shall be checked using a well-characterized linear **ultrasonic transducer** 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.

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

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. The amount of dissolved oxygen in the degassed water shall be < 4 mg/l during all measurements. Overall uncertainty of measurement expressed at the 95 % confidence level shall be determined (see 9.3) and shall be better than ±15 %. Measurements shall 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.

All measurements of **effective radiating area** shall be undertaken with the equipment set in **continuous wave** mode at intensities low enough to avoid cavitation. Using degassed water in the measurement system is good practice to ensure that 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 needle **hydrophones** used. The validity of extrapolating these values to higher power levels more typical of therapeutic treatment is demonstrated in Annex G.

NOTE 2 **Treatment heads** with $a \leq 10$ mm, when compared with **treatment heads** of larger dimensions operating at similar **equipment** output settings, have been observed to produce higher **temporal-peak acoustic pressure** levels. For **treatment heads** with an **acoustic-working frequency** of 1 MHz or less, this increases the risk of cavitation occurring. The lower limit of 0,2 W/cm^2 for these small ka **treatment heads** minimizes this likelihood.

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 shall 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 by **hydrophone** scanning in accordance with IEC 62127-1. The second plane surface (see 3.12) shall initially be chosen as $A_{\mathrm{ERN}}/(3\pi\lambda)$. If it is not possible to locate a single peak at or close to this distance, the larger distance of $2A_{\mathrm{ERN}}/(\pi\lambda)$ shall 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 **maximum RMS acoustic pressure**, z_{p}, and the position of the last axial maximum, z_N, shall be determined. It may occur that z_{p} and z_N are equal.

The step size of the axial plot shall 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 Effective radiating area measurements

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** shall be derived from the **beam cross-sectional area**, A_{BCS}. The general requirements for raster scans are given in Clauses B.1 and B.2. The actual procedure for the reference measurements and the analysis of the results are given in 7.4.2 to 7.4.7. Under normal test conditions, the results using the test methods described shall 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 shall achieve a measurement uncertainty (at the 95 % confidence level) of less than ±15 %.

7.4.2 Hydrophone positioning

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 RMS acoustic pressure**, $p_{max,RMS}$, in the field.

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

7.4.3 Beam cross-sectional area determination

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 Clause B.3. The analysis yields the **beam cross-sectional areas**, A_{BCS}(0,3 cm) and $A_{BCS}(z_N)$ and the **total mean square acoustic pressure**, pms_t, at each measurement plane.

7.4.4 Active area gradient determination

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

7.4.5 Beam type determination

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

$$\begin{aligned} Q &\geq 0{,}1\ \text{cm}^{-1} && \textbf{divergent} \\ -0{,}05\ \text{cm}^{-1} \leq Q &\leq 0{,}1\ \text{cm}^{-1} && \textbf{collimated} \\ Q &< -0{,}05\ \text{cm}^{-1} && \textbf{convergent} \end{aligned} \tag{10}$$

7.4.6 Effective radiating area calculation

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

$$A_{\text{ER}} = F_{\text{ac}} A_{\text{BCS}}(0{,}3\ \text{cm}) = 1{,}333 A_{\text{BCS}}\ (0{,}3\ \text{cm}) \tag{11}$$

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 Beam non-uniformity ratio calculation

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

$$R_{\text{BN}} = \frac{p_{\text{max}}^2 \cdot A_{\text{ER}}}{\overline{pms_{\text{t}} \cdot s^2}} \tag{12}$$

where

$$\overline{pms_{\text{t}} \cdot s^2} = \frac{1}{2}\left\{\left[pms_{\text{t}}(0{,}3) \cdot s^2(0{,}3)\right] + \left[pms_{\text{t}}(z_N) \cdot s^2(z_N)\right]\right\} \tag{13}$$

NOTE 1 Although $p_{\text{max,RMS}}$ and pms_{t} are referred to as acoustic pressure or pressure-squared parameters, only their ratio is used for the determination of R_{BN}, hence the **end-of-cable loaded sensitivity** of the **hydrophone** is not needed.

NOTE 2 The product $pms_{\text{t}} \cdot s^2$ 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. In ideal cases, it is invariant with distance from the **treatment head**.

7.4.8 Testing requirements

The procedures given in 7.4.1 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_{awf});
– the distance from the face of the **treatment head** to the **peak RMS acoustic pressure** on the **beam alignment axis** (z_p);
– **beam non-uniformity ratio** (R_{BN});
– **beam type**;
– **pulse duration**, **pulse repetition period** (prp) 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 as follows:

– **rated output power**;
– **effective radiating area** (A_{ER}) of the **treatment head**;
– **acoustic-working frequency** (f_{awf});
– **pulse duration**, **pulse repetition period** (prp) 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** shall be set up in the test vessel in accordance with Clause 6. However, alignment of the **treatment head** shall 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. 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 $p_{RMS,max}$ may be determined. It may occur that z_p and z_N are equal.

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.

8.3.4 The **effective radiating area**, A_{ER}, can 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** absorbing material with low reflection loss. 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 is considered 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 in accordance with 7.4.7.

8.5 Effective intensity

The **effective intensity** shall be determined in accordance with 3.22.

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 7.4 and 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 nominally identical units of the **ultrasonic physiotherapy equipment**.

9.2 Routine measurements

The routine measurements shall be undertaken as the basis of good manufacturing practice. Normally, they shall 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 shall 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 document, normal uncertainty analysis and estimation methods shall be used (see Annex J for guidance).

Annex A
(normative)

Guidance for performance and safety

A.1 General

Clauses A.2 to A.4 reflect the established approach on acceptable values of a few safety related parameters.

A.2 Rated output power

According to IEC 60601-2-5, the **rated output power** shall not vary by more than ±20 % for variations of the mains voltage of ±10 %. Manual readjustment of the equipment for compliance with this requirement is not permitted.

*Compliance is 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** shall be checked at mains voltages of 230 (±10 %) V.*

The term "rated" is defined in IEC 60601-1 as the "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; so, from IEC 60601-2-5, the power output needs to be checked for variation at 90 %, 100 % and 110 % of the declared value even when there is a range.

A.3 Effective intensity

According to IEC 60601-2-5, the **absolute maximum effective intensity** shall be less than or equal to 3,0 W /cm^2.

*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

According to IEC 60601-2-5, the **absolute maximum beam non-uniformity ratio** shall 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 can result in excessive heating in small regions of the tissue being treated, resulting in potential harmful effects to the patient.

Transducers of **ultrasonic physiotherapy equipment** are not designed to provide highly localized tissue treatment. Consequently, the transducers addressed in this document are planar. The characterization of focusing transducers capable of generating high intensity beams which are being used in therapeutic applications is the subject of other documents (see IEC 62555 and IEC TS 62556).

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.

If, as in a plane wave, the intensity is derived from the acoustic pressure alone, the ratio between the time-average intensity distribution (I_p) in a field and average intensity of the piston source (I_0) 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 four. Even in the correct treatment where the true intensity (I) is given by the product of acoustic pressure and particle velocity, the maximum is four and will be found at one near-field length (s_n = 1 in Figure A.1). From the distance of about one transducer element radius, (z/a = 1), back to the element itself, the maximum ratio will decrease typically to a value of the order of two.

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 characteristic acoustic impedance. This formula cannot strictly be used 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 formula of the R_{BN} can be simplified as stated in this document as follows.

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

$$I_{spta} = \frac{u_p^2}{\left|\underline{M}_L\right|^2 \rho c} \tag{A.1}$$

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

$$pms_t = \sum_{i=1}^{N} \frac{u_i^{\,2}}{\left|\underline{M}_L\right|^2} \tag{A.2}$$

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:

$$I_{sata} = \frac{P}{A_{ER}} = \frac{A_0 \cdot pms_t}{\rho \cdot c \cdot A_{ER}} \tag{A.3}$$

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

$$R_{BN} = \frac{u_p^2 A_{ER}}{A_0 (z_j) \sum_{i=1}^{N} u_i^2 (z_j)} \tag{A.4}$$

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

In the above formulae, the parameters are as follows:

u_p is the maximum value of u_i;

u_i is the RMS **hydrophone** voltage at the i-th point of measurement;

$\underline{M}_L$ is the **end-of-cable loaded sensitivity** of the **hydrophone**;

P is the acoustic power;

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

ρ is the density of water;

c is the speed of sound in water;

A_0 is the unit area of the scan ($A_0 = s^2$ 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 Formula (A.4) are presented for 37 different **treatment heads**, along with the frequency with which 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 three to seven, but some transducers having a R_{BN} greater than eight are shown and these may be considered to have a high R_{BN}.

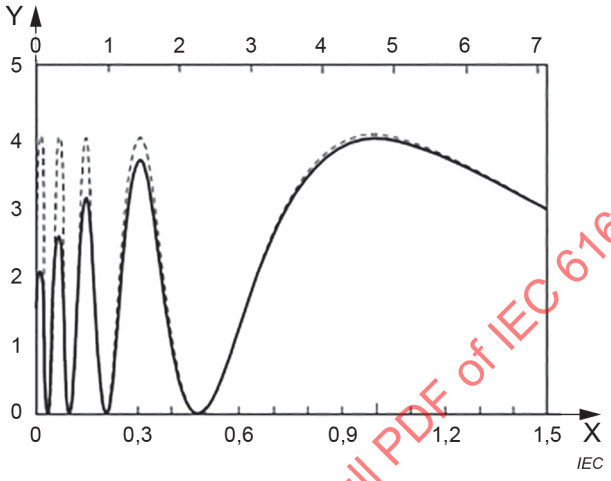
The limiting value of eight has been identified in this document for the following reasons.

– In **ultrasound** physiotherapy the treatment protocol (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 two seems to be quite reasonable. As can be seen in Figure A.2, for normal behaving practical transducers, R_{BN} values less than eight can readily be attained.

– Physiotherapists have no current requirement for a focusing transducer. If a transducer is focusing, 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 in 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.



Key

X bottom axis: s_n

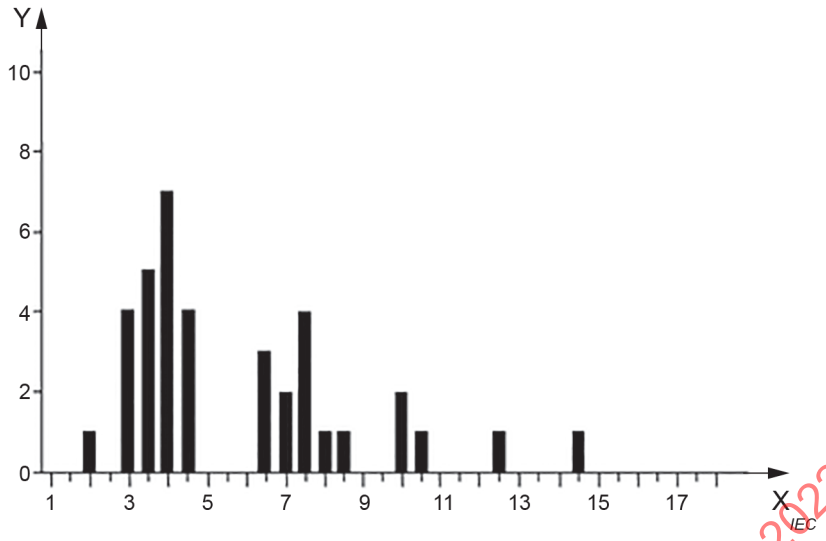
X top axis: z/a

Y solid line: I/I

Y broken line: I_p/I_p

NOTE In [2], the symbol "s" is used to describe the normalized distance. To avoid confusion with the raster scan step size definition used in this document, the normalized distance symbol here has been changed to s_n.

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



Key

X R_{BN}

Y Number of transducers

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

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

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 RMS 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 that 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 voltage 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:

$$u_i' = (u_i^2 - u_{\mathrm{n}}^2)^{1/2} \tag{B.1}$$

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

B.3.1 General

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

B.3.2 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:

$$pms_t = \sum_{i=1}^{N} u_i'^2 \Big/ |\underline{M}_L|^2 \qquad \text{(B.2)}$$

where

N is the total number of points in the scan;

u_i' is the noise-corrected voltage (either peak or RMS) of the i-th point in the scan;

$\underline{M}_L$ 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.2) to convert the measured voltage to acoustic pressure. However, due to cancellation, when pms_t is introduced into Equation (B.3), its absolute value is not needed.

B.3.3 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:

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^{n} u_i'^2 \leq 0{,}75\ pms_t \qquad \text{(B.3)}$$

$$\frac{1}{|\underline{M}_L|^2} \sum_{i=1}^{n+1} u_i'^2 > 0{,}75\ pms_t$$

The value of A_{BCS} is then given by $A_0 \cdot n$, where A_0 is the unit area of the raster scan ($A_0 = s^2$ where s is the distance 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 8 may be performed using diametrical or line scans. The term line scan is used within Annex C. If line scans are used, then the procedures and analysis methods specified in Clauses C.2 and C.3 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 RMS 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 can be of different step size. Here, for ease of analysis, they are 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 is 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 scans

C.3.1 The individual line scans will be analysed in the following way.

NOTE In the steps described in Clause C.3, the symbols [A] and [B] refer to data arrays and are not references to publications in the bibliography.

