

TECHNICAL SPECIFICATION



Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems

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TECHNICAL SPECIFICATION



Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems

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**ULTRASONICS – FIELD CHARACTERIZATION – SPECIFICATION
AND MEASUREMENT OF FIELD PARAMETERS FOR HIGH INTENSITY
THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS**

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The text of this technical specification is based on the following documents:

Enquiry draft	Report on voting
87/521/DTS	87/545/RVC

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

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

NOTE 1 The following point types are used:

- Requirements: in roman type
- Notes: small roman type
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: in *Times New Roman + Italic*.

NOTE 2 There are some inconsistencies in font type for symbols and formulae between some of the normative references and this technical specification. They will be resolved in a future revision of the normative references.

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

- transformed into an International standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

The use of **high intensity therapeutic ultrasound (HITU)** has advanced to the point where systems have achieved clinical approval for general use in numerous countries. Medical applications and product development are continuing rapidly. Fast development in preclinical medicine, clinical medicine, and product manufacture has created an urgent need to standardize measurements of the basic acoustic parameters and the field characteristics of HITU. In order to promote the further development of HITU and to ensure its safe and effective use, common technical Specifications are required.

This technical specification is relevant to the measurement and specification of ultrasound fields intended for medical therapeutic purposes. It addresses the requirements for **high intensity therapeutic ultrasound (HITU)** fields, including those generally referred to as **high intensity focused ultrasound (HIFU)**. Lithotripsy and physiotherapy are excluded, since there are existing International Standards for these applications.

As described in Annex A, because measurement at full output power from HITU systems still presents technical challenges, this standard specifies measurement methods at relatively low output levels and methodology for extrapolating these to higher therapeutic level fields.

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ULTRASONICS – FIELD CHARACTERIZATION – SPECIFICATION AND MEASUREMENT OF FIELD PARAMETERS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS

1 Scope

This technical specification is applicable to **high intensity therapeutic ultrasound (HITU)** devices, specifying:

- relevant parameters for quantifying the field;
- measurement methods at relatively low output levels and methodology for extrapolating these to higher therapeutic level fields;
- consideration of sidelobes and pre-focal maxima;
- parameters relevant to HITU transducers of different construction and geometry, including non-focusing, focusing with or without lenses, collimated, diverging and convergent transducers, multi-element transducers, scanning transducers and multiple sources.

This technical specification is intended to support the ultrasonic measurement requirements given in IEC 60601-2-62.

These specifications would have use in quality assurance, safety testing, and the standardization of communications regarding the clinical performance of HITU systems. Where possible, this technical specification incorporates specifications from other related standards.

This technical specification does *not* apply to the following types of devices, which are covered by other standards:

- lithotripters (see IEC 61846);
- surgical equipment (see IEC 61847);
- physiotherapy devices (see IEC 61689).

Throughout this technical specification SI units are used. In the specification of certain parameters, such as beam-areas and intensities, it may be convenient to use decimal multiples or sub-multiples. For example, beam-area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2 .

2 Normative references

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

IEC 60050 (all parts), *International Electrotechnical Vocabulary* (available at <http://www.electropedia.org>)

IEC 60601-2-62, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment*

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

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

IEC 61828:2001, *Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields*

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

IEC 62127-1:2007/AMD1:2013

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

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

IEC 62555, *Ultrasonics – Power measurement – High intensity therapeutic ultrasound (HITU) transducers and systems*

ISO/IEC Guide 98-3:2008: *Guide to the expression of uncertainty in measurement (GUM:1995)*

3 Terms and definitions

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

3.1

acoustic pulse waveform

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

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

[SOURCE: IEC 62127-1:2007, 3.1]

3.2

acoustic repetition period

arp

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

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

[SOURCE: IEC 62127-1:2007, 3.2]

3.3

acoustic frequency

acoustic-working frequency

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

Note 1 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 3.3.1 and 3.3.2.

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]

3.3.1

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: This frequency is intended for continuous-wave systems only.

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.3.1, modified – The second and third notes in the original definition have been deleted.]

3.3.2

arithmetic-mean acoustic-working frequency

f_{awf}

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

Note 1 to entry: This frequency is intended for pulse-wave systems only.

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.

Note 4 to entry: See IEC 62127-1 for methods of determining the arithmetic-mean acoustic working frequency.

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.3.2, modified – A fourth note to entry has been added to the definition.]

3.4

azimuth axis

axis formed by the junction of the **azimuth plane** and the **source aperture plane** (measurement) or **transducer aperture plane** (design)

SEE: Figures 1 to 4.

Note 1 to entry: The selection of this axis is arbitrary for a circularly-symmetric HITU transducer without a hole in its centre but is perpendicular to the elevation axis.

Note 2 to entry: If a HITU transducer has a hole in its centre, within which is a diagnostic imaging transducer, then this axis is aligned with the azimuth axis of the imaging transducer.

[SOURCE: IEC 61828:2001, 4.2.7, modified – Two notes to entry have been added.]

3.5

azimuth plane

for a scanning **ultrasonic transducer**: this is the **scan plane**; for a non-scanning **ultrasonic transducer**: this is the **principal longitudinal plane**

SEE: Figure 1.

[SOURCE: IEC 61828:2001, 4.2.8, modified – A note in the original has been deleted.]

3.6

bandwidth

BW

difference in the most widely separated frequencies f_1 and f_2 at which the magnitude of the acoustic pressure spectrum becomes 3 dB below the peak magnitude, at a specified point in the acoustic field

Note 1 to entry: **Bandwidth** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.6]

3.7

beam area

$A_{b,6}$, $A_{b,12}$, $A_{b,20}$

area in a specified plane perpendicular to the **beam axis** consisting of all points at which the **pulse-pressure-squared integral** is greater than a specified fraction of the maximum value of the **pulse-pressure-squared integral** in that plane

Note 1 to entry: If the position of the plane is not specified, it is the plane passing through the point corresponding to the maximum value of the **pulse-pressure-squared integral** in the whole acoustic field.

Note 2 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced everywhere in the above definition by any linearly related quantity, e.g.:

- a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,
- b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

Note 3 to entry: Some specified fractions are 0,25 and 0,01 for the -6 dB and -20 dB beam areas, respectively.

Note 4 to entry: **Beam area** is expressed in square metres (m²).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.7, modified – the symbol has been modified to include $A_{b,12}$.]

3.8

beam axis

straight line that passes through the **beam centrepoints** of two planes perpendicular to the line which connects the point of maximal **pulse-pressure-squared integral** with the centre of the **external transducer surface plane**

SEE: Figure 1.

Note 1 to entry: The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal scan lines (x and y axes) used for the first plane.

Note 2 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.:

- a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,
- b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

[SOURCE: IEC 62127-1:2007, 3.7]

3.9

beam centrepoint

position determined by the intersection of two lines passing through the **beamwidth midpoints** of two orthogonal planes, xz and yz

[SOURCE: IEC 61828:2001, 4.2.13.]

3.10

beam maximum

b_m

maximum measured **pulse-pressure-squared integral** on the **beam axis**

3.11

beam maximum depth

L_{bm}

smallest distance between two points on the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the **beam axis** by 6 dB

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689.

Note 2 to entry: **Beam maximum depth** is expressed in metres (m).

3.12

beam maximum point

position on the **beam axis** where the maximum **pulse-pressure-squared integral** is measured

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave by the mean square acoustic pressure as defined in IEC 61689.

3.13

beam maximum volume

V_{bm}

volume in a specified space, consisting of all points at which the **pulse-pressure-squared integral** is greater than -6 dB of the **pulse-pressure-squared integral** value at the **beam maximum point**

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689.

Note 2 to entry: **Beam maximum volume** is expressed in cubic metres (m³).

3.14

beamwidth midpoint

linear average of the location of the centres of **beamwidths** in a plane

Note 1 to entry: The average is taken over as many beamwidth levels given in Table B.2 of IEC 61828:2001, as signal level permits.

[SOURCE: IEC 61828:2001, 4.2.17, modified – The second sentence of the original definition has been transformed into a note to entry here.]

3.15

beamwidth

w_6, w_{12}, w_{20}

greatest distance between two points on a specified axis perpendicular to the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the specified axis by a specified amount

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.:

- a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,
- b) in cases where signal synchronisation with the scanframe is not available, the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

Note 2 to entry: Commonly used **beamwidths** are specified at –6 dB, –12 dB and –20 dB levels below the maximum. The decibel calculation implies taking 10 times the logarithm of the ratios of the integrals.

Note 3 to entry: **Beamwidth** is expressed in metre (m).

[SOURCE: IEC 62127-1:2007, 3.11]

3.16 central scan line

for automatic scanning systems, the ultrasonic scan line closest to the symmetry axis of the **scan plane**

[SOURCE: IEC 62127-1:2007, 3.13]

3.17 clinical driving conditions

settings of duty factor and **transducer driving voltage** when an ultrasonic transducer is operated for purposes of treatment

3.18 diametrical beam scan

set of measurements of the **hydrophone** output voltage made while moving the **hydrophone** in a straight line passing through a point on the **beam axis** and in a direction normal to the **beam axis**

Note 1 to entry: The **diametrical beam scan** may extend to different distances on either side of the **beam axis**.