C.3.2 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.3.3 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.3.4 For the measurement point which lies on the **beam alignment axis** (designated the j = 0 point) the contribution to such an area will be A_0, given in centimetres squared, by:

$$A_0 = \frac{\pi \cdot s^2}{4} \tag{C.1}$$

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

C.3.5 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 by the expression:

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

$$A_j = 2\pi \cdot j \cdot s^2 \tag{C.2}$$

C.3.6 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_0. By dividing A_j given in Equation (C.2) by A_0 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:

$$n_j = 8j \tag{C.3}$$

C.3.7 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_0^2	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)	$u^2_{(N_1-1)/2}$	$4(N_1 - 1)$
NOTE The j-th ($j > 0$) 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.3.8 In a similar manner to the analysis undertaken using the raster scan data in B.2.4, the RMS noise level u_n shall be subtracted from each line-scan data point, to account for the contribution of noise. If the **hydrophone** signal at each point in the line scan is u_j, then the **hydrophone** signal after correcting for the contribution from noise, u_j' is:

$$u_j' = \left(u_j^2 - u_n^2\right)^{1/2} \tag{C.4}$$

C.3.9 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:

$$pms_t = \frac{1}{|\underline{M}_L|^2} u_0'^2 + \frac{1}{|\underline{M}_L|^2} \sum_{j=1}^{\left(\frac{N_1-1}{2}\right)} 8j\, u_j'^2 \tag{C.5}$$

C.3.10 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.3.11 The **beam cross-sectional area**, A_{BCS}, of the half-line scan is given by $A_{BCS} = \frac{n \cdot \pi \cdot s^2}{4}$, where s is the step size.

C.3.12 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:

$$\sigma^2 = \frac{1}{7}\sum_{j=1}^{8}\left(A_{\mathrm{BCS}j}(z) - \bar{A}_{\mathrm{BCS}}(z)\right)^2 \tag{C.6}$$

where

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

$\bar{A}_{\mathrm{BCS}}(z)$ 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 need 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 is part of a plane located at or close to the **treatment head**, through which almost all of the **ultrasound** power passes. It is defined in this document 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 (7.4). It also may be estimated by using circular absorbing apertures (8.3.4).

The parameter, **beam cross-sectional area**, as defined in 3.13, 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 document represents the outcome of studies, based on actual measurements and theoretical calculations, to provide a useful definition and a reliable measurement method [1], [3], [4], [5], [6], [7].

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 document requires the **effective radiating area**, A_{ER}, to be derived from the **beam cross-sectional area** close to the face of the **treatment head**, $A_{BCS}(0{,}3\ \text{cm})$. 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:

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

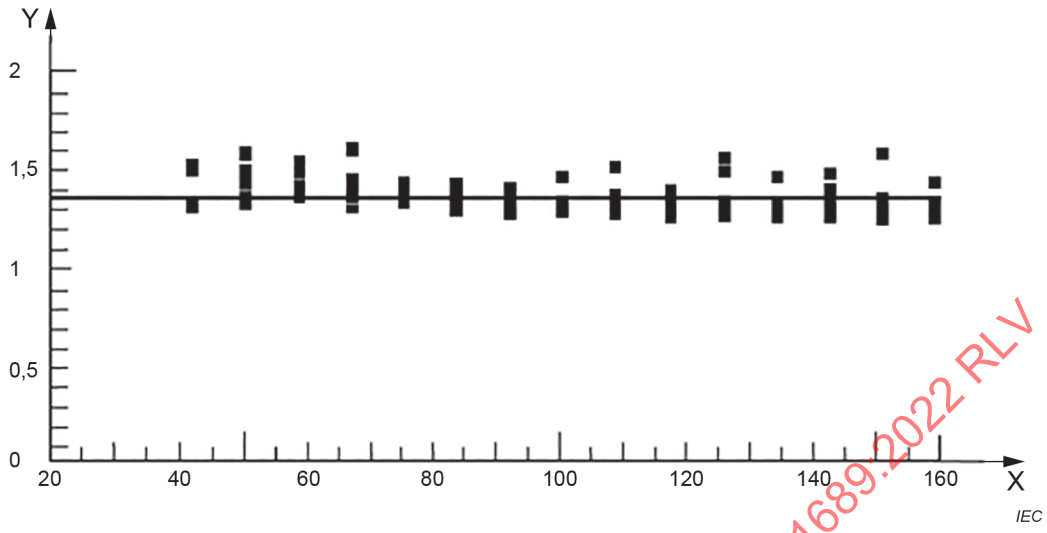
From the physical point of view, it can be expected that the simplified model is useful for values of ka that are not too small ($k = 2\pi/\lambda$ is the circular wavenumber; a is the geometrical radius of the active element of the **treatment head**). With smaller values of ka, diffraction effects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

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 (from [3]) 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.

A study has been carried out on a large sample of small ka physiotherapy **treatment heads** [4] and has defined the approach described in 7.3 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 $A_{BCS}(0{,}3\ \text{cm})$ 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**.

The numerical investigations performed in the above studies did confirm agreement, within the uncertainty achieved, with the value obtained using the simplified sound field model. For the sample size studied (66 points), the standard deviation of the mean value is approximately 0,09. The deviation of the mean value ($F_{ac} = 1{,}354$) from the value obtained using the simplified sound field model ($F_{ac} = 1{,}333$) was less than this standard deviation. To avoid that, possibly large, uncertainties need to be taken into account in the determination of the **effective radiating area**, it has been agreed to use $F_{ac} = 1{,}333$ without the need to consider an uncertainty contribution for this fixed conversion factor.



Key

X ka

Y F_{ac}

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

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

Annex F
(informative)

Determining acoustic power through radiation force measurements

This document 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 needs to be large enough to cover the whole ultrasonic field. Subclause A.5.3 of IEC 61161:2013 gives formulae for calculating the minimum value of the target radius b as a function of the target distance z, the wavelength and a_1, the effective radius of the active element of the **treatment head**. The formulae given in IEC 61161:2013 are based on theoretical calculations using a piston field approach [8]. 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**, $A_{BCS}(z)$. An equivalent radius b_{eq} can be determined from:

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

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 measurement. 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, IEC TR 62781 and [1]). The amount of dissolved oxygen in the degassed water should be < 4 mg/l during all measurements.

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 document, 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 61161:2013).

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 in accordance with A.5.3.1 of IEC 61161:2013 (see [8])

Effective radius of the treatment head a_1 cm	Ultrasonic frequency f MHz	Target distance z cm	Minimum target radius b 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)

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 (from [3]) presents the verification that values of **beam cross-sectional area** obtained at low powers are valid at higher operating powers employed for physiotherapy treatments. Table G.1 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 operated normally whilst B was characterized as a "hot spot" transducer exhibiting a large axial peak at 2,9 cm. The measurements for transducer B 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	Transducer A [a]	Transducer B [b]
W	$A_{BCS}(z)$ cm^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

[a] 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 4,0 cm.

[b] 1,5 MHz; diameter 2,8 cm; A_{BCS} determined at 2,9 cm, the distance of the **maximum RMS 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 document to accurately determine the **effective radiating area** of a **treatment head** require 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 because 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 $A_{BCS}(z)$ between 1 % and 3 %.

With currently utilized physiotherapy **treatment head** frequencies and diameters, the most stringent test of 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 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 mm	**Measurement**	**Treatment head-hydrophone separation, z** cm			
		1,0	2,0	4,0	8,0
A ceramic a_g = 0,3	$A_{BCS}(z)$ cm^2	2,00	1,97	2,01	2,07
	R[a]	1,55	1,57	1,68	2,69
C ceramic a_g = 0,5	$A_{BCS}(z)$ cm^2	1,93	1,96	1,99	2,08
	R[a]	1,68	1,69	1,60	2,26
PVDF bilaminar membrane a_g = 2	$A_{BCS}(z)$ cm^2	2,01	2,00	2,02	2,10
	R[a]	1,95	1,91	2,04	2,33

NOTE Measurements were made on a 3 MHz **treatment head** at four distances.

[a] The R values have been derived using the averaged p^2 value evaluated in the specified measurement plane.

Annex I
(informative)

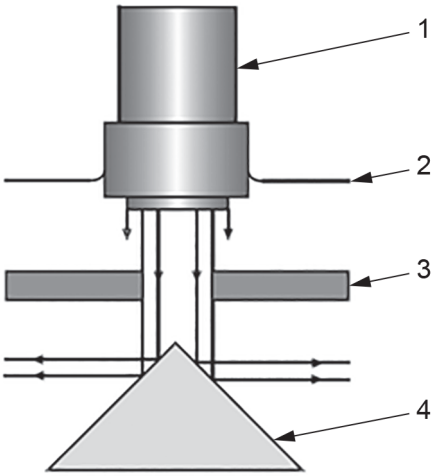
Effective radiating area measurements using a radiation force balance and absorbing apertures

I.1 General

This Annex I provides details of a method for determining the **effective radiating area** (A_{ER}) of physiotherapy **treatment heads** that utilizes a radiation force balance and a series of masks for measuring its ultrasonic **output power**. Such approaches are described in [9] and [10]. Radiation force balances are widely available within hospitals, and it is anticipated that this method could be applied as a simple method of "in-service" checking of the **effective radiating area**. The method described in this Annex I is not intended as a replacement for the procedures described in Clause 7, which represent 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 Clause I.5, is to compute the area through 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 I, the term "aperture" will be used to represent the mask and the circular hole cut therein.



Key

1 treatment head

2 water surface

3 aperture mask (I.3.2)

4 radiation force balance target

NOTE Figure I.1 portrays a "vertical" arrangement of radiation force balance with a reflecting target, although alternative arrangements can also be used (IEC 61161).

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

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 is less than −30 dB, and

– the transmission loss of **ultrasound** through the material is greater than 25 dB.

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

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

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

I.3.2.2 Aperture diameter

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, 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 is reset to a nominally identical power value, to ensure that it is operating under nominally identical conditions.

I.4.3 A power setting of 5 W is recommended for large **treatment heads** (effective diameter greater than 2,0 cm) as this represents a compromise between measurement sensitivity and restricting the extent of heating of any aperture mask material, which may be important.

NOTE The effective diameter is equal to twice the effective radius of the **treatment head** radius, a_1. The effective radius can be derived from the manufacturer's value of the **effective radiating area**, using the expression $a_1 = (A_{ER}/\pi)^{½}$. If the A_{ER} is not available, then the nominal **effective radiating area** (A_{ERN}) can be used to derive a value for a_1.

I.4.4 For small **treatment heads** (effective diameters less than 1,5 cm), the maximum power output should be used, and this may typically lie in the range 0,9 W to 1,8 W. In addition, to restrict the irradiation time used, the switch ON time shall be limited to 5 s for each aperture to minimize any heating of the aperture surface.

I.4.5 In setting up, the **treatment head** shall be positioned as close to the aperture surface as possible but not touching – separations in the range 0,2 cm to 0,4 cm are acceptable. The surface of the **treatment head** and the front face of the aperture should be as parallel as possible.

I.4.6 It is important that the axis of symmetry of the reflecting target (if used) and the aperture axis are co-axial. The sensitivity of the results obtained using the aperture technique to alignment has been assessed [11], and it is sufficient to align the system by eye. The **treatment head** is then positioned centrally over the aperture, again purely by eye, such that the acoustic axis of the beam is assumed to be nominally coincident with that of the aperture and target. No re-positioning of the **treatment head** in the plane of the aperture is carried out for subsequent apertures.

NOTE 1 In order to aid alignment of the aperture below the surface of the **treatment head**, alignment cross-hairs can be marked on the surfaces of the aperture mask.

NOTE 2 Alignment of the target relative to the aperture is expected to be less critical for radiation force balances which employ an absorbing target.

NOTE 3 The co-axiality of the aperture and **treatment head** assumes that the spatial distribution of the intensity within the ultrasonic beam is broadly symmetrical and centred on the geometrical axis of the transducer. In situations where crystal damage has occurred, this is unlikely to be the case and scanning the **treatment head** in the plane of a small diameter aperture (0,4 cm to 0,6 cm) will provide some guidance on how the power is distributed.

I.4.7 As in the case of power measurements, care should be taken to ensure there are no bubbles in the intervening path or on the surfaces of the aperture masks. These can normally be wiped clear using a paint-brush.

NOTE It can be found that small bubbles adhere to parts of the aperture. If these are generally positioned well away from the acoustic beam, they are unlikely to influence the transmitted power. Pre-soaking of the apertures in water containing a small amount of detergent can also reduce this effect.

I.4.8 For each aperture, typically three or four switches OFF to ON and ON to OFF should be carried out and an average power taken in order to improve the statistics. Using the minimal irradiation time identified in I.4.4, this process should take around 30 s to 40 s in total.

I.4.9 In-between the aperture measurements, and certainly at the beginning and end of the run, a number of checks of the "free" or "unapertured"' power should be made with no aperture in place.

I.4.10 A set of aperture measurements will typically comprise the results of around 12 apertures, along with three or four "unapertured" power measurements.

I.4.11 For small **treatment heads** whose effective diameter is less than 1,5 cm, these could typically cover aperture diameters in the range 0,4 cm to 1,8 cm.

I.4.12 For larger **treatment heads** whose effective diameter is greater than 2,0 cm, these could typically cover aperture diameters in the range 0,6 cm to 3,0 cm.

I.4.13 In either case, a reasonably even distribution of aperture sizes should be used.

NOTE With care in the experimental technique, values of power produced by a particular aperture are expected to be reproducible to within ±3 % to ±4 %.

I.4.14 In some situations, a "blank" aperture (essentially a layer of the mask material with no hole present, so it represents a continuous piece of absorber) might be useful. When this is placed in front of the **treatment head**, the power balance should read zero. If it does not, then there may be other signals affecting the balance reading (for example, radio-frequency electrical signals emitted by the transducer).

I.5 Analysis of raw data to derive the effective radiating area

I.5.1 This Clause I.5 provides a step-by-step breakdown of the data analysis procedure, taking a typical set of raw data. These have been derived from measurements made on a commercially available 1 MHz **treatment head** of effective diameter 2,2 cm, with the data having been acquired using nominal aperture diameters in the range 0,8 cm to 3,0 cm, using the method described in [9]. Table I.1 represents the raw data derived from a typical measurement run, showing transmitted power as a function of aperture diameter.

Table I.1 – Aperture measurement check sheet

Date: **/**/**

Operator: **

Treatment head: *****-*** ***

Serial number: ********

Drive unit setting: 5,4 W

Frequency: 1 MHz

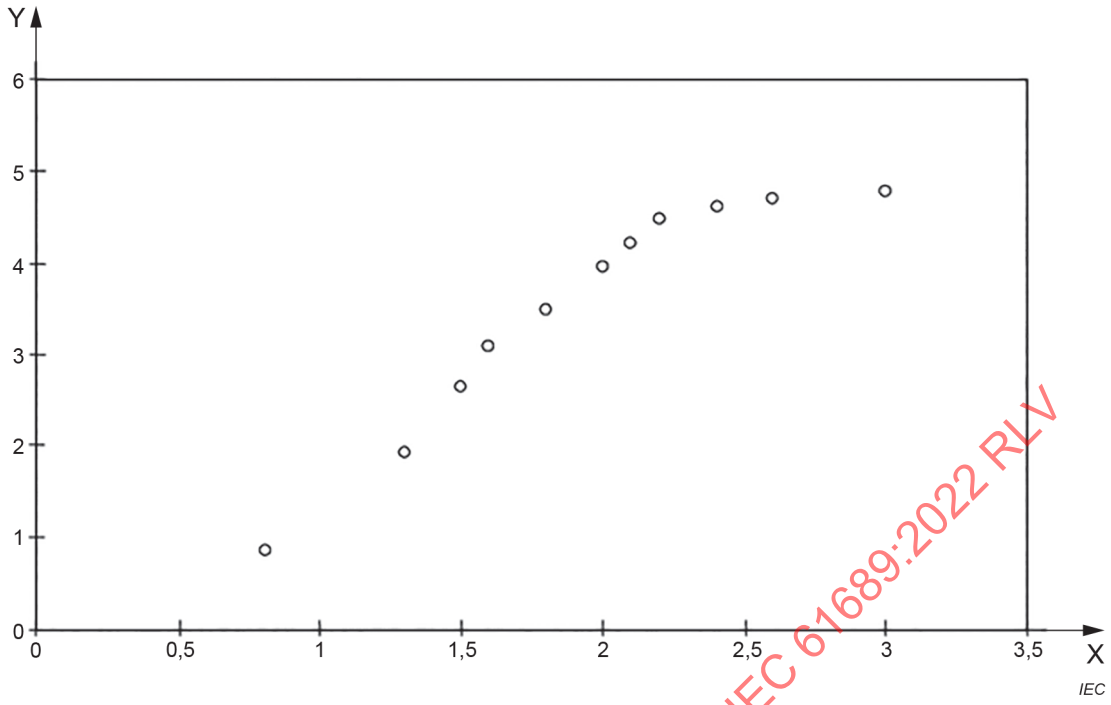
Aperture diameter cm	Radiation force balance readings (W)				
	OFF 1	ON 1	OFF 2	ON 2	Mean reading
No aperture	0,00	4,98	0,02	4,97	4,965
2,0	0,00	3,92	0,04	4,00	3,93
2,4	0,00	4,59	0,02	4,64	4,593
3,0	0,00	4,76	0,01	4,80	4,767
No aperture	0,00	4,88	0,01	4,90	4,88
2,6	0,00	4,70	0,03	4,74	4,693
2,0	0,00	3,96	0,02	3,92	3,933
2,1	0,00	4,26	0,01	4,34	4,28
2,2	0,00	4,52	0,02	4,49	4,497
1,6	0,00	3,07	0,00	3,12	3,087
No aperture	0,00	4,97	0,00	4,99	4,98
1,8	0,00	3,47	0,01	3,54	3,487
1,5	0,00	2,65	0,01	2,72	2,653
1,3	0,00	1,93	0,00	1,95	1,937
0,8	0,00	0,89	0,01	0,83	0,86
2,4	0,00	4,64	0,01	4,66	4,64
No aperture	0,00	4,87	0,01	4,94	4,887
2,0	0,00	4,00	0,01	4,02	4,00
1,8	0,00	3,49	0,00	3,52	3,5
2,1	0,00	4,16	0,00	4,17	4,163
2,2	0,00	4,55	0,01	4,58	4,553
1,6	0,00	3,13	0,02	3,10	3,107
2,6	0,00	4,75	0,01	4,72	4,733
3,0	0,00	4,86	0,00	4,80	4,84
No aperture	0,00	5,01	0,03	4,99	4,98

The data have been derived by switching the **treatment head** ON and OFF in the sequence indicated, the mean reading being calculated from:

$$[(ON1 - OFF1) + (ON1 - OFF2) + (ON2 - OFF2)]/3.$$

NOTE The data set has been derived using eleven apertures. Repeats have been carried out on several apertures to check on the reproducibility of the measurements. The "no aperture" power measurement has been repeated five times to improve statistics.

I.5.2 The data listed in Table I.1 are used to produce a graph, shown in Figure I.2. This demonstrates the expected variation in power as a function of aperture diameter.



Key

X aperture diameter (cm)

Y measured power (W)

Figure I.2 – Measured power as a function of aperture diameter for commercially available 1 MHz physiotherapy treatment heads

To derive a value for **effective radiating area**, further data manipulation is required: the reason for this lies in the spatial distribution of **ultrasound** in the field produced by the physiotherapy **treatment head**, and in the fact that the **effective radiating area** is itself defined via a secondary parameter, the **beam cross-sectional area** (A_{BCS}), which describes the minimum area through which the majority of the ultrasonic power is distributed. The raw data are actually analysed and "sorted" in a manner analogous to that described in Annex B. This procedure is described below in a step-by-step format.

I.5.3 From the raw data (power as a function of aperture diameter), the nominal aperture diameters are converted to areas.

I.5.4 Considering the 0,8 cm diameter aperture, it transmits a power of 0,86 W (see Table I.1). By increasing the aperture size to 1,3 cm, the transmitted power is 1,94 W, and so the power difference of 1,08 W is assumed to be distributed evenly over an area equal to the annulus formed by the two apertures. By then taking the 1,5 cm aperture and identifying its power contribution relative to the 1,3 cm aperture (0,72 W), a representation of the power distribution may be built up. This is done for all adjacent aperture pairs and the data obtained is illustrated in Table I.2.

NOTE For the 0,8 cm diameter aperture, the power is clearly distributed over a circle of radius 0,4 cm, and not an annulus.

Table I.2 – Annular power contributions

Aperture pair	Power contribution W
0 to 0,8	0,86
0,8 to 1,3	1,08
1,3 to 1,5	0,72
1,5 to 1,6	0,44
1,6 to 1,8	0,40
1,8 to 2,0	0,47
2,0 to 2,1	0,26
2,1 to 2,2	0,27
2,2 to 2,4	0,12
2,4 to 2,6	0,097
2,6 to 3,0	0,091

I.5.5 The power contributions from each annulus are converted into intensity contributions, by dividing the power contained in a particular annulus by the area of that annulus. This produces a data set of intensity contributions from each pair of successive apertures and is shown in Table I.3.

Table I.3 – Annular intensity contributions

Aperture pair	Area of larger aperture cm^2	Annulus area cm^2	Power contribution W	Intensity contribution $W\ cm^{-2}$
0 to 0,8	0,503	0,503	0,86	1,71
0,8 to 1,3	1,327	0,825	1,08	1,31
1,3 to 1,5	1,767	0,440	0,72	1,64
1,5 to 1,6	2,011	0,243	0,44	1,81
1,6 to 1,8	2,545	0,534	0,40	0,75
1,8 to 2,0	3,142	0,597	0,47	0,79
2,0 to 2,1	3,464	0,322	0,26	0,81
2,1 to 2,2	3,801	0,338	0,27	0,80
2,2 to 2,4	4,524	0,723	0,12	0,17
2,4 to 2,6	5,309	0,785	0,097	0,12
2,6 to 3,0	7,069	1,759	0,091	0,05

I.5.6 The intensity contributions are then sorted in descending order, ensuring that the association is kept of the annulus area (aperture pair) that produced each contribution. This is shown in Table I.4.

Table I.4 – Annular intensity contributions, sorted in descending order

Aperture pair	Intensity contribution W cm^{-2}	Annulus area cm^2
1,5 to 1,6	1,81	0,243
0 to 0,8	1,71	0,503
1,3 to 1,5	1,64	0,44
0,8 to 1,3	1,31	0,825
2,0 to 2,1	0,81	0,322
2,1 to 2,2	0,8	0,338
1,8 to 2,0	0,79	0,597
1,6 to 1,8	0,75	0,534
2,2 to 2,4	0,17	0,723
2,4 to 2,6	0,12	0,785
2,6 to 3,0	0,05	1,759

NOTE From this data set, it is clear that most of the intensity lies centred about the acoustic beam axis between apertures 0 and 1,6 cm.

I.5.7 Each intensity value is converted back to a power value by multiplying by the corresponding annular area. This produces a data set of power contributions and annular areas, which have actually been sorted in order of descending intensity. This is shown in Table I.5.

Table I.5 – Annular power contributions, sorted in descending order of intensity contribution

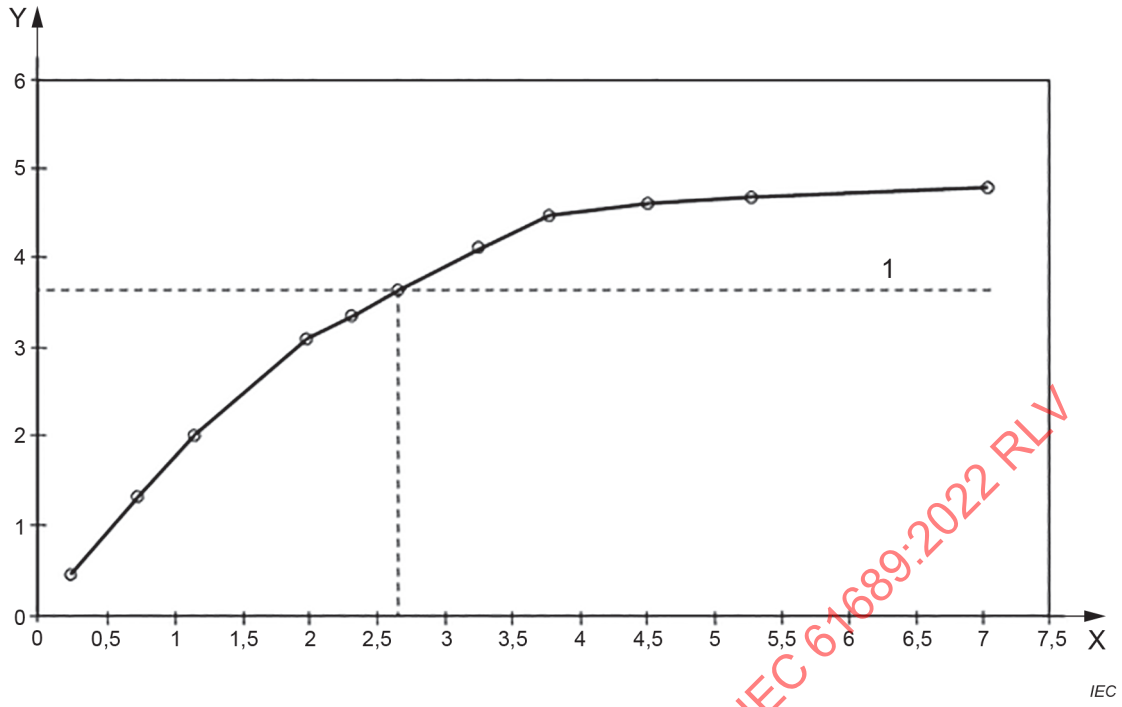
Aperture pair	Intensity contribution W cm^{-2}	Annulus area cm^2	Power contribution W
1,5 to 1,6	1,81	0,243	0,44
0 to 0,8	1,71	0,503	0,86
1,3 to 1,5	1,64	0,44	0,72
0,8 to 1,3	1,31	0,825	1,08
2,0 to 2,1	0,81	0,322	0,26
2,1 to 2,2	0,8	0,338	0,27
1,8 to 2,0	0,79	0,597	0,47
1,6 to 1,8	0,75	0,534	0,40
2,2 to 2,4	0,17	0,723	0,12
2,4 to 2,6	0,12	0,785	0,09
2,6 to 3,0	0,05	1,759	0,09

I.5.8 A running sum is then produced of cumulative power against cumulative area, by summing the values down the table (the cumulative power total should be equal to the power transmitted through the largest aperture). This is shown in Table I.6.