[SOURCE: IEC 62127-1:2007, 3.14]

3.19 distance z_e

z_e
distance along the **beam axis** between the **patient entry plane** and the **external transducer surface plane**

Note 1 to entry: **Distance** z_e is expressed in metres (m).

3.20 distance z_{slpta}

z_{slpta}
distance along the **beam axis** between the plane containing the **side-lobe peak temporal average intensity** and the **source aperture plane**

Note 1 to entry: **Distance** z_{slpta} is expressed in metres (m).

3.21 distance z_p

z_p
distance along the **beam axis** between the plane containing the **focal point** (or for non-focusing transducers, to the plane containing the **beam maximum**), and the **source aperture plane**

Note 1 to entry: **Distance** z_p is expressed in metre (m).

3.22 duty factor

 F_d

ratio of the **pulse duration** to the **pulse repetition period**

[SOURCE: IEC 60469:2013, 3.2.9, modified – Reference to the specific context of a periodic pulse train has been removed and the original note has been deleted.]

3.23 effective focusing surface

surface of constant phase whose periphery intersects the **external transducer surface plane**

Note 1 to entry: In the case of arrays, focusing results from applying a phase delay to the electrical excitation applied to each element of an array to produce focusing and steering of a **scan line**. In this case, a total phase delay along a line normal to each element may be calculated by adding the excitation's phase delay to the propagation delay along that line corresponding to the sound speed and distance along the line. A surface of constant phase may then be defined as a surface intersecting all such normals, such that all points of intersection have the same total phase.

3.24 effective hydrophone radius

 a_h, a_{h3}, a_{h6}

radius of a stiff disc receiver **hydrophone** that has a predicted directional response function with an angular width equal to the observed angular width

Note 1 to entry: The angular width is determined at a specified level below the peak of the **directional response** function. For the specified levels of 3 dB and 6 dB, the radii are denoted by a_{h3} and a_{h6} respectively.

Note 2 to entry: The radius is usually the function of frequency. For representative experimental data, see [1¹]

Note 3 to entry: **Effective hydrophone radius** is expressed in metres (m).

[SOURCE: IEC 62127-3, 3.2.]

3.25 effective path length

 d_{eff}

distance that is the equivalent total acoustical path length (between a specified field point and a specified point on the effective focusing surface of a transducer)

Note 1 to entry: In the case of a transducer with a lens, the part of the path through the lens is multiplied by the ratio c_W / c_L where c_L is lens speed of sound and c_W is water (or measurement medium) speed of sound

Note 2 to entry: In most cases, this definition applies to transducers of known construction; otherwise, it can be measured as time delay between the two points specified above divided by the water (or measurement medium) speed of sound. See also **geometric focus** and **effective focusing surface**.

Note 3 to entry: **Effective path length** is expressed in metres, (m).

3.26 effective radius of a non-focusing ultrasonic transducer

 a_t

radius of a perfect disc piston-like **ultrasonic transducer** that has a predicted axial acoustic pressure distribution approximately equivalent to the observed axial acoustic pressure distribution over an axial distance until at least the last axial maximum has passed

Note 1 to entry: **Effective radius of a non-focusing ultrasonic transducer** is expressed in metres (m).

Note 2 to entry: A transducer with a hole in its centre does not have an effective radius.

¹ Numbers in square brackets refer to the Bibliography.

3.27 effective wavelength

 λ

longitudinal speed of sound in the propagation medium divided by the **acoustic-working frequency**

Note 1 to entry: **effective wavelength** is expressed in metre (m).

3.28 electric load impedance

 Z_L

complex electric input impedance (consisting of a real and an imaginary part) to which the **hydrophone** unit output cable is connected or is to be connected

Note 1 to entry: **Electric load impedance** is expressed in ohm (Ω).

[SOURCE: IEC 62127-3:2007, 3.3, modified – The original definition specifies "hydrophone or hydrophone assembly output" instead of "hydrophone unit output cable".]

3.29 elevation axis

line in the **source aperture plane** (measurement) or **external transducer surface plane** (design) that is perpendicular to the **azimuth axis**

SEE: Figures 1 to 4.

Note 1 to entry: The selection of this axis is arbitrary for a circularly-symmetric HITU transducer without a hole in its centre.

Note 2 to entry: If a HITU transducer has a hole in its centre within which is a diagnostic imaging transducer, then this axis is aligned with the elevation axis of the imaging transducer.

[SOURCE: IEC 61828:2001, 4.2.25, modified – The reference in the original definition to "transducer surface plane" has been changed to specify "**external transducer surface plane**" and two notes to entry have been added to the definition.]

3.30 elevation plane longitudinal plane containing the elevation axis

[SOURCE: IEC 61828:2001, 4.2.26, modified – An indication that the plane is orthogonal to the **azimuth axis** has been deleted from the definition.]

3.31 end-of-cable loaded sensitivity of a hydrophone or hydrophone-assembly

 $M_L(f)$

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

Note 1 to entry: **End-of-cable loaded sensitivity** is expressed in volt per pascal (V/Pa).

[SOURCE: IEC 62127-3:2007, 3.5, modified – The symbol has changed from M_L to $M_L(f)$.]

3.32**end-of-cable open-circuit sensitivity**
end-of-cable open-circuit sensitivity of a hydrophone $M_c(f)$

ratio of the instantaneous open-circuit voltage at the end of any integral cable or output connector of a **hydrophone** 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 open-circuit sensitivity** is expressed in volts per pascal (V/Pa).

[SOURCE: IEC 62127-3:2007, 3.6, modified – The symbol has changed from M_c to $M_c(f)$ and the second note of the original definition has been deleted.]

3.33**external transducer surface**
external transducer aperture

part of the surface of the **ultrasonic transducer** or **ultrasonic transducer element group** assembly that emits ultrasonic radiation into the propagation medium

Note 1 to entry: This surface is assumed to be accessible for measurements using a hydrophone in a chosen propagation medium (usually water).

Note 2 to entry: This surface is either directly in contact with the patient or is in contact with a water or liquid path to the patient.

[SOURCE: IEC 61828:2001, 4.2.27, modified – A variation of the term has been added, the second sentence of the original definition has been transformed into a note to entry and a second note to entry has been added.]

3.34**external transducer surface plane**
external transducer aperture plane

plane that is orthogonal to the **beam axis** of the unsteered beam, or the axis of symmetry of the **azimuth plane** for an automatic scanner, and is adjacent physically to the **ultrasonic transducer** and **external transducer surface**

Note 1 to entry: If the **ultrasonic transducer** is flat, the plane is coplanar with the radiating surface of the **ultrasonic transducer**; if it is concave, the plane touches the periphery of the radiating surface; if it is convex, the plane is tangent to the centre of the radiating surface at the point of contact (see Figure 5).

[SOURCE: IEC 61828:2001, 4.2.72, modified – A variation of the term has been added and both the definition and note to entry have been modified vis-à-vis the original term "transducer aperture plane".]

3.35**far field**

region of the field where $z > z_T$ aligned along the **beam axis** for planar non-focusing transducers

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 International Standard 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: If the shape of the transducer aperture produces several **transition distances**, the one furthest from the transducer is used.

[SOURCE: IEC 62127-1:2007/AMD 1:2013,3.28]

3.36
focal depth

L_6
beam maximum depth for a **focusing transducer**

Note 1 to entry: **Focal depth** is expressed in metre (m).

3.37
focal gain

G_p
gain at beam maximum for a **focusing transducer**

3.38
focal point
beam maximum point for a **focusing transducer**

3.39
focal volume

V_{foc}
beam maximum volume for a **focusing transducer**

Note 1 to entry: **Beam maximum volume** is expressed in cubic metres (m³).

3.40
focusing transducer

electro-acoustic device that produces, at any distance less than half of the **transition distance** from the **source aperture plane**, a -6 dB **beamwidth** in a **longitudinal plane** that is less than one-half the -20 dB **source aperture width**

3.41
gain at beam maximum

G_{bm}
ratio of the maximum pressure amplitude at the beam maximum to the average pressure amplitude at the **external transducer surface plane**

3.42
geometric focal gain

G_{focal}
for the measurement case in which **geometric foci** of all **longitudinal planes** coincide, the square root of the ratio of the **pulse-pressure-squared-integral** at the **geometric focus** divided by the average **pulse-pressure-squared-integral** over the active portion of the transducer (i.e., the region corresponding to the **transducer aperture area**).

For transducers of known construction, the following theoretical definitions apply: For unapodized **transducers** meeting this criterion, the **geometrical focal gain** is theoretically equal to the ratio of the **transducer aperture area** to the product of the **geometric focal length** and the **effective wavelength**.

For an apodized circularly symmetric source, the **geometric focal gain** is $G_{\text{focal}} = \pi z_T / F_{\text{geo}}$ with the **transition distance** defined for apodization.

For unapodized **ultrasonic transducer** cases in which the focuses in different **longitudinal planes** are not coincident, a **geometric focal gain** can be defined for a specified **longitudinal plane** as the ratio of the **transducer aperture width** in that plane to the square root of the product of the **effective wavelength** and the **geometric focal length** in that plane.

For the apodized case for a specified **longitudinal plane** and a rectangular transducer with a **transducer aperture width** L_{TA} , the geometric focal gain is $G_{\text{focal}} = (\pi z_T / F_{\text{geo}})^{1/2}$, where z_T is the **transition distance** defined for transducers with apodization. The overall geometric focal gain is the product of the **geometric focal gains** in each plane if the **geometric focal lengths** are coincident

Note 1 to entry: The theoretical definitions of focal gain do not apply to a HITU transducer with a hole in its centre.

Note 2 to entry: This definition applies only to focusing transducers.

[SOURCE: IEC 61828:2001, 4.2.37, modified – The definition has been modified and expanded and two notes to entry have been added.]

3.43 geometric focal length

F_{geo}
distance from the **geometric focus** to the position where the **beam axis** intersects the **effective focusing surface**

Note 1 to entry: Applies to transducers of known construction.

Note 2 to entry: **Geometric focal length** is expressed in metres (m).

Note 3 to entry: This definition applies only to focusing transducers.

[SOURCE: IEC 61828:2001, 4.2.37, modified – The definition has been modified and two notes to entry have been added.]

3.44 geometric focus

point for which all of the **effective path lengths** in a specified longitudinal plane are equal. Also, point for which the arrival times of all waves from the transducer have the same delay relative to the voltage excitation of the transducer, as viewed in the approximation of geometrical acoustics, neglecting diffraction

Note 1 to entry: This definition applies only to focusing transducers.

[SOURCE: IEC 61828:2001, 4.2.39, modified – The phrase "relative to the voltage excitation of the transducer" has been added to the definition and a note to entry has been added.]

3.45 high intensity therapeutic ultrasound (HITU) equipment HITU equipment

equipment for the generation and application of ultrasound to a patient for therapeutic purposes with the intention to destroy, disrupt or denature living tissues or non-tissue elements (e.g. liquids, bubbles, micro-capsules, etc.) and which aims notably at making treatments through actions of ultrasound having mechanical, thermal and more generally physical, chemical or biochemical effects

Note 1 to entry: Essentially the **HITU equipment** comprises a generator of electric high-frequency power and a transducer for converting this to ultrasound. In many cases this equipment also includes a targeting and monitoring device.

Note 2 to entry: **HITU equipment** may as a side effect by its operation induce hyperthermia, however it should not be confused with this technique, which heats much less rapidly and to much lower therapeutic temperatures (in general 42 °C to 50 °C and thermal equivalent times of 0,2 min to 120 min) as compared with HITU-induced temperature rises in excess of 55 °C and much shorter times and also ultrasound-induced bioeffects by means other than heat.

Note 3 to entry: This definition does not apply to: **ultrasound equipment** used for physiotherapy, **ultrasound equipment** used for lithotripsy or **ultrasound equipment** used for general pain relief.

Note 4 to entry: See Annex AA of IEC 60601-2-62 for a few examples of equipment for which this technical specification should be used.

[SOURCE: IEC 60601-2-62:2013, 201.3.218, modified – the second and third notes to entry have been modified vis-à-vis the original.]

3.46**hydrophone**

transducer that produces electric signals in response to waterborne acoustic signals

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

3.47**hydrophone assembly**

combination of **hydrophone** and **hydrophone pre-amplifier**

[SOURCE: IEC 62127-3: 2007, 3.10]

3.48**hydrophone compressional pressure limit**

P_{+lim}

limit on the maximum compressional pressure that a **hydrophone** can withstand without damage or corruption of the measurement. This quantity is preferably specified by the **hydrophone** manufacturer, or may be set by the user based on measurement evidence

Note 1 to entry: **Hydrophone compressional pressure limit** is expressed in pascals (Pa).

3.49**hydrophone geometrical radius**

a_g

radius defined by the dimensions of the active element of a **hydrophone**

Note 1 to entry: The **hydrophone geometrical radius** is expressed in metres (m).

[SOURCE: IEC 62127-3:2007, 3.8]

3.50**hydrophone intensity limit**

$I_{ta,lim}$

limit on the maximum **temporal-average intensity** that a **hydrophone** can withstand without damage or corruption of the measurement.

Note 1 to entry: This quantity is preferably specified by the hydrophone manufacturer, or may be set by the user based on measurement evidence.

Note 2 to entry: The **hydrophone intensity limit** is expressed in watt per square metre (W/m^2).

3.51**hydrophone pre-amplifier**

active electronic device connected to, or to be connected to, a particular **hydrophone** and reducing its output impedance

Note 1 to entry: A **hydrophone pre-amplifier** requires a supply voltage (or supply voltages).

3.52**hydrophone rarefactional pressure limit**

P_{-lim}

limit on the maximum rarefactional pressures that a **hydrophone** can withstand without damage or corruption of the measurement.

Note 1 to entry: This quantity is preferably specified by the **hydrophone** manufacturer, or may be set by the user based on measurement evidence

Note 2 to entry: The hydrophone rarefactional pressure limit is expressed in pascal (Pa).

3.53**instantaneous acoustic pressure** $p(t)$

pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field (see also IEC 60050-801, 801-21-19)

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

[SOURCE: IEC 62127-1:2007, 3.33]

3.54**instantaneous intensity** $I(t)$

acoustic energy transmitted per unit time in the direction of acoustic wave propagation per unit area normal to this direction at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: **Instantaneous intensity** is the product of **instantaneous acoustic pressure** and particle velocity. It is difficult to measure intensity in the ultrasound frequency range. For the measurement purposes referred to in this International Standard and under conditions of sufficient distance from the **external transducer aperture** (at least one transducer diameter, or an equivalent transducer dimension in the case of a non-circular transducer) the **instantaneous intensity** can be approximated by the **derived instantaneous intensity**.

Note 2 to entry: **Instantaneous intensity** is expressed in watts per square metre (W/m^2)

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.34]

3.54.1**derived instantaneous intensity**

quotient of squared **instantaneous acoustic pressure** and characteristic acoustic impedance of the medium at a particular instant in time at a particular point in an acoustic field

$$I(t) = \frac{p(t)^2}{\rho c} \quad (1)$$

where:

$p(t)$ is the **instantaneous acoustic pressure**;

ρ is the density of the medium;

c is the speed of sound in the medium

Note 1 to entry: For measurement purposes referred to in this International Standard the **derived instantaneous intensity** is an approximation of the **instantaneous intensity**.

Note 2 to entry: Increased uncertainty should be taken into account for measurements very close to the transducer.

Note 3 to entry: **Derived instantaneous intensity** is expressed in watts per square metre (W/m^2).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.78]

3.55**local area factor** F_a

the square root of the ratio of the **source aperture area** to the **beam area** at the point of interest. The relevant local beam area, A_b , is that for which the **pulse-pressure-squared integral** is greater than 0,135 (that is, $1/e^2$) times the maximum value in the cross-section.

$$F_a = \sqrt{\frac{0,69 A_{SAeff}}{A_{b,6}}} \quad (2)$$

Note 1 to entry: If the beam profile is approximately Gaussian at the distance of interest and the area at the -6 dB level, $A_{b,6}$, is known, the local **beam area** can be calculated as $A_b = A_{b,6} / 0,69$: ($0,69 = 3 \ln(10)/10$).

[SOURCE: IEC/TS 61949:2007, 3.11, modified – The source definition refers to "source area" rather than "source aperture area", and the second sentence of the definition has been changed and given in the form of a note to entry.]

3.56
local distortion parameter

σ_q
index which permits the prediction of nonlinear distortion of ultrasound for a specific **ultrasonic transducer**, and is given by σ_q from:

$$\sigma_q = z_p p_m \frac{2\pi f_{awf} \beta}{\rho \cdot c^3} \frac{1}{\sqrt{F_a}} \quad (3)$$

where:

- z_p is the axial distance of the point of interest to the **source aperture plane**
- p_m is the **mean-peak-cycle acoustic pressure** at the point in the acoustic field corresponding to the **spatial-peak temporal-peak acoustic pressure**.
- β is the nonlinearity parameter ($\beta = 3,5$ for pure water at 20 °C);
- f_{awf} is the **acoustic-working frequency**;
- F_a is the **local area factor**

Note 1 to entry: If the **offset distance** is not zero, its value shall be estimated and added to the value of z in Equation (3). This will yield a new and more accurate calculation of the **local distortion parameter**, which shall be used.

[SOURCE: IEC/TS 61949:2007, 3.12, modified – The definition has been changed to refer to nonlinear distortion of ultrasound, and a note to entry has been added.]

3.57
longitudinal plane
plane defined by the **beam axis** and a specified orthogonal axis

SEE: Figure 1.