Table I.6 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contribution, and the cumulative sum of their respective annular areas

Intensity contribution W cm^{-2}	Annulus area cm^2	Power contribution W	Cumulative area cm^2	Cumulative power W
1,81	0,243	0,44	0,24	0,44
1,71	0,503	0,86	0,75	1,30
1,64	0,44	0,72	1,19	2,02
1,31	0,825	1,08	2,01	3,10
0,81	0,322	0,26	2,33	3,36
0,8	0,338	0,27	2,67	3,63
0,79	0,597	0,47	3,27	4,11
0,75	0,534	0,40	3,80	4,51
0,17	0,723	0,12	4,53	4,63
0,12	0,785	0,09	5,31	4,72
0,05	1,759	0,09	7,07	4,81

I.5.9 A figure should then be plotted, of cumulative power as a function of cumulative area, as in Figure I.3. From the value of power measured for the "unapertured" case (4,89 W), calculate the 75 % transmitted power (3,67 W), and read off the cumulative area at this power level. The cumulative area value is finally divided by 0,75 to derive an estimate of the **effective radiating area** of the **treatment head**.



Key

X cumulative area (cm^2)

Y cumulative power (W)

1 75 % level of power

Figure I.3 – Cumulative sum of annular power contributions, previously sorted in descending order of intensity contributions, plotted against the cumulative sum of their respective annular areas

NOTE The **treatment head** analysed in this case has an **effective radiating area** of 3,5 cm^2, given by the quotient of 2,65 cm^2 to 0,75.

I.6 Implementation of the aperture technique

It is envisaged that the aperture method will be applied in a number of different ways, for example:

– as a means of acceptance testing prior to a **treatment head** being placed into clinical service, a full characterization could be carried out using many apertures (> 12). This would then produce a reference curve for that **treatment head**;

– as a means of routine evaluation, on an annual basis, using only two or three apertures to compare with the reference curve;

– as a means of verifying continual reliable performance, if a **treatment head** has been dropped or damaged: again, this could be done using a limited number of apertures, followed by more extensive tests if differences are noted.

I.7 Relationship of results to reference testing method

Bibliographic reference [9] represents a comparison of the aperture method with **hydrophone** measurements carried out using the test procedures given in Clause 7 for seventeen **treatment heads** commonly used in clinical practice. Although differences for some **treatment heads** were noticed of up to ±20 %, the typical level of agreement was ±11 %. Reference [11] contains details of measurements made using the apertures with implementations of a radiation force balance which utilizes absorbing and reflecting targets.

NOTE In general, the aperture technique gives best agreement (typically ±11 %) with results for the A_{ER} determined through **hydrophone** scanning for large ka transducers (ka > 50). For transducers with ka < 30, the agreement with the reference technique is typically ±20 %.

Annex J
(informative)

Guidance on uncertainty determination

To be truly meaningful, the result of a measurement needs to be accompanied by its associated uncertainty. In evaluating and expressing the uncertainty in the measurement, the guidance provided by [12] should be followed.

In general, uncertainty components are grouped in accordance with how the values are estimated.

– Type A: evaluated by statistical means.

– Type B: evaluated by other means.

The following is a list of common sources of uncertainty in the measurement of **ultrasonic physiotherapy equipment** that may be evaluated on a Type B basis. The list is not exhaustive but may be used as a guide when assessing uncertainties for a particular measurement system or method. Depending on the parameter under consideration, the measurement system and method chosen and its implementation, some (though possibly not all) of these sources will need assessing. For example, the errors from measuring instruments may be minimized by the use of the same measuring channel (amplifier, filter, voltmeter, etc.) for all signals. However, since this may not be the case in all implementations, components for these sources of error have been included in the list.

Sources of uncertainty applicable to **hydrophone** measurements in general:

- interference from acoustic reflections, leading to a lack of free-field conditions;
- lack of acoustic **far-field** conditions;
- spatial averaging effects of the **hydrophones** used due to their finite size and the lack of perfect plane-wave conditions;
- misalignment, particularly at higher frequencies where the **hydrophone** response may be far from omnidirectional;
- acoustic scattering from the **hydrophone** mount (or vibrations picked up and conducted by the mount);
- errors in measurement of the received voltage (including the accuracy of the measuring instrumentation – voltmeter, digitizers, etc.);
- inaccuracy of the gains of any amplifiers, filters and digitizers used;
- errors in the measurement of the drive current or voltage;
- errors due to the lack of linearity in the measurement system (the use of a calibrated attenuator to equalize the measured signals may significantly reduce this contribution);
- inaccuracy of any electrical signal attenuators used;
- electrical noise including RF pick-up;
- inaccuracy of any electrical loading corrections made to account for loading by extension cables and preamplifiers;
- bubbles or air clinging to transducers (this should be minimized by adequate wetting and soaking of transducers);
- errors in the values for acoustic frequency.

Sources of uncertainty specific to determination of **effective radiating area** and **total mean square acoustic pressure**:

- errors in the measurement of the separation distance;
- spatial resolution of the beam scans carried out (local structure which may be undersampled).

More details about uncertainty calculation of **effective radiating area**, **total mean square acoustic pressure** and **beam non-uniformity ratio** can be found in [13] and [14].

Annex K
(informative)

Examples of pulse duration and pulse repetition period of amplitude modulated waves

In Figure K.1, Figure K.2, Figure K.3, Figure K.4 and Figure K.5, the **pulse duration** and the **pulse repetition period** (prp) are illustrated for five simple **modulation waveforms**, shown as solid lines in each figure. For simplicity, the **acoustic pulse waveforms** are not shown in the figures. The **modulation waveforms** are considered to be represented by voltages $U(t)$ within this Annex K. Each figure contains two dots where the **modulation waveform** crosses the dashed reference line, which has value U_{ref}. The time between these two dots defines the **pulse duration** (3.33).

In the first three examples, the minimum value of the **modulation waveform** is zero. The reference value (U_{ref}) (see Note 1 to entry in 3.33) is equal to 10 % of the maximum value of the **modulation waveform** ($U_{ref} = 0{,}1 \cdot U_{max}$).

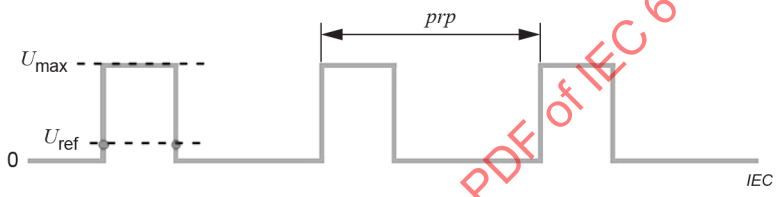


Figure K.1 – Example 1: Tone-burst (i.e. rectangular modulation waveform)

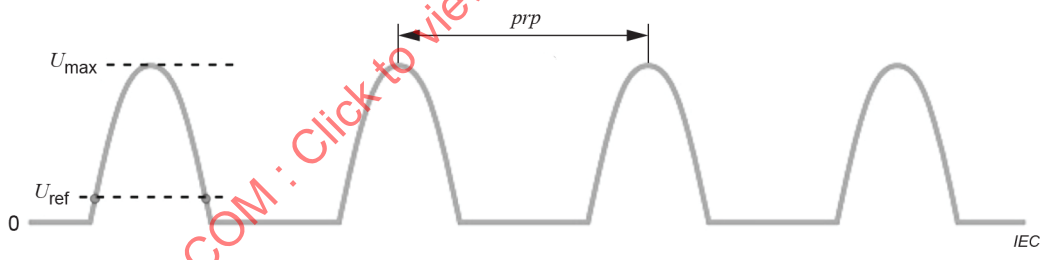


Figure K.2 – Example 2: Half-wave modulation with no filtering of the AC mains voltage

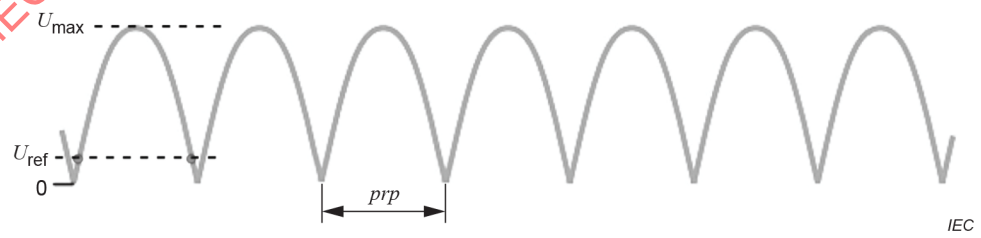


Figure K.3 – Example 3: Full-wave modulation with no filtering of the AC mains voltage

In the next two examples, the minimum value of the **modulation waveform** is greater than zero. The reference value (U_{ref}) is equal to the sum of the minimum value of the **modulation waveform** and 10 % of the difference between the maximum and minimum value of the **modulation waveform** [$U_{ref} = U_{min} + 0{,}1 \cdot (U_{max} - U_{min})$].

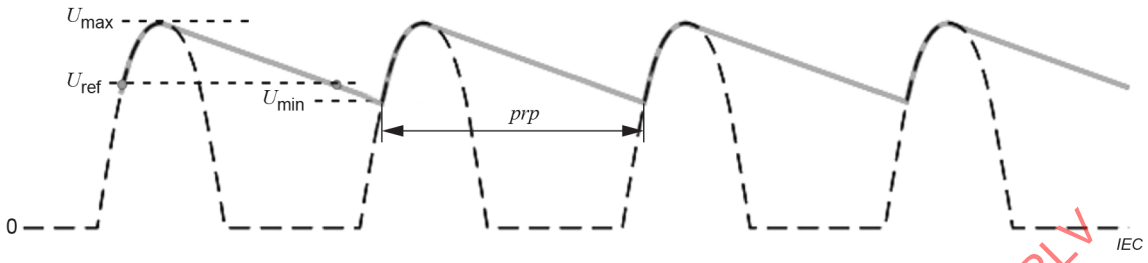


Figure K.4 – Example 4: Half-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)

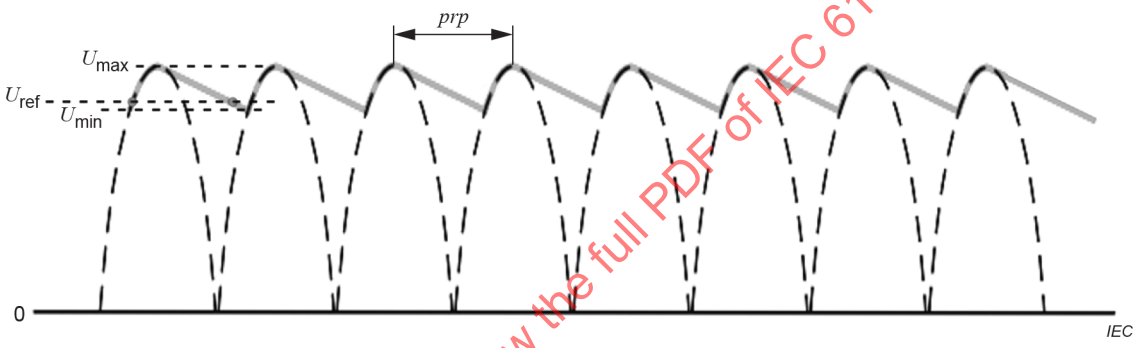


Figure K.5 – Example 5: Full-wave modulation with filtering of the AC mains voltage; filtering insufficient to define the wave as continuous wave (3.17)

In Examples 2 and 4 the **pulse repetition rate** ($prr = 1/prp$) is equal to the mains frequency; for example, prr = 50 Hz or prr = 60 Hz. In Examples 3 and 5 the **pulse repetition rate** ($prr = 1/prp$) is equal to twice the mains frequency; for example, prr = 100 Hz or prr = 120 Hz.

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SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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ULTRASONS – SYSTÈMES DE PHYSIOTHÉRAPIE – SPÉCIFICATIONS DES CHAMPS ET MÉTHODES DE MESURE DANS LA PLAGE DE FRÉQUENCES DE 0,5 MHz À 5 MHz

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L'IEC 61689 a été établie par le comité d'études 87 de l'IEC: Ultrasons. Il s'agit d'une Norme internationale.

Cette quatrième édition annule et remplace la troisième édition parue en 2013. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente.

a) L'exigence relative à la teneur en oxygène de l'eau est spécifiée en 6.1.
b) Les anciennes recommandations spécifiées en 6.2 ont été modifiées pour constituer des exigences.
c) Plusieurs définitions de l'Article 3 ont été actualisées conformément à d'autres documents qui relèvent du CE 87.

d) L'ancienne Annexe A informative a été modifiée en annexe normative, et contient désormais des informations détaillées sur la méthode selon laquelle la conformité aux exigences de l'IEC 60601-2-5 est vérifiée.

e) L'Annexe D a été raccourcie de manière importante et la référence à un document réglementaire désormais supprimé a été retirée.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
87/784/FDIS	87/789/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Le présent document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

NOTE Les caractères d'imprimerie suivants sont utilisés:

- Exigences: Arial 10 point
- Notes: Arial 8 point
- Les mots en **caractères gras** dans le texte sont définis à l'Article 0
- Les symboles et formules: *Times New Roman + Italique*
- Articles concernant la conformité: *Arial italique*

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- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Les **ultrasons** aux fréquences de quelques mégahertz sont largement utilisés en médecine pour les besoins de la physiothérapie. Ces appareils comportent un générateur de courant électrique à haute fréquence et généralement un **transducteur** tenu à la main, souvent appelé applicateur. Ce **transducteur** se compose d'un transducteur, généralement un disque en matériau piézoélectrique, qui convertit l'énergie électrique en **ultrasons** et est souvent conçu pour être en contact avec le corps humain.