[SOURCE: IEC 61828:2001, 4.2.43]

3.58
mean peak acoustic pressure

p_m
the arithmetic mean of the **peak-rarefactional acoustic pressure** and the **peak-compressional acoustic pressure**

[SOURCE: IEC/TS 61949:2007, 3.13]

3.59
non-scanning mode

mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that follow the same acoustic path

3.59.1

scanning mode

mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that do not follow the same acoustic path

Note 1 to entry: The sequence of pulses is not necessarily made up of identical pulses. For instance, the use of sequential multiple focal-zones is considered a scanning mode.

3.60

offset distance

d_{offset}

distance between the **source aperture plane** and the **external transducer surface plane**, measured along the beam axis

Note 1 to entry: **Offset distance** is expressed in metre (m).

3.61

patient entry plane

the plane that is closest to the **external transducer surface**, that is orthogonal to the **beam axis**, and that intersects any portion of a patient

3.62

peak acoustic pressure

p_r (or p_-) or p_c (or p_+)

either the **peak-compressional acoustic pressure** or the **peak-rarefactional acoustic pressure**, whichever is largest

Note 1 to entry: The term is used in relative determinations.

Note 2 to entry: **Peak acoustic pressure** is expressed in pascal (Pa).

[SOURCE: IEC 62127-1:2007/AMD 1:2013,3.43, modified – The phrase "whichever is largest" has been added to the definition.]

3.63

peak-compressional acoustic pressure

p_c (or p_+)

maximum positive **instantaneous acoustic pressure** in an acoustic field or in a specified plane during an **acoustic repetition period**

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

Note 2 to entry: The definition of **peak-compressional acoustic pressure** also applies to **peak-positive acoustic pressure** which is also in use in literature.

[SOURCE: IEC 62127-1:2007/AMD 1:2013,3.45]

3.64

peak-rarefactional acoustic pressure

p_r (or p_-)

maximum of the modulus of the negative **instantaneous acoustic pressure** in an acoustic field or in a specified plane during an **acoustic repetition period**

Note 1 to entry: **peak-rarefactional acoustic pressure** is expressed as a positive value.

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

Note 3 to entry: The definition of **peak-rarefactional acoustic pressure** also applies to peak-negative acoustic pressure which is also in use in literature.

[SOURCE: IEC 62127-1:2007/AMD 1:2013,3.44]

3.65**output power** P

time-average ultrasonic power emitted by an **ultrasonic transducer** into an approximately free field under specified conditions in a specified medium, preferably water

Note 1 to entry: **Output power** is expressed in watts (W).

[SOURCE: IEC 61161:2013, 3.3]

3.66**output power under clinical driving conditions** P_c

output power emitted by an **ultrasonic transducer** when it is operated under **clinical driving conditions** of **transducer driving voltage** and **duty factor**

3.67**output power under reduced quasi-linear conditions** P_q

output power emitted by an **ultrasonic transducer** when it is driven under reduced quasi-conditions

3.68**power within the -6 dB area at $z = z_p$ under clinical driving conditions** $P_{c,6}$

power contained within the –6 dB contour in the plane transverse to the beam axis at the **beam maximum point**, under **clinical driving conditions**

3.69**power within the -6 dB area at $z = z_p$ under reduced quasi-linear driving conditions** $P_{q,6}$

power contained within the –6 dB contour in the plane transverse to the beam axis at the **beam maximum point**, under **reduced quasi-linear driving conditions**

3.70**pre-focal peak temporal average intensity** I_{pfpta}

largest local maximum of the **temporal-average intensity** on the **beam axis** which is not within the –6 dB **focal volume** or **beam maximum volume** and is located between the source aperture plane and the **focal volume** or **beam maximum volume**.

Note 1 to entry: **Pre-focal peak temporal average intensity** is expressed in watts per square metre (W/m^2).

3.71**principal longitudinal plane**

plane containing the **beam axis** and two points that define the minimum –6 dB **beamwidth**

SEE: Figures 1 to 4.

Note 1 to entry: The selection of this axis is arbitrary for a circularly-symmetric HITU transducer without a hole in its centre.

Note 2 to entry: If a HITU transducer has a hole in its centre within which is a diagnostic imaging transducer, then this axis is aligned with the azimuth axis of the imaging transducer.

Note 3 to entry: For rectangular ultrasonic transducers, it is the plane parallel to their longest side.

[SOURCE: IEC 61828:2001, 4.2.9, modified – The definition contains the additional phrase "two points that define", and three notes to entry have been added.]

3.72**pulse-average intensity***I_{pa}*

quotient of the **pulse-intensity integral** to the **pulse duration** at a particular point in an acoustic field

Note 1 to entry: This definition applies to pulses and bursts

Note 2 to entry: **Pulse-average intensity** is expressed in watts per square metre (W/m²).

[SOURCE: IEC 62127-1:2007, 3.47, modified – The first note to entry here is additional.]

3.73**pulse duration***t_d*

1,25 times the interval between the time when the time integral of the square of the **instantaneous acoustic pressure** reaches 10 % and 90 % of its final value

Note 1 to entry: The final value of the time integral of the square of the **instantaneous acoustic pressure** is the **pulse-pressure-squared integral**.

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

[SOURCE: IEC 62127-1:2007, 3.48.]

3.74**pulse-intensity integral***p_{ii}*

time integral of the **instantaneous intensity** at a particular point in an acoustic field integrated over the **acoustic pulse waveform**

Note 1 to entry: For measurement purposes referred to in this technical specification, **pulse-intensity integral** is proportional to **pulse-pressure-squared integral**.

Note 2 to entry: The **pulse-intensity integral** is expressed in joules per square metre (J/m²).

[SOURCE: IEC 62127-1]:2007, 3.49

3.75**pulse-pressure-squared integral***p_{psi}*

time integral of the square of the **instantaneous acoustic pressure** at a particular point in an acoustic field integrated over the **acoustic pulse waveform**

Note 1 to entry: The **pulse-pressure-squared integral** is expressed in pascal squared seconds (Pa²s).

[SOURCE: IEC 62127-1]

3.76**pulse repetition period***prp*

time interval between equivalent points on successive pulses or tone-bursts

Note 1 to entry: This applies to single element non-automatic scanning systems and automatic scanning systems.

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

[SOURCE: IEC 62127-1:29007, 3.51]

3.77**pulse repetition rate***pr*

reciprocal of the pulse repetition period

Note 1 to entry: **Pulse repetition rate** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.52]

3.78**quasi-linear**

a condition of the ultrasonic field between the source and a plane at a specified axial depth for which, at every point, less than a specified, small proportion of the energy has transferred from the fundamental frequency to other frequencies through nonlinear propagation effects

Note 1 to entry: For purposes of this TS this condition is met when the local distortion parameter σ_q is less than 0,5.

[SOURCE: IEC/TS 61949:2007, 3.17, modified – A note to entry has been added.]

3.79**reduced quasi-linear driving conditions**

settings under which transducer driving voltage achieves quasi-linear conditions in the field, and under which the duty factor is set so that hydrophone measurements stay below the hydrophone intensity limit

3.80**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]

3.81**scaling factor***S*

the ratio between the acoustic pressure at a location close to the transducer to the acoustic pressure at the same location under **quasi-linear** conditions

[SOURCE: IEC/TS 61949:2007, 3.18, modified – The definition has been shortened and the references to "mean peak acoustic pressure" have been replaced by "acoustic pressure".]

3.82**scan-area***A_s*

for automatic scanning systems, the area on a specified plane (or surface) consisting of all points within the **beam area** of any beam passing through the surface during the scan

Note 1 to entry: The specified plane (or surface) follows the same shape as the **external transducer surface plane**.

Note 2 to entry: The **scan-area** is expressed in square metres (m²).

[SOURCE: IEC 62127-1:2007, 3.54, modified – The note to entry refers to the "external transducer surface plan" instead of "external transducer aperture".]

3.83**scan plane**

for automatic scanning systems, a plane containing all the **ultrasonic scan lines**

[SOURCE: IEC 62127-1:2007, 3.56, modified – The original notes have been deleted.]

3.84**scan repetition period**

srp

time interval between identical points on two successive frames, sectors or scans, applying to automatic scanning systems with a periodic scan sequence only

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

[SOURCE: IEC 62127-1:2007, 3.57, modified – The first note in the original has been deleted.]

3.85**scan repetition rate**

srr

reciprocal of the **scan repetition period**

Note 1 to entry: The **scan repetition rate** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.58]

3.86**side lobe peak temporal average intensity**

$I_{s\text{lpta}}$

maximum value of the **temporal average intensity** measured at a local maximum which is not within the –6 dB **focal volume** (for focusing transducers) or **beam maximum volume** (for non-focusing transducers)

Note 1 to entry: **Side lobe peak temporal average intensity** is expressed in watts per square metre (W/m²).

3.87**source aperture area**

A_{SAeff}

equivalent aperture area for an **ultrasonic transducer**, measured as the –20 dB **pulse-pressure-squared-integral** contour, in the **source aperture plane**

Note 1 to entry: If the HITU transducer is circularly symmetric without a hole in its centre, a radial line scan is sufficient to determine the contour.

Note 2 to entry: If a HITU transducer has a hole in its centre within it, the –20 dB contour does not include the hole.

Note 3 to entry: **Source aperture area** is expressed in square metres (m²).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.82, modified – The definition has been shortened and two new notes to entry have been added.]

3.88**source aperture plane**

closest possible measurement plane to the **external transducer surface plane**, that is perpendicular to the **beam axis**

Note 1 to entry: If the **offset distance** is zero, the **source aperture plane** can be coincident with the **external transducer aperture plane** (see Figs 1-4).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.83, modified – The definition refers to the "external transducer surface plane" rather than the "external transducer aperture", and a note to entry has been added.]

3.89 source aperture width

I_{SA}
in a specified **longitudinal plane**, the greatest –20 dB **beamwidth** along the **line** of intersection between the designated **longitudinal plane** and the **source aperture plane**

SEE: Figure 5.

Note 1 to entry: If the HITU transducer is circularly-symmetric without a hole in its centre, a radial line scan is sufficient to determine the width.

Note 2 to entry: If a HITU transducer has a hole in its centre, the beginning and ending –20 dB points of the width are measured and noted with reference to the centre.

Note 3 to entry: : **Source aperture width** is expressed in metres (m).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.83, modified – Two notes to entry have been added.]

3.90 spatial average intensity under linear conditions

I_{sal}
intensity spatially averaged over the area enclosed by the half-pressure-maximum contour in the plane containing the **focal point** (for focusing transducers) or **beam maximum** (for non-focusing transducers), as determined under linear conditions

Note 1 to entry: **Spatial average intensity under linear conditions** is expressed in watts per square metre (W/m^2).

3.91 spatial-peak temporal-peak acoustic pressure

p_{sptp}

larger of the **peak-positive acoustic pressure** or the **peak-negative acoustic pressure**

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

[SOURCE: IEC 62127-1:2007, 3.63, modified – The definition refers to "peak-positive acoustic pressure" and "peak-negative acoustic pressure" rather than "peak-compressional acoustic pressure" and "peak-rarefactional acoustic pressure".]

3.92 spatial-peak temporal-average intensity

I_{spta}
maximum value of the **temporal-average intensity** in an acoustic field or in a specified plane

Note 1 to entry: For systems in **combined-operating mode**, the time interval over which the temporal average is taken is sufficient to include any period during which scanning may not be taking place.

Note 2 to entry: **Spatial-peak temporal-average intensity** is expressed in watts per square metre (W/m^2).

[SOURCE: IEC 62127-1:2007, 3.62]

3.93 temporal-average intensity

I_{ta}
time-average of the **instantaneous intensity** at a particular point in an acoustic field

Note 1 to entry: The time-average should be taken over an integral number of **acoustic repetition periods**.

Note 2 to entry: **Temporal-average intensity** is expressed in watts per square metre (W/m^2).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.65, modified – The note concerning diagnostic equipment has not been retained.]

3.94

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]

3.95

transducer aperture area

A_{TA}

effective area of an **ultrasonic transducer**, as determined by the -20 dB **pulse-pressure-squared-integral** contour in the **source aperture plane**

Note 1 to entry: If the HITU transducer is circularly-symmetric without a hole in its centre, a radial line scan is sufficient to determine the contour.

Note 2 to entry: If a HITU transducer has a hole in its centre within it, the **transducer aperture area** is the area between the inner and outer -20 dB contours, so that the hole is not counted.

Note 3 to entry: **Transducer aperture area** is expressed in square metre (m^2).

[SOURCE: IEC 61828:2001, 4.2.71, modified – The definition is worded differently and three notes to entry have been added.]

3.96

transducer assembly

those parts of **HITU equipment** comprising the **ultrasonic transducer** and/or **ultrasonic transducer element group**, together with any integral components, such as an acoustic lens or integral stand-off

Note 1 to entry: The **transducer assembly** is usually separable from the ultrasound instrument console.

[SOURCE: IEC 62127-1:2007, 3.69, modified – The definition specifies "HITU equipment" rather than "medical diagnostic ultrasonic equipment".]

3.97

transducer driving voltage

U

voltage supplied to the terminals of the HITU source transducer

Note 1 to entry: **Transducer driving voltage** is expressed in volts (V).

3.98

transducer driving voltage at clinical levels

U_c

the **transducer driving voltage** representative of clinical use

3.99 transducer driving voltage at quasi-linear levels

U_q

maximum **transducer driving voltage** when the acoustic field is quasi-linear at depths less than the position of **spatial-peak-temporal average intensity** z_p

3.100 transition distance

z_T

for a given **longitudinal plane**, for design: the **transducer aperture area** of the **ultrasonic transducer** divided by π times the **effective wavelength** λ , i.e. $A_{TA}/(\pi\lambda)$; for measurements: the **transducer aperture area** is replaced by the **source aperture area** so that the **transition distance** is given by $A_{SAeff}/(\pi\lambda)$.

For design, for an unapodized **ultrasonic transducer** with circular symmetry about the **beam axis**, the **source aperture area** is πa_e^2 , where a_e is the effective radius; therefore the **transition distance** is $z_T = a_e^2/\lambda$.

For design, for an unapodized rectangular **ultrasonic transducer** which has a **transducer aperture width**, L_{TA1} , in a specified **longitudinal plane**, the effective in-plane area is $(L_{TA1})^2$. Therefore, for this plane, the **transition distance** is $z_{T1} = (L_{TA1})^2/(\pi\lambda)$. The **transition distance** for the orthogonal longitudinal plane including the second **transducer aperture width** is $z_{T2} = (L_{TA2})^2/(\pi\lambda)$. Similarly, for measurements in each specified longitudinal plane, the **source aperture width** in that plane is used, or $z_{T1} = (L_{SA1})^2/(\pi\lambda)$; in the other orthogonal plane, $z_{T2} = (L_{SA2})^2/(\pi\lambda)$.

Note 1 to entry: A transducer with a hole in its centre does not have an effective radius; for these cases see [2].

Note 2 to entry: **Transition distance** is expressed in metres (m).

[SOURCE: IEC 61828:2001, 4.2.75, modified – The definition is worded differently and two notes to entry have replaced the original notes.]

3.101 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]

3.102 ultrasonic transducer element

element of an **ultrasonic transducer** that is excited in order to produce an acoustic signal

[SOURCE: IEC 62127-1:2007, 3.74]

3.103 ultrasonic transducer element group

group of elements of an **ultrasonic transducer** which are excited together in order to produce an acoustic signal

[SOURCE: IEC 62127-1:2007, 3.75]

3.104 ultrasonic transducer element group dimensions

dimensions of the surface of the group of elements of an **ultrasonic transducer element group** which includes the distance between the elements, hence representing the overall dimensions

Note 1 to entry: **Ultrasonic transducer element group dimensions** are expressed in metres (m).

[SOURCE: IEC 62127-1:2007, 3.76]

3.105

uncertainty

parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

Note 1 to entry: See the ISO Guide to the Expression of Uncertainty in Measurement [3], 2.2.3.

[SOURCE: IEC 62127-1:2007, 3.77]

3.106

circular wave number

k

the ratio of 2π divided by the **effective wavelength**

3.107

wave vector's vector component along the x -axis or

wave vector's vector component along the y -axis

k_x, k_y

for a plane wave, the wave vector component along a coordinate axis is given by the product of the circular wave number and the cosine of the angle formed between the direction of propagation and that axis, e.g., $k_x = k \hat{r} \cdot \hat{x}$ where \hat{r} is the unit vector in the direction of propagation and \hat{x} is the unit vector in the direction of the x -axis

4 List of symbols

a_h	effective hydrophone radius
a_g	hydrophone geometrical radius
a_t	effective radius of a non-focusing ultrasonic transducer
a_{h3}, a_{h6}	effective hydrophone radius , determined from directional response measurements, at the -3 dB and -6 dB levels
a_{max}	maximum effective radius for a specific hydrophone application
arp	acoustic repetition period
A_b	beam area
$A_{b,6}, A_{b,12}, A_{b,20}$	beam area (at -6 dB and -12 dB and -20 dB levels)
A_g	geometrical area of an ultrasonic transducer
A_{ob}	output beam area
A_s	scan-area
A_{SA}	transducer aperture area
A_{SAeff}	source aperture area
BW	bandwidth
bm	beam maximum
c	speed of sound in the medium (usually water)
d_{eff}	effective path length
d_{offset}	offset distance
F_d	duty factor
f_{awf}	acoustic frequency, acoustic-working frequency
F_a	local area factor