ULTRASONS – SYSTÈMES DE PHYSIOTHÉRAPIE – SPÉCIFICATIONS DES CHAMPS ET MÉTHODES DE MESURE DANS LA PLAGE DE FRÉQUENCES DE 0,5 MHz À 5 MHz

1 Domaine d'application

Le présent document est applicable aux appareils à ultrasons, conçus pour la physiothérapie, qui comprennent un **transducteur ultrasonique** fournissant des **ultrasons** à onde entretenue ou quasi entretenue (par exemple, salve d'impulsions) dans la plage de fréquences de 0,5 MHz à 5 MHz. Le présent document ne traite que des **appareils à ultrasons pour physiothérapie** qui emploient un seul transducteur circulaire plan sans focalisation par transducteur, produisant des faisceaux statiques perpendiculaires à la face de ce même **transducteur**.

Le présent document spécifie:

- les méthodes de mesure et la caractérisation de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai de référence;
- les caractéristiques à spécifier par les fabricants des **appareils à ultrasons pour physiothérapie** qui reposent sur des méthodes d'essai de référence;
- les lignes directrices de sécurité du champ ultrasonique créé par les **appareils à ultrasons pour physiothérapie**;
- les méthodes de mesure et la caractérisation de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai individuel de série;
- les critères d'aptitude relatifs aux aspects de la sortie des **appareils à ultrasons pour physiothérapie**, qui reposent sur des méthodes d'essai individuel de série.

La valeur thérapeutique et les modes d'utilisation des **appareils à ultrasons pour physiothérapie** n'entrent pas dans le domaine d'application du présent document.

Les **appareils à ultrasons pour physiothérapie** qui utilisent des **ultrasons** dont la plage de fréquences est comprise entre 20 kHz et 500 kHz sont couverts par l'IEC 63009.

2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*

IEC 60601-2-5, *Appareils électromédicaux – Partie 2-5: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à ultrasons pour physiothérapie*

IEC 61161, *Ultrasons – Mesurage de puissance – Balances de forces de rayonnement et exigences de fonctionnement*

IEC 62127-1, *Ultrasons – Hydrophones – Partie 1: Mesurage et caractérisation des champs ultrasoniques médicaux jusqu'à 40 MHz*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

3.1
puissance de sortie assignée maximale absolue
somme de la **puissance de sortie assignée**, de l'incertitude globale pour une confiance à 95 % dans la **puissance de sortie assignée** et de tout accroissement maximal de la **puissance de sortie assignée** pour une variation de ±10 % de la tension assignée du réseau

Note 1 à l'article: Il convient de vérifier la possibilité de variation de la **puissance de sortie assignée** issue d'une variation de ±10 % de la tension assignée du réseau à l'aide d'un transformateur de sortie variable entre la tension **d'alimentation** du réseau et l'**appareil à ultrasons pour physiothérapie**. Voir l'Article A.2 pour plus de recommandations.

Note 2 à l'article: La **puissance de sortie assignée maximale absolue** est exprimée en watts (W).

3.2
coefficient de régression linéaire
Q
quotient du **gradient de régression linéaire,** m, et de la **surface de la section droite du faisceau** à 0,3 cm de la face du **transducteur**, A_{BCS}(0,3 cm)

Note 1 à l'article: Le **coefficient de régression linéaire** est exprimé en unités de un par mètre (m^{-1}).

3.3
gradient de régression linéaire
m
quotient de la différence de la **surface de la section droite du faisceau** à la valeur z_N, $A_{BCS}(z_N)$, sur la **surface de la section droite du faisceau** à 0,3 cm de la face du **transducteur,** A_{BCS}(0,3 cm), divisé par la différence des distances respectives

$$m = \frac{A_{BCS}(z_N) - A_{BCS}(0{,}3\ \text{cm})}{z_N - 0{,}3\ \text{cm}} \quad (1)$$

où

A_{BCS} est la **surface de la section droite du faisceau**;

z_N est la distance entre la face du **transducteur** et la dernière valeur maximale de la **pression acoustique efficace** de l'**axe d'alignement du faisceau**

Note 1 à l'article: Le **gradient de régression linéaire** est exprimé en mètres (m).

[SOURCE: IEC 61689:2013, 3.3, modifié – Le programme de calcul du gradient a été ajouté à la définition, et la formule a été ajoutée.]

3.4
taux de non-conformité du faisceau maximal absolu
taux de non-conformité du faisceau plus l'incertitude globale pour une confiance à 95 % dans le **taux de non-conformité du faisceau**

3.5
intensité efficace maximale absolue
valeur de l'**intensité efficace** qui correspond à la **puissance de sortie assignée maximale absolue** et à la **surface émettrice efficace minimale absolue** de l'**appareil**

3.6
surface émettrice efficace minimale absolue
surface émettrice efficace moins l'incertitude globale pour une confiance à 95 % dans la **surface émettrice efficace**

3.7
fréquence d'application acoustique
fréquence acoustique
f_{awf}
fréquence d'un signal acoustique fondée sur l'observation de la sortie d'un **hydrophone** placé dans un champ acoustique à la position correspondant à la **pression acoustique à la crête spatiale et temporelle**

Note 1 à l'article: Le signal est analysé à l'aide de la technique de la **fréquence d'application acoustique de passage à zéro** ou de la méthode d'exploration du spectre. Les fréquences d'application acoustique sont définies en 3.7.1 et 3.7.2.

Note 2 à l'article: Dans un certain nombre de cas, la présente définition n'est pas très utile ou pratique, particulièrement pour les **transducteurs** à large bande. Dans ce cas, il convient de donner une description complète du spectre de fréquences afin de permettre une correction en fonction de la fréquence par rapport au signal.

Note 3 à l'article: La **fréquence acoustique** est exprimée en hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.3]

3.7.1
fréquence d'application acoustique, moyenne arithmétique
f_{awf}
moyenne arithmétique des fréquences les plus largement séparées f_1 et f_2, dans la gamme de trois fois f_1, à laquelle l'amplitude du spectre de la pression acoustique est inférieure de 3 dB à l'amplitude de crête

Note 1 à l'article: Cette définition de fréquence est généralement destinée aux systèmes qui produisent des impulsions courtes qui ne contiennent que quelques cycles, mais peut être utilisée pour des salves d'impulsions.

Note 2 à l'article: Il est supposé que $f_1 < f_2$.

Note 3 à l'article: Si f_2 ne se situe pas dans la gamme < $3f_1$, f_2 est à considérer comme la fréquence la plus basse au-dessus de cette gamme à laquelle l'amplitude du spectre est de -3 dB de l'amplitude de crête.

[SOURCE: IEC 62127-1:2007 et IEC 62127-1:2007/AMD1:2013, 3.3.2, modifié – La Note 1 à l'article a été modifiée.]

3.7.2
fréquence d'application acoustique de passage à zéro
f_{awf}
nombre, n, de demi-périodes consécutives (indépendamment de la polarité) divisé par deux fois le temps qui s'écoule entre le début de la première demi-période et la fin de la n-ème demi-période

Note 1 à l'article: Il convient qu'aucune des n demi-périodes consécutives ne présente un changement de phase évident.

Note 2 à l'article: Il convient de réaliser les mesurages, dans le récepteur, aux bornes qui sont le plus proche possible du transducteur de réception (**hydrophone**) et, dans tous les cas, avant redressement.

Note 3 à l'article: Cette fréquence est déterminée conformément à la procédure spécifiée dans l'IEC TR 60854.

Note 4 à l'article: Cette fréquence est destinée aux systèmes à **ondes entretenues** ou quasi entretenues (par exemple, salve d'impulsion) uniquement.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.3.1, modifié – Dans la Note 4 à l'article, "ou quasi entretenues (par exemple, salve d'impulsion)" a été ajouté.]

3.8
forme d'onde des impulsions acoustiques
forme d'onde temporelle de la **pression acoustique instantanée** en une position spécifiée d'un champ acoustique, présentée sur une période suffisamment longue pour inclure toutes les indications acoustiques significatives dans une impulsion, une salve d'impulsions ou un ou plusieurs cycles d'une **onde entretenue**

Note 1 à l'article: La forme d'onde temporelle est une représentation (par exemple, présentation par oscilloscope ou équation) de la **pression acoustique instantanée**.

[SOURCE: IEC 62127-1:2007 et IEC 62127-1:2007/AMD1:2013, 3.1]

3.9
période acoustique de répétition
par
période de répétition des impulsions égale à l'intervalle de temps entre les points correspondants des cycles consécutifs des systèmes à **ondes entretenues**

Note 1 à l'article: La **période acoustique de répétition** est exprimée en seconde (s).

[SOURCE: IEC 62127-1:2007, 3.2, modifié – la définition a été adaptée aux systèmes non explorateurs.]

3.10
onde modulée en amplitude
onde pour laquelle le quotient $p_{tp}/(\sqrt{2}p_{RMS})$ en tout point du champ lointain sur l'**axe d'alignement du faisceau** est supérieur à 1,05, où p_{tp} est la **pression acoustique à la crête temporelle** et p_{RMS} est la **pression acoustique efficace**

3.11
adaptateur
accessoire destiné à être attaché au **transducteur** dans le but de modifier les caractéristiques du faisceau ultrasonore

[SOURCE: IEC 60601-2-5:2009, 201-3-202]

3.12
axe d'alignement du faisceau
droite qui relie deux points de **pression acoustique efficace maximale** sur deux surfaces planes parallèles aux faces du **transducteur** à des distances spécifiques

Note 1 à l'article: Un plan est à une distance approximativement égale à a^2/λ où a est le rayon géométrique de l'élément actif du **transducteur**. La surface du second plan se situe à une distance de $2a^2/\lambda$ ou de $a^2/(3\lambda)$, selon la valeur la plus appropriée. Pour les besoins de l'alignement, cette droite peut être projetée sur la face du **transducteur**.

Note 2 à l'article: Comme l'**axe d'alignement du faisceau** n'est utilisé que pour les besoins de l'alignement, les définitions des distances spécifiques peuvent être légèrement élargies pour tenir compte des contraintes du dispositif de mesure utilisé. Par exemple, certains **transducteurs** ont une distance a^2/λ bien supérieure à 12 cm, auquel cas une distance maximale de 12 cm peut être utilisée pour définir le premier plan. Des lignes directrices générales pour la détermination de l'**axe d'alignement du faisceau** sont fournies en 7.3.

3.13
surface de la section droite du faisceau
A_{BCS}
surface minimale dans un plan spécifié perpendiculaire à l'**axe d'alignement du faisceau** pour laquelle la somme des **pressions acoustiques carrées moyennes** est égale à 75 % de la **pression acoustique carrée moyenne totale**

Note 1 à l'article: La **surface de la section droite du faisceau** est exprimée en unités de mètre carré (m^2).

Note 2 à l'article: La justification de la définition est décrite à l'Annexe D.

3.14
intensité maximale du faisceau
produit du **taux de non-conformité** du faisceau par l'**intensité efficace**

Note 1 à l'article: L'**intensité maximale du faisceau** est exprimée en unités de watt par mètre carré (W/m^2).

3.15
taux de non-conformité du faisceau
R_{BN}
quotient du carré de la **pression acoustique efficace maximale** par la moyenne spatiale du carré de la **pression acoustique efficace**, où la moyenne spatiale est prise sur la **surface émettrice efficace**

$$R_{BN} = \frac{p^2_{max,RMS} A_{ER}}{pms_t A_0} \quad (2)$$

où

$p_{max,RMS}$ est la **pression acoustique efficace maximale**;

A_{ER} est la **surface émettrice efficace**;

pms_t est la **pression acoustique carrée moyenne totale**;

A_0 est l'unité de surface du balayage de trame.

3.16
type de faisceau
classification descriptive du faisceau ultrasonore

Note 1 à l'article: Il existe trois types de faisceaux: **parallèle** (3.18), **convergent** (3.19) et **divergent** (3.20).

3.17
onde entretenue
onde pour laquelle le quotient $p_{tp}/(\sqrt{2}\, p_{RMS})$, en tout point du **champ lointain** sur l'**axe d'alignement du faisceau**, est inférieur ou égal à 1,05, où p_{tp} est la **pression acoustique à la crête temporelle** et p_{RMS} est la **pression acoustique efficace**

3.18
parallèle
<faisceau> qui présente un **coefficient de régression linéaire**, Q, qui obéit à l'inégalité suivante

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

3.19
convergent
<faisceau> qui présente un **coefficient de régression linéaire**, Q, qui obéit à l'inégalité suivante

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

3.20
divergent
<faisceau> qui présente un **coefficient de régression linéaire**, Q, qui obéit à l'inégalité suivante

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

3.21
facteur d'utilisation
quotient de la **durée d'impulsion** par la **période de répétition des impulsions**

3.22
intensité efficace
I_e
intensité donnée par $I_e = P/A_{ER}$ où P est la **puissance de sortie** et A_{ER} est la **surface émettrice efficace**

Note 1 à l'article: L'**intensité efficace** est exprimée en unités de watt par mètre carré (W/m^2).

3.23
surface émettrice efficace
A_{ER}
surface de la section droite du faisceau déterminée à une distance de 0,3 cm de la face avant du **transducteur,** $A_{BCS}(0{,}3\ \text{cm})$, multipliée par un facteur sans dimension, F_{ac}, égal à 1,333

Note 1 à l'article: Le facteur de conversion F_{ac} est utilisé ici pour déduire la surface proche du **transducteur** qui contient 100 % de la **pression acoustique carrée moyenne totale**. L'origine de la valeur de F_{ac} est décrite dans l'Annexe E.