F_d	duty factor
F_{geo}	geometric focal length
G_{focal}	geometric focal gain
G_p	focal gain
G_{bm}	gain at beam maximum
$I(t)$	instantaneous intensity
I_{ob}	output beam intensity
I_{pa}	pulse-average intensity
I_{pfpta}	pre- focal peak temporal average intensity
I_{spta}	spatial-peak temporal-average intensity
I_{ta}	temporal-average intensity
$I_{\text{ta,lim}}$	hydrophone intensity limit
k	circular wave number ($2\pi/\lambda$)
k_x	wave vector's vector component along the x-axis
k_y	wave vector's vector component along the y-axis
L_{SA}	source aperture width
L_6	focal depth
L_{bm}	beam maximum depth
$M_L(f)$	end-of-cable loaded sensitivity of a hydrophone or hydrophone-assembly
$M_C(f)$	end-of-cable open-circuit sensitivity
P	output power of an ultrasonic transducer
P_C	output power under clinical driving conditions
P_q	output power under reduced quasi-linear driving conditions
$P_{c,6}$	power within the –6 dB beam area under clinical driving conditions
$P_{q,6}$	power within the –6 dB beam area under reduced quasi-linear driving conditions
$p(t)$	instantaneous acoustic pressure
p_0	pressure amplitude averaged over transducer aperture area
p_{ii}	pulse-intensity integral
p_{psi}	pulse-pressure-squared integral
p_m	mean peak acoustic pressure
p_{tp}	temporal-peak acoustic pressure
p_{rr}	pulse repetition rate
p_{rp}	pulse repetition period
p_{spr}	spatial-peak rms acoustic pressure
p_{sptp}	spatial-peak temporal-peak acoustic pressure
p_{rms}	rms acoustic pressure
$p_+ (p_c)$	peak-compressional acoustic pressure
$p_- (p_r)$	peak-rarefactional acoustic pressure
$p_{+\text{lim}}$	hydrophone compressional pressure limit
$p_{-\text{lim}}$	hydrophone rarefactional pressure limit
srp	scan repetition period

srr	scan repetition rate
S	scaling factor
t_d	pulse duration
U	transducer driving voltage
U_c	transducer driving voltage at clinical levels
U_q	transducer driving voltage at quasi-linear levels
$v(t)$	instantaneous particle velocity
X_{ob}, Y_{ob}	output beam dimensions
V_{bm}	beam maximum volume
V_{foc}	focal volume
w_6, w_{12}, w_{20}	beamwidth (at –6 dB and –12 dB and –20 dB levels)
z_e	distance z_e between the external transducer surface plane and the patient entry plane
z_p	distance between the source aperture plane and the plane containing the spatial-peak temporal-average intensity
z_{slpta}	distance between the source aperture plane and the position of the side-lobe peak temporal average intensity
z_T	transition distance
Z_L	electric load impedance
β	non-linearity parameter
λ	effective wavelength in a liquid
ρ	density of the medium (usually water)
σ_q	local distortion parameter
ω	$(2\pi f_{awf})$ circular frequency

5 Independent measurement of total acoustic output power

Measurements of total **output power** shall be performed according to the methods of IEC 62555. In some cases the power may be measured using planar scanning of a **hydrophone**, as described in Annex G. In these cases care should be taken to assure that the **hydrophone** measurement is made under quasi-linear conditions (see 7.2.5.1) and within the **hydrophone's** pressure and intensity limits (see 6.1.6 and 6.1.7).

6 Acoustic field measurement: equipment

6.1 Hydrophone

6.1.1 General

It is assumed throughout this technical specification that a **hydrophone** is a device which responds to acoustic waves in such a way that the output voltage is proportional to the acoustic pressure at a specified frequency. If $M_L(f)$ is the **end-of-cable loaded sensitivity of the hydrophone**, the **instantaneous acoustic pressure** $p(t)$ is related to the measured end-of-cable voltage $u_L(t)$ by

$$p(t) = \mathfrak{S}^{-1}[U_L(f)/M_L(f)] \quad (4)$$

where \mathfrak{F}^{-1} represents an inverse Fourier transform, and $U_L(f)$ is the Fourier transform result of $u_L(t)$. Because this technical specification prescribes measurements to be made in linear conditions, a narrow-band approximation as given in IEC 62127-1 may be applied:

$$p(t) = u_L(t) / M_L(f_{\text{awf}}) \quad (5)$$

6.1.2 Sensitivity of a hydrophone

When no **hydrophone pre-amplifier** is used, the sensitivity of the **hydrophone** shall refer to the **end-of-cable loaded sensitivity** and shall be determined for the particular electrical loading conditions.

When a **hydrophone pre-amplifier** is used, the sensitivity of the **hydrophone** shall refer to the **end-of-cable loaded sensitivity** which relates to the particular **hydrophone-assembly**.

NOTE The method outlined in IEC 62127-3 may be used for the determination of **end-of-cable loaded sensitivity** assuming the **end-of-cable open-circuit sensitivity of the hydrophone** is known.

6.1.3 Directional response of a hydrophone

The directional response of the **hydrophone** shall be known.

Symmetry of the directional response shall conform to IEC 62127-3.

There are two reasons to know the directional response of a **hydrophone**. First, it may be necessary as part of the field characterization procedures described in Clause 7, in which case the directional response should be known at the appropriate **acoustic-working frequency**. Secondly, the directional response is used to derive the **effective hydrophone radius**.

6.1.4 Effective hydrophone radius

The **effective hydrophone radius** shall be known and determined following the method described in IEC 62127-3.

6.1.5 Choice of the size of a hydrophone active element

6.1.5.1 General

The choice of the effective hydrophone radius for a specific application shall be determined by consideration of the following:

The effective radius of the element should ideally be comparable with or smaller than one quarter of the effective wavelength, so that phase and amplitude variations do not contribute significantly to measurement uncertainties.

It is not possible, because of the large range of types of **ultrasonic transducers**, to establish a simple relationship between the optimum effective element size of the **hydrophone** and parameters such as the **ultrasonic transducer** dimension, the effective wavelength and the distance from the **ultrasonic transducer**. However, in the **far field** it is reasonable to relax the above criterion. For unfocused circular **ultrasonic transducers**, the following criterion may be used as a guide to the determination of the maximum effective radius a_{max} of a **hydrophone** active element. a_{max} is given by [4]:

$$a_{\text{max}} = \frac{\lambda}{8a_1} (l^2 + a_1^2)^{1/2} \quad (6)$$

where:

- a_1 is the effective radius of the **ultrasonic transducer**;
 l is the distance between the **hydrophone** and the **source aperture plane**
 λ is the effective wavelength corresponding to the **acoustic-working frequency**.

See [4] and [5].

For a focusing **ultrasonic transducer**, the above relationship may still be used. For an **ultrasonic transducer** with a non-circular element, the above relationship may still be used by replacing a_1 by one half the maximum **ultrasonic transducer dimension** or **ultrasonic transducer element group dimension**.

For representative experimental data see [1].

6.1.5.2 Spatial averaging effect

The practical requirement of an adequate signal-to-noise ratio or other considerations can lead to the use of a **hydrophone** with an element size greater than that recommended above. In this case, care should be taken in interpreting measurements as a piezoelectric **hydrophone** is a phase sensitive detector that integrates the complex acoustic pressure over its active element. If applicable, corrections for spatial averaging should be made. See Annex E of IEC 62127-1:2007.

When the **hydrophone** is translated from the position of maximum received signal in any direction normal to the **beam axis** by an amount equal to the **effective hydrophone radius** element, the decrease in signal should be less than 1 dB. If this is not the case, corrections for spatial averaging should be made. See Annex E of IEC 62127-1:2007.

6.1.6 Hydrophone pressure limits

In order to avoid making corrupted measurements or damaging a **hydrophone**, pressure limits shall be defined for the **hydrophone** or **hydrophone assembly** and the user shall not expose the **hydrophone** to pressures beyond these limits. These need to be specified both as a separate positive (i.e. compressional) limit, known as the **hydrophone compressional pressure limit**, p_{+lim} and a negative (rarefactional) limit, known as the **hydrophone rarefactional pressure limit**, p_{-lim} .

p_{+lim} is most likely to arise from electrical saturation limits in a pre- or buffer-amplifier or from severe non-linearity in the **hydrophone's** response (see for example [5] and 3.5.1.2 of [6]) and may be defined as a property of the **hydrophone assembly**. p_{+lim} may be determined according 6.1.8.2 in this case.

p_{-lim} is most likely to arise from delamination of internal **hydrophone** structures, cavitation, or other non-linearity. This quantity is preferably specified by the **hydrophone** manufacturer, or may be set by the user based on measurement evidence.

NOTE p_{+lim} and p_{-lim} may be frequency-dependent.

It is expected that pressure levels within the limits may be maintained by reducing the **driving voltage**, as discussed in 7.2.1 and 7.2.4.

6.1.7 Hydrophone intensity limits

In order to avoid making corrupted measurements or damaging a **hydrophone**, a **temporal-average intensity limit** $I_{ta,lim}$ shall be defined for the **hydrophone** or **hydrophone assembly** and the user shall not expose the **hydrophone** to intensities beyond these limits. $I_{ta,lim}$ may be independent of the pressure limits of 6.1.6, because high **temporal-average intensities** may result in heating of the **hydrophone** beyond acceptable limits, even though peak pressures may be below safe limits in accordance with 6.1.6. It is expected that safe

intensity levels may be maintained by reducing the **duty factor** of the driving voltage signal, as illustrated in 7.2.1 and 7.2.4.