Note 2 à l'article: La **surface émettrice efficace** est exprimée en unités de mètre carré (m^2).

3.24
sensibilité chargée en bout de câble
$\underline{M}_L(f)$
<d'un **hydrophone** ou d'un ensemble d'hydrophones> quotient de la transformée de Fourier du signal tension-temps de l'**hydrophone** $\mathcal{F}(u_L(t))$ à l'extrémité de tout câble intégré ou connecteur de sortie d'un **hydrophone** ou d'un ensemble d'hydrophones, lorsqu'il est connecté à une impédance de charge électrique spécifiée, et de la transformée de Fourier de la **forme d'onde des impulsions acoustiques** $\mathcal{F}(p(t))$ dans le champ libre non perturbé d'une onde plane à la position du centre de référence de l'**hydrophone** si l'**hydrophone** a été retiré

$$\underline{M}_L(f) = \frac{\mathcal{F}(u_L(t))}{\mathcal{F}(p(t))} \tag{3}$$

Note 1 à l'article: La **sensibilité chargée en bout de câble** est un paramètre à valeurs complexes. Son module est exprimé en unités de volt par pascal (V/Pa). Son angle de phase est exprimé en degrés et représente la différence de phase entre la tension électrique et la pression acoustique.

[SOURCE: IEC 61828:2020, 3.50, modifié – La traduction incomplète du terme a été corrigée en ajoutant le mot chargée]

3.25
champ lointain
région du champ où $z > z_T$ est alignée sur l'axe du faisceau pour des transducteurs plans sans focalisation, où z est la distance entre la face du **transducteur** et un point spécifié sur l'**axe d'alignement du faisceau**

Note 1 à l'article: Dans le **champ lointain**, la pression acoustique apparaît comme sphériquement **divergente** depuis un point situé sur ou à proximité de la surface émettrice. Ainsi, la pression produite par la source acoustique est à peu près inversement proportionnelle à la distance depuis la source.

Note 2 à l'article: Le terme "**champ lointain**" n'est utilisé dans le présent document que dans le cas de transducteurs sources sans focalisation. Pour les transducteurs à focalisation, une terminologie différente s'applique aux différentes parties du champ émis (voir l'IEC 61828).

Note 3 à l'article: Pour les besoins du présent document, le **champ lointain** débute à une distance où $z_T = A_{ERN}/(\pi\lambda)$ où A_{ERN} est la valeur nominale de la **surface émettrice efficace** du **transducteur** et λ est la longueur d'onde des **ultrasons** correspondant à la **fréquence d'application acoustique**.

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.28, modifié – Dans la définition, la spécification de z a été ajoutée et la Note 3 à l'article a été remplacée afin de fournir des informations spécifiques relatives à z_T]

3.26
hydrophone
transducteur qui produit des signaux électriques en réponse aux variations de pression dans l'eau

Note 1 à l'article: Il s'agit principalement d'un dispositif passif conçu et fabriqué pour répondre à la pression acoustique.

Note 2 à l'article: Dans certaines applications, il sert de dispositif actif pour l'émission du son.

[SOURCE: IEC 60050-801:2021, 801-32-26]

3.27
pression acoustique instantanée
$p(t)$
pression à un instant et un point donnés dans un champ acoustique, diminuée de la pression ambiante

Note 1 à l'article: La **pression acoustique instantanée** est exprimée en pascal (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03]

3.28
pression acoustique efficace maximale
$p_{max,RMS}$
valeur maximale de la **pression acoustique efficace** sur tout le champ acoustique

Note 1 à l'article: La **pression acoustique efficace maximale** est exprimée en pascals (Pa).

3.29
pression acoustique carrée moyenne
carré moyen de la **pression acoustique instantanée** en un point donné du champ acoustique, pris sur un nombre entier de **périodes acoustiques de répétition**

Note 1 à l'article: En pratique, la valeur moyenne est souvent déduite des mesurages en valeur efficace.

Note 2 à l'article: La **pression acoustique carrée moyenne** est exprimée en unités de pascal carré (Pa^2).

3.30
forme d'onde en modulation
forme de l'enveloppe d'onde dans le temps de l'**onde modulée en amplitude** au point de **pression acoustique efficace de crête** sur l'**axe d'alignement du faisceau**, mise en évidence sur une période suffisamment longue pour prendre en compte toutes les informations acoustiques importantes de l'**onde modulée en amplitude**

Note 1 à l'article: L'Annexe K présente des exemples.

3.31
puissance de sortie
P
moyenne temporelle de la puissance ultrasonore émise par le **transducteur** d'un **appareil à ultrasons pour physiothérapie** dans un champ pratiquement libre dans des conditions spécifiées et dans un milieu spécifié, soit l'eau de préférence

Note 1 à l'article: La **puissance de sortie** est exprimée en watts (W).

[SOURCE: IEC 61161:2013, 3.3, modifié – Dans la définition, "**transducteur ultrasonore**" a été remplacé par "**transducteur** d'un **appareil à ultrasons pour physiothérapie**".]

3.32
pression acoustique efficace de crête
valeur maximale de la **pression acoustique efficace** sur une région, une ligne ou un plan spécifiés dans un champ acoustique

Note 1 à l'article: La **pression acoustique efficace de crête** est exprimée en pascals (Pa).

3.33
durée d'impulsion
intervalle de temps commençant au moment auquel la **forme d'onde en modulation** dépasse une valeur de référence et finissant au moment auquel la **forme d'onde en modulation** revient à cette valeur

Note 1 à l'article: La valeur de référence est égale à la somme de la **forme d'onde en modulation** minimale et 10 % de la différence entre les **formes d'onde en modulation** maximale et minimale.

Note 2 à l'article: Cette définition diffère de celle donnée dans l'IEC 62127-1:2007 afin d'être applicables aux **ondes modulées en amplitude**.

Note 3 à l'article: L'Annexe K présente des exemples.

Note 4 à l'article: La **durée d'impulsion** est exprimée en secondes (s).

3.34
période de répétition des impulsions
prp
intervalle de temps entre des points équivalents sur la **forme d'onde en modulation** pour une **onde modulée en amplitude**

Note 1 à l'article: L'Annexe K présente des exemples.

Note 2 à l'article: La **période de répétition des impulsions** est exprimée en secondes (s).

3.35
régime de répétition des impulsions
prr
inverse de la **période de répétition des impulsions**

Note 1 à l'article: Le **régime de répétition des impulsions** est égal à la fréquence de répétition de la forme d'onde modulée.

Note 2 à l'article: Le **régime de répétition des impulsions** est exprimé en hertz (Hz).

Note 3 à l'article: L'abréviation "prr" est dérivée du terme anglais développé correspondant "pulse repetition rate"

[SOURCE: IEC 62127-1:2007, 3.52, modifié – La Note 1 à l'article diffère de la NOTE 1 d'origine.]

3.36
puissance de sortie assignée
puissance de sortie maximale de l'**appareil à ultrasons pour physiothérapie** à la tension assignée du réseau, avec une configuration des réglages qui permet de délivrer la **puissance de sortie** maximale

Note 1 à l'article: La **puissance de sortie assignée** est exprimée en watts (W).

3.37
pression acoustique efficace
p_{RMS}
valeur efficace de la **pression acoustique instantanée** en un point donné du champ acoustique

Note 1 à l'article: Sauf indication contraire, il convient de prendre la moyenne sur un nombre entier de **période acoustique de répétition**.

Note 2 à l'article: La **pression acoustique efficace** est exprimée en pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.53]

3.38
pression acoustique à la crête spatiale et temporelle
p_{sptp}
valeur supérieure de la pression acoustique de compression de crête ou de la pression acoustique de raréfaction de crête

Note 1 à l'article: La **pression acoustique à la crête spatiale et temporelle** est exprimée en pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.63]

3.39
puissance de sortie maximale temporelle
P_{tm}
<d'une **onde modulée en amplitude**> **puissance de sortie** réelle dimensionnée par la moitié du quotient de la **pression acoustique à la crête temporelle** par la **pression acoustique efficace** au carré

$$P_{tm} = \frac{1}{2}\left(\frac{p_{tp}}{p_{RMS}}\right)^2 \times P \qquad (4)$$

où

P est la **puissance de sortie** réelle dans les conditions d'**onde modulée en amplitude**;

p_{tp} est la **pression acoustique à la crête temporelle**;

p_{RMS} est la **pression acoustique efficace**.

Note 1 à l'article: Les deux pressions p_{tp} et p_{RMS} sont mesurées en un point spécifié de l'**axe d'alignement du faisceau.**

Note 2 à l'article: La **puissance de sortie maximale temporelle** est exprimée en watts (W).

3.40
pression acoustique carrée moyenne totale
pms_t
somme des valeurs de la **pression acoustique carrée moyenne** dans un plan spécifié pour des limites spécifiées de sommation, chaque valeur ayant une surface différentielle spécifiée

Note 1 à l'article: La **pression acoustique carrée moyenne totale** est exprimée en unités de pascal carré (Pa^2).

3.41
intensité maximale temporelle
I_m
<pour une **onde modulée en amplitude**> quotient de la **puissance de sortie maximale temporelle** et de la **surface émettrice efficace**

$$I_m = \frac{P_{tm}}{A_{ER}} \tag{5}$$

où

P_{tm} est la **puissance de sortie maximale temporelle**;

A_{ER} est la **surface émettrice efficace**.

Note 1 à l'article: L'**intensité maximale temporelle** est exprimée en unités de watt par mètre carré (W/m^2).

3.42
pression acoustique à la crête temporelle
p_{tp}
valeur maximale du module de la **pression acoustique instantanée** en un point particulier d'un champ acoustique

Note 1 à l'article: La **pression acoustique à la crête temporelle** est exprimée en pascals (Pa).

[SOURCE: IEC 62127-1:2007, 3.67]

3.43
transducteur
ensemble comprenant un **transducteur ultrasonore** et les parties associées pour une application locale d'**ultrason**s à un patient

[SOURCE: IEC 60601-2-5:2009, 201.3.214, modifié – La NOTE n'a pas été incluse.]

3.44
transducteur ultrasonique
appareil permettant de convertir l'énergie électrique en énergie mécanique dans la gamme de fréquences ultrasonores et/ou, réciproquement, l'énergie mécanique en énergie électrique

[SOURCE: IEC 62127-1:2007, 3.73]

3.45
ultrason
vibration acoustique dont la fréquence est supérieure à la limite supérieure des fréquences des sons audibles (environ 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

3.46
appareil à ultrasons pour physiothérapie
appareil
appareil conçu pour la production d'**ultrasons** et l'application de ceux-ci à un patient à des fins thérapeutiques

Note 1 à l'article: Les appareils exclus comprennent, entre autres:

– les appareils avec lesquels les ondes **ultrasonores** émises sont destinées à détruire des conglomérats (par exemple, des calculs rénaux ou biliaires) ou des tissus de tout type;
– les appareils avec lesquels un outil est entraîné par **ultrasons** (par exemple, scalpels chirurgicaux, phacoémulseurs, instruments à détartrer dentaires, lithotripteurs intracorporels);
– les appareils avec lesquels les ondes **ultrasonores** sont destinées à sensibiliser les tissus à d'autres thérapies (par exemple, rayonnement ou chimiothérapie);
– les appareils avec lesquels les ondes **ultrasonores** sont destinées à traiter les tissus cancéreux (c'est-à-dire, malins) ou précancéreux, voire les masses bénignes. Il s'agit par exemple des ultrasons focalisés de haute intensité (HIFU - high intensity focused ultrasound) ou des ultrasons thérapeutiques de haute intensité (HITU - high intensity therapeutic ultrasound).

[SOURCE: IEC 60601-2-5:2009, 201.3.216, modifié – La NOTE a été modifiée afin de fournir quelques exemples d'appareils exclus.]

4 Symboles

a	rayon géométrique de l'élément actif d'un **transducteur**
A_{BCS}	**surface de la section droite du faisceau**
$A_{BCS}(0{,}3\ cm)$	**surface de la section droite du faisceau** évaluée à 0,3 cm de la face frontale du **transducteur**
$A_{BCS}(z_N)$	**surface de la section droite du faisceau** évaluée à l'endroit du dernier maximum axial, z_N
A_{ER}	**surface émettrice efficace** d'un **transducteur**
a_g	rayon géométrique de l'élément actif d'un **hydrophone**
a_{max}	taille maximale efficace de l'**hydrophone**, définie dans l'IEC 62127-1
A_o	unité de surface du balayage de trame
par	**période acoustique de répétition**
b	rayon minimal d'une cible de balance de forces de rayonnement
c	vitesse du son dans l'eau
ERD	echo reduction (réduction de l'écho)
f_{awf}	**fréquence d'application acoustique**
F_{ac}	facteur de conversion pour convertir $A_{BCS}(0{,}3\ cm)$ en A_{ER}
I_e	**intensité efficace**
I_m	**intensité maximale temporelle**
k	(= $2\pi/\lambda$) nombre d'onde circulaire
m	**gradient de régression linéaire**
$\underline{M}_L$	**sensibilité chargée en bout de câble** d'un **hydrophone**
P	**puissance de sortie** d'un **transducteur**
P_{tm}	**puissance de sortie maximale temporelle**
$p(t)$	**pression acoustique instantanée**
p_{tp}	**pression acoustique à la crête temporelle**

p_{sptp}	**pression acoustique à la crête spatiale et temporelle**
$p_{max,RMS}$	**pression acoustique efficace maximale**
p_{RMS}	**pression acoustique efficace**
pms_t	**pression acoustique carrée moyenne totale**
prp	**période de répétition des impulsions**
prr	**régime de répétition des impulsions**
Q	**coefficient de régression linéaire**
R	quotient de la **pression acoustique efficace de crête** par la moyenne de la **pression acoustique efficace** sur la **surface de la section droite du faisceau** dans un plan spécifié
R_{BN}	**taux de non-conformité du faisceau**
s	dimension du pas de balayage de trame
s_n	distance normalisée entre la face du transducteur et un point spécifié sur l'**axe d'alignement du faisceau**
u	tension en bout de câble d'un **hydrophone**
u_i	signal de l'**hydrophone** pour le i-ème point de balayage
u_n	tension de bruit en valeur efficace
z	distance entre la face du **transducteur** et un point spécifié sur l'**axe d'alignement du faisceau**
z_j	distance entre la face du **transducteur** et le plan de mesure (perpendiculaire à l'**axe d'alignement du faisceau**) considéré
z_N	distance entre la face du **transducteur** et la dernière valeur maximale de la **pression acoustique efficace** de l'**axe d'alignement du faisceau**
z_p	distance entre la face du **transducteur** et la **pression acoustique efficace de crête** sur l'**axe d'alignement du faisceau**
λ	longueur d'onde ultrasonore
ρ	densité de l'eau

5 Spécifications du champ ultrasonique

Outre les exigences générales spécifiées dans l'IEC 60601-1 et les exigences particulières spécifiées dans l'IEC 60601-2-5, les fabricants doivent déclarer les valeurs nominales des paramètres suivants dans les ouvrages de référence d'accompagnement pour chaque type de **transducteur**:

– la **puissance de sortie assignée** (±20 %);
– la **surface émettrice efficace** (A_{ERN}) du **transducteur** (±20 %);
– l'**intensité efficace** (I_e) pour les mêmes réglages de l'appareil que pour la valeur nominale de la **puissance de sortie assignée** (±30 %);
– la **fréquence d'application acoustique** (f_{awf}) (±10 %);
– le **taux de non-conformité du faisceau** (R_{BN}) (±30 %);
– l'**intensité maximale du faisceau** (±30 %);
– le **type** de **faisceau**;
– la **durée d'impulsion**, la **période de répétition des impulsions** (prp), le **facteur d'utilisation** et le quotient de la **puissance de sortie maximale temporelle** sur la **puissance de sortie** pour chaque réglage de modulation (±5 %);

– la **forme d'onde en modulation** pour chaque réglage de modulation.

Les valeurs données entre parenthèses sont les tolérances qui définissent la plage des valeurs acceptables pour les résultats soit des mesurages de référence des essais de type spécifiés à l'Article 7, soit des mesurages individuels de série spécifiés à l'Article 8. Lorsque l'exigence de tolérance publiée ne peut pas être respectée, alors il convient de consigner le niveau de confiance à 95 % qu'il est possible d'atteindre. Il doit alors être démontré que la valeur consignée, lorsqu'elle est incorporée à la tolérance de manière à produire la valeur "du cas le plus défavorable", reste dans la plage des valeurs acceptables, comme cela est spécifié dans l'IEC 60601-2-5, et pour laquelle l'Annexe A fournit de plus amples informations.

La plage de températures doit être précisée pour les paramètres spécifiés ci-dessus. La plage des tensions d'alimentation doit aussi être spécifiée.

Pour les **appareils à ultrasons pour physiothérapie** qui utilisent un **transducteur** capable de fonctionner à plus d'une valeur nominale de **fréquence d'application acoustique**, les paramètres énumérés ci-dessus doivent être spécifiés pour chaque valeur nominale de la **fréquence d'application acoustique**.

De plus, pour les **appareils à ultrasons pour physiothérapie** qui peuvent utiliser un **adaptateur**, les paramètres énumérés ci-dessus doivent être spécifiés pour chaque combinaison d'**adaptateur** et de **transducteur**.

NOTE Le présent document ne contient aucune exigence relative à la sécurité: ces exigences sont couvertes dans l'IEC 60601-2-5. Toutefois, les exigences de l'IEC 60601-2-5 concernant les paramètres du présent document, ainsi que des recommandations relatives aux performances et à la sécurité sont disponibles dans l'Annexe A.

6 Conditions de mesure et appareils d'essai utilisés

6.1 Généralités

Tous les mesurages réalisés dans l'eau doivent être effectués dans des conditions approximativement en champ libre à une température de 22 °C ± 3 °C.

Lorsque les mesurages sont effectués à d'autres températures, un essai doit être réalisé pour indiquer que les résultats, déterminés selon 7.6 et 8.6, sont indépendants de la température à laquelle les essais ont été réalisés.

De l'eau dégazée doit être utilisée pour le mesurage de la puissance ultrasonore, voir l'Article 7. La quantité d'oxygène dissous dans l'eau dégazée doit être < 4 mg/l pendant tous les mesurages.

NOTE L'eau dégazée est indispensable pour éviter la cavitation quand les appareils de physiothérapie fonctionnent à la **puissance de sortie** maximale ou à une **puissance de sortie** proche. Des informations sur la préparation d'une eau convenant aux mesurages en physiothérapie peuvent être consultées dans l'IEC 61161, l'IEC TR 62781 et en [1][1].

Tous les mesurages doivent être réalisés après la durée d'échauffement spécifiée par le fabricant. Lorsqu'aucune durée de ce type n'est spécifiée, une durée de 30 min doit être utilisée.

6.2 Bac d'essai

Le bac d'essai utilisé pour tous les mesurages des **hydrophones** doit être assez grand pour permettre d'immerger à la fois le **transducteur** et l'**hydrophone.** Il convient que la dimension du récipient soit conforme à l'IEC 62127-1.

1 Les chiffres entre crochets renvoient à la Bibliographie.

La position relative et l'orientation angulaire du **transducteur** et de l'**hydrophone** doivent être réglables pour les besoins de l'alignement conformément à l'IEC 62127-1. Des degrés totaux de liberté de mouvement des deux appareils peuvent être assurés, bien que l'exigence minimale soit que le **transducteur** ou l'**hydrophone** doit posséder trois degrés indépendants de mouvement de translation. Les mesurages doivent être réalisés dans des conditions en champ libre. Pour obtenir ces conditions, il peut être nécessaire de garnir les parois du bac d'essai, ainsi que les montants utilisés pour maintenir le **transducteur** et l'**hydrophone** avec des absorbeurs ou un ou plusieurs réflecteurs d'angle et un ou plusieurs absorbeurs avec un amortissement plus élevé et une dispersion plus faible. Les conditions en champ libre sont suffisamment satisfaites lorsque l'écho global est réduit de plus de 25 dB. Différentes méthodes peuvent être utilisées pour vérifier la conformité de la réduction de l'écho des matériaux utilisés pour le revêtement du récipient.

La conformité pour la réduction d'écho global d'un absorbeur acoustique peut être vérifiée à l'aide du mode opératoire décrit dans l'IEC TS 63081. Lorsque la réduction d'écho est déterminée, elle doit être mesurée à la ***fréquence d'application acoustique*** *du* ***transducteur*** *soumis à l'essai au moyen d'****ultrasons*** *à salve d'impulsions avec l'absorbeur acoustique situé dans le* ***champ lointain*** *du* ***transducteur ultrasonique*** *piloté séparément. L'amplitude de pression de la réflexion sur la face avant de l'absorbeur acoustique, $p_{absorbeur}$, est comparée à celle produite par un réflecteur plan parfait, $p_{réflecteur}$. L'alignement de l'absorbeur acoustique et du réflecteur de référence doit être quasi perpendiculaire à l'****axe d'alignement du faisceau****, avec inclinaison de l'absorbeur et du réflecteur de manière que le signal réfléchi puisse être intercepté par l'****hydrophone****. Étant donné que le coefficient de réflexion d'amplitude d'un réflecteur de référence $R_{p,réflecteur}$, tel qu'un réflecteur en acier inoxydable ($R_{p,réflecteur}$ = 0,938 9) est légèrement inférieur à celui d'un réflecteur parfait ($R_{p,réflecteur}$ = 1), l'amplitude de pression de réflexion mesurée $p_{absorbeur}$ peut être ajustée afin de tenir compte de la réflexion imparfaite selon*

$$\hat{p}_{\text{absorbeur}}(f) = p_{\text{absorbeur}}(f) \cdot R_{p,\text{réflecteur}} \tag{6}$$

La réduction d'écho ERD en décibels (dB) est alors calculée par

$$ERD = -20\, log_{10}\left[\frac{\hat{p}_{\text{absorbeur}}}{p_{\text{réflecteur}}}\right] \text{dB} \tag{7}$$

Lorsqu'un réflecteur de référence est utilisé, son épaisseur doit être suffisante pour que les réflexions de sa surface arrière n'introduisent pas des artéfacts de mesure indésirables.

La conformité du bac d'essai aux conditions en champ libre est vérifiée en relevant la constance du produit $pms_t\, s^2$ (voir 7.4.7) après achèvement des mesurages spécifiés à l'Article 7.

NOTE Pour certains **transducteurs,** des **ultrasons** réfléchis par retour sur le **transducteur** peuvent modifier la **puissance de sortie**, particulièrement en cas de réflexions cohérentes à partir des absorbeurs à surfaces lisses planes. Dans ce type de cas, une meilleure approximation des conditions en champ libre peut être obtenue au moyen d'absorbeurs acoustiques à surface granulée.

6.3 Hydrophone

Tous les mesurages de la pression doivent être réalisés à l'aide d'un **hydrophone**, par exemple, avec un élément actif en polymère piézoélectrique ou en céramique. Le signal électrique émis par l'**hydrophone** peut être amplifié pour une exactitude de mesure adaptée. Le rayon efficace maximal de l'**hydrophone** utilisé pour les mesurages doit être a_{max} tel que:

$$a_{max} / \lambda \leq 0,4 \quad (8)$$

NOTE 1 Pour plus d'informations sur l'utilisation des **hydrophones**, voir l'IEC 62127-1.

NOTE 2 L'influence du rayon efficace de l'**hydrophone** sur le mesurage est décrite à l'Annexe H.

NOTE 3 L'IEC 62127-3 fournit des informations sur le rayon efficace ou la taille de l'**hydrophone** en fonction de la fréquence, ainsi que sa déduction à partir des mesurages de réponse directionnelle.

6.4 Mesurage du signal de crête efficace

La tension $u_L(t)$ mesurée en bout de câble au niveau de l'**hydrophone** doit être associée à la **pression acoustique instantanée** p qui applique la **sensibilité chargée en bout de câble** $\underline{M}_L$ de l'**hydrophone** conformément à l'IEC 62127-1. Lorsque la déformation due aux effets d'une propagation non linéaire est négligeable, l'approximation de la bande étroite peut être appliquée, et la **pression acoustique instantanée** peut être déterminée à partir de l'équation

$$p(t) = u_L(t) / |\underline{M}_L(f_{awf})| \quad (9)$$

où $|\underline{M}_L(f_{awf})|$ est le module de la **sensibilité chargée en bout de câble** de l'**hydrophone** à la **fréquence d'application acoustique**. Toutefois, en pratique, les valeurs absolues de la pression acoustique ne sont pas exigées puisque l'analyse des données mesurées dans le présent document repose sur des mesurages relatifs pour l'**hydrophone**.

NOTE 1 Pour de plus amples informations sur les critères pour l'approximation de la bande étroite, et des méthodes alternatives pour les mesurages à large bande qui utilisent la sensibilité dépendant de la fréquence de **l'hydrophone**, voir l'IEC 62127-1.

NOTE 2 Pour de plus amples informations sur la détermination de la sensibilité de l'**hydrophone**, voir l'IEC 62127-2.

Les références suivantes à la pression acoustique se rapportent à la **pression acoustique efficace** par commodité. En fait, lorsque la déformation due aux effets d'une propagation non linéaire est négligeable, auquel cas la **pression acoustique à la crête temporelle** est proportionnelle à la **pression acoustique efficace** parallèlement à l'augmentation de la tension d'excitation du **transducteur ultrasonique**, la **pression acoustique à la crête temporelle** peut également être choisie. Il est nécessaire que tous les mesurages reposent sur la même méthode.

La linéarité de la réponse de la combinaison de l'**hydrophone**, de l'**hydrophone**/amplificateur et du dispositif de détection en valeur efficace ou en valeur de crête doit être déterminée et, lorsque cela est approprié, des corrections doivent être apportées aux données mesurées.

*La conformité de la linéarité doit être vérifiée à l'aide d'un **transducteur ultrasonique** linéaire parfaitement caractérisé, et par mesure du signal reçu par l'**hydrophone** et le dispositif de mesure en fonction de l'excitation en tension appliquée au **transducteur ultrasonique**.*

7 Modes opératoires et mesurages de référence pour les essais de type

7.1 Généralités

Les modes opératoires spécifiés de 7.2 à 7.4 doivent être utilisés pour déterminer les valeurs de référence des essais de type, relatives aux paramètres spécifiés en 7.5.