$I_{ta,lim}$ is preferably specified by the **hydrophone's** manufacturer, although it may be set by the user based on measurement evidence. This limit may be frequency dependent, because the absorption of sound energy and its conversion to heat within the **hydrophone** is likely to be frequency dependent.

6.1.8 Hydrophone cable length and amplifiers

6.1.8.1 Cable length

A connecting cable of a length and characteristic impedance which ensures that electrical resonance in the connecting cable does not affect the defined **bandwidth** of the **hydrophone** or **hydrophone-assembly** shall be chosen. The cable shall also be terminated appropriately.

To minimize the effect of resonance in the connecting cable located between the **hydrophone's** sensitive element and a preamplifier or waveform digitizer input, the numerical value of the length of that cable in metre shall be much less than $50/(f_{awf}/\text{MHz} + BW_{20}/\text{MHz})$ where f_{awf} is the **acoustic-working frequency** and BW_{20} is the -20 dB **bandwidth** of the **hydrophone** signal. In most cases a cable length of ≤ 15 cm should be adequate (see [7]).

Attention should be paid to the appropriateness of the output impedance of the **hydrophone/amplifier** in relation to the input impedance of the connected measuring device.

6.1.8.2 Preamplifier linearity

The manufacturer of any pre- or buffer-amplifier shall define the maximum voltage over which the output of the amplifier will be linear with respect to the input voltage, to within 10 %. The manufacturer shall then provide all information necessary to calculate the maximum pressure corresponding to this maximum voltage for the **hydrophone assembly**.

6.2 Requirements for positioning and water baths

6.2.1 General

There are various possible systems that may be used to mount the **ultrasonic transducer** and **hydrophone**. The general performance requirements for such systems are specified here, and these are considered as optimum for the purposes of this technical specification. Alternative positioning systems may be used providing equivalence with those described in this subclause is demonstrated.

Annex C shows a simple configuration of tank, **ultrasonic transducer** and **hydrophone** intended to show only the coordinate axes and degrees of freedom referred to in this technical specification.

6.2.2 Positioning systems

6.2.2.1 Transducer positioning

The **ultrasonic transducer** under test shall be supported using a positioning system such that its face is fully immersed in the water bath and at a distance from any adjacent surface, for instance, a water/air interface, such that reflected ultrasound from this surface does not interfere with the main received signal. For the situation when the surface is parallel to the **beam axis**, the following criterion shall be satisfied.

If z is the distance between the active element of a **hydrophone** and the **source aperture plane** of an **ultrasonic transducer**, c is the speed of sound, and t is the time between the arrival of the direct pulse at the **hydrophone** and the end of the measurement acquisition

period, then the minimum distance, h , between the **beam axis** and the reflecting surface shall be determined from:

$$(z^2 + 4h^2)^{1/2} - z > c t \quad (7)$$

It is preferable to immerse the transducer and not to use a membrane between the **source aperture plane** of the **ultrasonic transducer** and the water bath. If, however, a membrane is needed, then the membrane should be as thin as practicable and should be kept as close to the front surface of the **ultrasonic transducer** as is possible. Close acoustic coupling should be ensured by using a water-based coupling agent, taking care to exclude bubbles of air. Measurements of acoustic parameters should be corrected for transmission loss of the membrane, if significant.

6.2.2.2 Hydrophone positioning

The **hydrophone** shall be set up in the coordinate positioning system such that the normal to the direction of maximum sensitivity of the **hydrophone** is approximately parallel to the anticipated direction of the **beam axis** of the **ultrasonic transducer** to be measured. To avoid effects on the measurements made on continuous wave fields due to reflection of ultrasound from the surface of membrane **hydrophones**, the **hydrophone** may be tilted

NOTE Tilting ensures that the reflected ultrasound either does not interfere significantly with the transducer or is not subsequently reflected from the transducer face, producing interference effects. Two methods used to determine the rotation required are described in Annex B of IEC 62127-1:2007.

6.2.2.3 Spatial positioning

The **hydrophone** and/or the **ultrasonic transducer** shall be supported from a positioning system to allow them to be positioned relative to each other at any desired point within a space with the following degrees of freedom:

- Spatial positioning along three orthogonal axes (named x , y and z), one (designated the z -axis) being the **beam axis** of the active element of the **ultrasonic transducer**.
- To be able to reproduce positions, all translation and rotation systems should be provided with position indicators.
- The repeatability of positioning should be $0,10 \lambda$ or $0,05 \text{ mm}$, whichever is smaller.

After alignment, the z -axis should be parallel to the **beam axis** of the **ultrasonic transducer**.

NOTE It is possible to relax the requirement of the reproducibility for many measurements. A reasonable basis is to relate the precision of the positioning system to the diameter of the active element of the **hydrophone**. In the direction perpendicular to the direction of propagation of the ultrasound, a precision equivalent to 10 % of the diameter of the active element of the **hydrophone** is usually adequate, while in a direction parallel to the propagation direction a precision equivalent to the diameter of the active element is usually adequate.

6.2.3 Water bath

6.2.3.1 General

The size of the measurement vessel shall be such that the **ultrasonic transducer** and **hydrophone** can be moved relative to each other by an amount large enough to permit the active element of the **hydrophone** to be positioned at any point in the acoustic field at which measurements are required.

Means shall be incorporated to minimize effects on the measurement of reflection from any part within the water bath or the walls (see also 6.2.3.2).

In a direction parallel to the **beam axis** for non-automatic scanning systems or the **symmetry axis of the azimuth plane** for automatic scanning systems, the wall of the water bath should be at a distance from the **ultrasonic transducer** which is significantly greater (30 % to

100 %) than the maximum separation distance between the **ultrasonic transducer** and the **hydrophone**.

In a direction perpendicular to the **beam axis** for non-automatic scanning systems or the **symmetry axis of the azimuth plane** for automatic scanning systems, the wall of the water bath should be at a distance which is significantly greater (30 % to 100 %) than the maximum distance of the **hydrophone** from the **beam axis** in the case of non-automatic scanning systems, or from an extreme **scan line** in the case of automatic scanning systems.

The size of the **hydrophone** should also be considered. For membrane **hydrophones**, extra width in the direction perpendicular to the **beam axis** might be needed.

NOTE The criterion for the choice of the size of the water bath referred to above is adequate for **pulse durations** less than 10 μs . For longer **pulse durations**, refer to 6.2.2.1.

6.2.3.2 Lining material

The measurements should be performed under conditions that approximate an acoustic free field. In the case of **ultrasonic transducers** excited under continuous wave conditions, acoustic absorbers should be placed to intercept as much of the ultrasound incident on the walls of the water bath as is possible. For pulsed **ultrasonic transducers**, and when techniques using gated signals are employed for detection of the **hydrophone** signal, it is not essential to use acoustic absorbers. However, it is often advisable to place absorbers on the walls of the water bath at positions such that they intercept the main incident acoustic field from the **ultrasonic transducer**.

The following tests may be used to determine the necessity for acoustic absorbers:

The criterion that may be applied is that acoustic absorbers should be used if reflected ultrasound increases the general background noise level of the **hydrophone** signal uniformly or if spurious **hydrophone** signals are detected in the vicinity of the main received signal.

A convenient test for the presence of spurious signals consists of translating the **ultrasonic transducer** relative to the water bath and the **hydrophone** in the direction along the z axis (see Figure C.1), and observing the signal with an oscilloscope. Some spurious signals are observed to move at least twice the speed of the directly received signal, others are received in an incorrect time window when comparing the **ultrasonic transducer – hydrophone** distance. This test is possible only on pulsed systems.

The free field conditions shall be met sufficiently when the overall echo is reduced by more than 25 dB. Various methods may be used to check the compliance of the echo reduction of the tank lining materials used, with this subclause. One example that may be used to check the absorbing or scattering materials used is given in Annex B of IEC 62127-1.

For measurements in high pressure fields or on high power continuous wave excited **ultrasonic transducers**, cavitation effects can be significant, and, in this case, degassed water shall be used (see Annex I for guidance).

The water should be distilled or de-ionized water at a known temperature. When a single-layer, electrically unshielded membrane [polyvinylidene fluoride (PVDF)] **hydrophone** is used, the electrical conductivity of the water should be less than 5 $\mu\text{S cm}^{-1}$.

6.3 Requirements for data acquisition and analysis systems

The transfer characteristics of the data acquisition and analysis system shall be adequate to ensure that, when used in combination with the **hydrophone**, pre-amplifier and amplifier, the requirements of 6.1.6 to 6.1.8 are met for the combination.

6.4 Requirements and recommendations for ultrasonic equipment being characterized

This technical specification requires that the ultrasonic equipment under test allows adjustment to both the **transducer driving voltage**, and the **duty factor**, in order to assure that quasi-linear conditions which satisfy the **hydrophone's** pressure and intensity limits are met.

If using the projection method as discussed in Annex E wherein a pre-focal plane is measured, this requirement may be relaxed.