Tout **appareil à ultrasons pour physiothérapie** qui contient des circuits de contrôle de la sortie acoustique du **transducteur ultrasonique** en réponse aux modifications de l'impédance acoustique du milieu de propagation doit être configuré de manière à désactiver les circuits de contrôle si cela est possible.

7.2 Puissance de sortie assignée

La **puissance de sortie** de l'**appareil à ultrasons pour physiothérapie** doit être déterminée conformément à l'IEC 61161. La **puissance de sortie assignée** doit être déterminée par réglage de toutes les commandes de l'appareil pour obtenir la **puissance de sortie** maximale. Pour éviter la cavitation, de l'eau dégazée doit être utilisée entre la face de sortie du **transducteur** et l'entrée du dispositif de mesure de la puissance. La quantité d'oxygène dissous dans l'eau dégazée doit être < 4 mg/l pendant tous les mesurages. L'incertitude globale de mesure, exprimée pour un niveau de confiance à 95 %, doit être déterminée (voir 9.3) et doit être inférieure à ±15 %. Les mesurages doivent pouvoir être identifiés par rapport à des étalons de mesure nationaux. La **puissance de sortie assignée maximale absolue** doit être déterminée à partir de la somme de la **puissance de sortie assignée**, de l'incertitude globale pour la valeur moyenne de la **puissance de sortie assignée** mesurée et de l'accroissement maximal de la **puissance de sortie assignée** pour une variation de ±10 % de la tension d'alimentation nominale. (Voir l'Annexe F.)

7.3 Mesurages de l'hydrophone

Le **transducteur** doit être mis en place dans le bac d'essai selon l'Article 6.

Tous les mesurages de la **surface émettrice efficace** doivent être réalisés avec l'appareil réglé pour un mode à **onde entretenue** avec des intensités suffisamment faibles pour éviter la cavitation. L'utilisation d'eau dégazée dans le dispositif de mesure constitue une bonne pratique qui permet d'assurer l'absence de bulles d'air à la surface du **transducteur** ou sur l'**hydrophone**.

NOTE 1 Les mesurages de la **surface de la section droite du faisceau** sont réalisés à faible puissance pour protéger les **hydrophones** à aiguille utilisés. La validité de l'extrapolation de ces valeurs pour des niveaux de puissance plus élevés, qui sont plus typiques des traitements thérapeutiques, est démontrée à l'Annexe G.

NOTE 2 Les **transducteurs** avec $a \leq 10$ mm, comparés aux **transducteurs** de plus grandes dimensions qui fonctionnent à des réglages de sortie d'**appareils** similaires, ont produit des niveaux plus élevés de **pression acoustique à la crête temporelle**. Pour les **transducteurs** qui présentent une **fréquence d'application acoustique** de 1 MHz ou moins, cette situation augmente le risque de cavitation. La limite inférieure de 0,2 W/cm^2 pour ces **transducteurs** de ka réduit permet de réduire le plus possible cette probabilité.

Pour réduire les effets éventuels des réflexions acoustiques sur le signal reçu de l'**hydrophone**, il est admis de mesurer l'hydrophone avec l'**appareil à ultrasons pour physiothérapie** qui fonctionne en mode à salve d'impulsions produisant une **onde modulée en amplitude**. Lorsque les mesurages sont effectués de cette manière, il doit être démontré que la dérivation des paramètres mesurés par rapport au champ acoustique de l'**onde modulée en amplitude** est équivalente à celle des paramètres déterminés dans le cas de l'**onde entretenue**. Il convient également d'évaluer l'effet des mesurages dans le cas du champ acoustique de l'**onde modulée en amplitude** sur les incertitudes des valeurs nominales des paramètres énumérés à l'Article 5.

L'**axe d'alignement du faisceau** du **transducteur** doit être établi par exploration par **hydrophone** conformément à l'IEC 62127-1. La surface du second plan (voir 3.12) doit être initialement choisie pour $A_{\mathrm{ERN}}/(3\pi\lambda)$. S'il n'est pas possible de situer une crête isolée à cette distance ou à proximité, la distance la plus grande de $2A_{\mathrm{ERN}}/(\pi\lambda)$ doit être choisie. Si cette dernière distance est trop grande, placer un autre plan de mesure à une distance suffisante du premier pour déterminer avec fiabilité l'**axe d'alignement du faisceau**. Après alignement, un tracé axial doit être effectué le long de l'**axe d'alignement du faisceau** et la distance du plan de la **pression acoustique efficace maximale**, z_{p}, et la position du dernier maximum axial, z_N, doivent être déterminées. Les valeurs z_{p} et z_N peuvent être égales.

La dimension du pas du tracé axial doit généralement être comprise entre 0,5 mm et 1,0 mm et ne doit pas dépasser 2 mm.

La **fréquence d'application acoustique** doit être déterminée avec l'**hydrophone** placé à une distance z_p du **transducteur**.

Avec l'**hydrophone** placé au même endroit, la **durée d'impulsion**, la **période de répétition des impulsions** et le **facteur d'utilisation** doivent être déterminés, et la **forme d'onde en modulation** doit être enregistrée pour les différents réglages de modulation de l'**appareil**. Le quotient de la **pression acoustique à la crête temporelle** à la **pression acoustique efficace** doit être déterminé pour chaque réglage de modulation. La **puissance de sortie maximale temporelle** doit alors être déterminée au moyen de la **puissance de sortie** déterminée en 7.2.

7.4 Surface émettrice efficace

7.4.1 Mesurages de la surface émettrice efficace

La **surface émettrice efficace**, A_{ER}, du **transducteur** doit être déterminée par un balayage de trame du champ acoustique dans un plan perpendiculaire à l'**axe d'alignement du faisceau** à 0,3 cm de la face de sortie du **transducteur,** à l'aide d'un **hydrophone**. Par suite de ce balayage, la **surface émettrice efficace** du **transducteur** doit être déduite de la **surface de la section droite du faisceau**, A_{BCS}. Les exigences générales pour les balayages de trame sont données aux Articles B.1 et B.2. Le mode opératoire réel pour les mesurages de référence et l'analyse des résultats sont donnés de 7.4.2 à 7.4.7. Dans les conditions normales d'essai, les résultats des méthodes d'essai décrites doivent produire une incertitude globale dans la détermination de la **surface émettrice efficace** (à un niveau de confiance à 95 %) de ±10 %.

Pour la détermination du **taux de non-conformité du faisceau**, R_{BN}, dans les conditions normales d'essai, les méthodes d'essai doivent obtenir une incertitude de mesure (à un niveau de confiance à 95 %) inférieure à ±15 %.

7.4.2 Positionnement de l'hydrophone

Avec l'**hydrophone** à la distance z_p, sa position doit être ajustée dans le plan perpendiculaire à l'**axe d'alignement du faisceau** pour obtenir la **pression acoustique efficace maximale**, $p_{max,RMS}$, dans le champ.

Cette opération doit être réalisée soit par un balayage de trame dans une zone limitée du champ acoustique, soit par translation manuelle.

7.4.3 Détermination de la surface de la section droite du faisceau

La **surface de la section droite du faisceau** doit être déterminée à 0,3 cm de la face de sortie du **transducteur**, et à la position du dernier maximum axial, z_N. L'analyse des balayages de trame doit être effectuée selon l'Article B.3. L'analyse fournit les **surfaces de la section droite du faisceau**, A_{BCS}(0,3 cm) et $A_{BCS}(z_N)$ et la **pression acoustique carrée moyenne totale**, pms_t, pour chaque plan de mesure.

7.4.4 Détermination du gradient de régression linéaire

Le **gradient de régression linéaire**, m, et le **coefficient de régression linéaire**, Q, [$Q = m/A_{BCS}$(0,3 cm)] doivent être déterminés.

7.4.5 Détermination du type de faisceau

Le **type de faisceau** doit être déterminé par:

$$\begin{array}{ll} Q \geq 0{,}1\ \text{cm}^{-1} & \textbf{divergent} \\ -0{,}05\ \text{cm}^{-1} \leq Q \leq 0{,}1\ \text{cm}^{-1} & \textbf{parallèle} \\ Q < -0{,}05\ \text{cm}^{-1} & \textbf{convergent} \end{array} \quad (10)$$

7.4.6 Calcul de la surface émettrice efficace

La **surface émettrice efficace**, A_{ER}, du **transducteur** doit être déterminée comme suit:

$$A_{\text{ER}} = F_{\text{ac}} A_{\text{BCS}}(0{,}3\ \text{cm}) = 1{,}333 A_{\text{BCS}}\ (0{,}3\ \text{cm}) \quad (11)$$

NOTE Des études ont indiqué que des valeurs physiquement irréalistes pour la **surface émettrice efficace** du **transducteur** peuvent être obtenues lors de l'application de modes opératoires d'extrapolation linéaire à des balayages effectués dans quatre plans de **transducteurs** de ka réduit. L'analyse décrite ci-dessus, dans laquelle la **surface émettrice efficace** est déterminée à partir de mesurages réalisés dans un plan situé à 0,3 cm de la face de sortie du **transducteur,** produit des données physiquement réalistes.

7.4.7 Calcul du taux de non-conformité du faisceau

Le **taux de non-conformité du faisceau**, R_{BN}, doit être calculé par:

$$R_{\text{BN}} = \frac{p_{\text{max}}^2 \cdot A_{\text{ER}}}{\overline{pms_{\text{t}} \cdot s^2}} \quad (12)$$

où

$$\overline{pms_{\text{t}} \cdot s^2} = \frac{1}{2}\left\{\left[pms_{\text{t}}(0{,}3) \cdot s^2(0{,}3)\right] + \left[pms_{\text{t}}(z_N) \cdot s^2(z_N)\right]\right\} \quad (13)$$

NOTE 1 Bien que $p_{\text{max,RMS}}$ et pms_{t} soient considérés comme des paramètres de pression acoustique ou des paramètres au carré de la pression, seul leur taux est utilisé pour déterminer R_{BN}, la **sensibilité chargée en bout de câble** de l'**hydrophone** n'est donc pas nécessaire.

NOTE 2 Le produit $pms_{\text{t}} \cdot s^2$ se rapporte à la puissance acoustique et est calculé par sommation des valeurs au carré de la pression sur la surface des balayages de trames dans le plan à 0,3 cm du **transducteur,** et également du plan z_N. En théorie, ce produit ne varie pas avec la distance par rapport au **transducteur**.

7.4.8 Exigences d'essai

Les modes opératoires donnés de 7.4.1 à 7.4.7 se rapportent à des **mesurages** réalisés sur un **transducteur**. Après achèvement des mesurages réalisés sur le groupe de **transducteurs** selon les exigences d'échantillonnage du paragraphe 9.1, les valeurs moyennes des différents paramètres spécifiés en 7.5 doivent être déterminées.

7.5 Paramètres des essais de type de référence

Pour les besoins des essais de type de référence, les valeurs des paramètres suivants doivent être déterminées et enregistrées:

– la **puissance de sortie assignée**;
– la **surface émettrice efficace** (A_{ER}) du **transducteur**;
– l'**intensité efficace** (I_e) aux mêmes réglages de l'appareil que la **puissance de sortie assignée**;
– la **fréquence d'application acoustique** (f_{awf});
– la distance entre la face du **transducteur** et la **pression acoustique efficace de crête** sur l'**axe d'alignement du faisceau** (z_p);
– le **taux de non-conformité du faisceau** (R_{BN});
– le **type de faisceau**;
– la **durée d'impulsion**, la **période de répétition des impulsions** (prp) et le **facteur d'utilisation** pour chaque réglage de modulation;
– la **forme d'onde en modulation** pour chaque réglage de modulation.

NOTE Cet ensemble de paramètres peut être utilisé dans le but d'enregistrer les performances d'un seul élément de l'**appareil à ultrasons pour physiothérapie**.

Les valeurs doivent être les valeurs moyennes fondées sur l'échantillonnage spécifié en 9.1. L'incertitude globale à un niveau de confiance à 95 % doit également être déterminée d'après les méthodes spécifiées à l'Annexe J.

De plus, les valeurs maximales absolues ou minimales absolues de certains paramètres doivent être déterminées comme suit.

La **surface émettrice efficace minimale absolue** doit être déterminée en soustrayant l'incertitude globale avec une confiance à 95 % dans la **surface émettrice efficace**, de la valeur moyenne de la **surface émettrice efficace**.

Le **taux de non-conformité du faisceau maximal absolu** doit être déterminé en ajoutant l'incertitude globale avec une confiance à 95 % dans la détermination du **taux de non-conformité du faisceau** à la valeur moyenne du **taux de non-conformité du faisceau**.

7.6 Critères d'acceptation des essais de type de référence

Pour les paramètres énumérés ci-dessous, les critères d'acceptation pour chaque **transducteur** doivent spécifier que les valeurs mesurées compte tenu plus ou moins de l'incertitude globale avec un niveau de confiance à 95 % dans les valeurs mesurées, doivent être totalement comprises dans la plage définie par les valeurs nominales et leurs tolérances spécifiées à l'Article 5. Les paramètres sont les suivants:

– la **puissance de sortie assignée**;
– la **surface émettrice efficace** (A_{ER}) du **transducteur**;
– la **fréquence d'application acoustique** (f_{awf});
– la **durée d'impulsion**, la **période de répétition des impulsions** (prp) et le **facteur d'utilisation** pour chaque réglage de modulation.

Pour le **type de faisceau**, le critère d'acceptation doit spécifier que le **type de faisceau** doit être le même que le **type de faisceau** nominal spécifié à l'Article 5.