Also, the measurements are to be undertaken with scanning frozen, if the system under test is an automatic scanning system.

To conduct the measurements in this technical specification, an electrical signal synchronized to the excitation of the transducer is recommended. If this cannot be obtained from the device under test directly, alternative methods include the use of an external electromagnetic pick-up coil or an auxiliary acoustic sensor placed in the ultrasonic field.

7 Measurement procedure

7.1 General

The procedures described in this clause are those which are particularly suitable for the characterisation of ultrasonic fields using piezoelectric **hydrophones**. Other procedures based on the use of piezoelectric or non-piezoelectric **hydrophones** may be employed provided equivalence with the techniques described in this clause is demonstrated. A flow-chart for the measurement scheme described in this clause is shown in Figure 6

7.2 Preparation and alignment

7.2.1 Initial adjustment to driving voltage

Some pressure fields may contain large regions over which the pressure exceeds the safety limits for the **hydrophone**, p_{+lim} or p_{-lim} or in which the intensities exceed the limit for the hydrophone $I_{ta,lim}$. In this case, it is advisable to reduce the driving voltage before measurements begin. An estimate can be made as follows:

Estimate average source pressure amplitude:

$$p_0 = \sqrt{2P_c Z_w / A_{TA}} \quad (8)$$

where

Z_w = the characteristic acoustic impedance of water = $1,5 \times 10^6 \text{ kg s}^{-1} \text{ m}^{-2}$

A_{TA} = **transducer aperture area**;

P_c = output **power** under **clinical driving conditions**.

Estimate focal gain:

- a) for a circularly symmetric nonfocusing source, the pressure amplitude ratio gain at the **transition distance** can be estimated as 2., i.e.,

$$G_{\text{focal}} = 2 \quad (9)$$

- b) For a focusing source at F_{geo} ,

$$G_{\text{focal}} = \sqrt{\left[\frac{4}{\pi}\right] A_{\text{TA}}} / (F_{\text{geo}} \lambda) \quad (10)$$

where

z_{T} = the **transition distance**;

F_{geo} = the **geometric focal length**;

λ = **effective wavelength**;

$A_{\text{TA}} = \pi a^2$ for a circularly symmetric spherical focusing source or circularly symmetric focusing source with a radius a in the **external transducer surface plane**;

$A_{\text{TA}} = \pi (a^2 - a_1^2)$ for a circularly symmetric spherical focusing source or circularly symmetric focusing source with a circular hole of radius a_1 in its centre in the **external transducer surface plane**;

$A_{\text{TA}} = L_1 L_2$ for a rectangular focusing source with sides $L_1 L_2$ in the **external transducer surface plane**;

$A_{\text{TA}} = (\pi a^2 - L_{1h} L_{2h})$ for a circularly symmetric spherical focusing source or circularly symmetric focusing source with a rectangular hole of sides L_{1h} and L_{2h} in its centre in the **external transducer surface plane**;

A_{TA} is replaced by A_{SAeff} (the **source aperture area**) for a measurement-based estimate and F_{geo} is replaced by the distance z_p .

Estimate maximum field pressure amplitude as

$$p_{\text{max,est}} = G_{\text{focal}} p_0 \quad (11)$$

Reduce the **transducer driving voltage** by a factor of $\min\{p_{+,lim}, p_{-,lim}\} / p_{\text{max,est}}$

Verify by repeating the total power measurement, that the power is reduced by a factor of $[\min\{p_{+,lim}, p_{-,lim}\} / p_{\text{max,est}}]^2$

If necessary reduce the duty factor F_d to make the **temporal-average intensity**, I_{ta} , less than the **hydrophone** intensity limit, $I_{\text{ta,lim}}$. This is equivalent to the following formula:

$$F_d < \frac{2I_{\text{ta,lim}} Z_w}{[\max\{p_{+,lim}, p_{-,lim}\}]^2} \quad (12)$$

Verify by repeating the total power measurement, that the power is reduced by a factor approximately equal to the ratio by which the duty factor was reduced.

If the offset distance is not zero, its value shall be estimated and added to the value of z_p . This will yield a new and more accurate calculation of focal gains in Equations (9) and (10).

If the projection method of Annex E is used in place of making measurements at $z = z_p$, the requirements of this clause may be relaxed, so long as items (iv) and (vi) are satisfied at the position of any measurements.

7.2.2 Preparation of source transducer

It may be necessary to seal various parts of the **ultrasonic transducer** to prevent ingress of water, especially around the cable entry point if the whole of the device is immersed. Manufacturer's advice should be sought.

Prior to use, the surfaces of the **ultrasonic transducer** and the **hydrophone** should be checked for contamination. If this is present, the surfaces should be cleaned according to the manufacturer's instructions. Any special precautions should be followed for the reliable use of **hydrophones** or **transducers** which may be specified by the manufacturer or which may have been found necessary by the user, such as immersion of a **hydrophone** for a certain time before use.

On insertion of both the **ultrasonic transducer** and the **hydrophone** in the water, care should be taken to ensure that all air bubbles are removed from the external surfaces of the **transducer assembly** and the **hydrophone**. Checks should be made during the course of the measurements to ensure bubbles do not appear.

7.2.3 Aligning an ultrasonic transducer and hydrophone

For reliable characterization of acoustic fields produced by **ultrasonic transducers** it is necessary to align the z -axis of the **hydrophone**, which itself is parallel to the direction of maximum sensitivity, such that it is parallel to the particular direction of propagation of the ultrasound of interest. For a method of aligning the **beam axis**, see 6.2 of IEC 61828. Refer to Figures 1 to 3 for different transducer geometries.

7.2.4 Beam-axis scan

The **hydrophone** shall be scanned down the beam-axis at steps no larger than one half of wavelength, and at every position the peak **compressional and rarefactional pressures** and **temporal average intensity** shall be recorded. The scan should start as close as possible to the **source aperture plane** of the beam, and extend to one-and-a-half times the nominal focal length of the transducer. If, at any point, $p_+ > p_{+lim}$ or $p_- > p_{-lim}$, the scan shall be stopped, and the driving voltage shall be reduced until the pressures are within the limits. Also, if at any point the **temporal average intensity** I_{ta} exceeds the **hydrophone** intensity limit $I_{ta,lim}$, the **duty factor** F_d should be reduced. After the driving voltage and duty factor are reduced, the scan should be continued and further reductions of the **driving voltage** and **duty factor** shall be made until the scan may be conducted throughout the specified range of depths without exceeding these limits. Then the scan shall be repeated at these settings, to determine the **distance** z_p , at which the **beam maximum point** is found.

NOTE In some situations it may not be possible to scan to the position of maximum spatial-peak temporal-average intensity, either because of an inaccessible geometry, or because the equipment under test does not support reduction of voltages or duty factors sufficiently to satisfy the limits set by the **hydrophone**. In that case an alternative is to scan to an intermediate depth, and then perform a raster scan at that depth in order to use the projection method of Annex E to predict the location z_p , and to predict instead of measure the field parameters – see 7.2.5.3.

7.2.5 Measurements to be made at $z = z_p$

NOTE Calculations made using the projection method outlined in Annex E offer an alternative to the measurements cited in this subclause, so long as validation is made as outlined in the note at the end of 7.2.5.3.

7.2.5.1 Adjustments to provide quasi-linear conditions

The **mean peak acoustic pressure** p_m shall be measured, and driving voltage shall be adjusted so that (from 6.1.1 of IEC/TS 61949)

$$\sigma_q = z_p p_m \frac{2\pi f_{awf} \beta}{\rho \cdot c^3} \frac{1}{\sqrt{F_a}} < 0,5 \quad (13)$$

where

p_m = **mean peak acoustic pressure** $(p_r + p_c)/2$

p_r = **peak-rarefactional acoustic pressure** at the point of interest

- p_c = **peak-compressional acoustic pressure** at the point of interest
- z_p = distance of the **beam maximum point** where the measurement is made and the **source aperture plane**
- f_{awf} = **acoustic working frequency**
- β = nonlinearity parameter for water, $\cong 3,5$
- F_a = **local area factor**

If using the projection method of Annex E, the criterion of Equation (13) should apply to the measurement plane at which the raster scan is performed.

If the **offset distance** is not zero, its value shall be estimated and added to the value of z_p in Equation (12). This will yield a new and more accurate calculation of the **local distortion parameter**, which shall be used.

7.2.5.2 Measurements at $z = z_p$

- i) **peak compressional pressure** p_+ (p_c)
- ii) **peak rarefactional pressure** p_- (p_r)
- iii) **Spatial-peak, temporal average intensity** I_{spta}
- iv) **acoustic working frequency** f_{awf}
- v) **pulse repetition rate** prf
- vi) the **beam maximum depth** L_{bm} , or, equivalently, the **focal depth**, L_6
- vii) $A_{b,6}$, the **–6 dB beam area**
- viii) $P_{c,6}$, the **power contained within the –6 dB beam area** (see Annex D)
- ix) the **–6 dB equivalent beam diameter**, given by $D_{-6,q} = \sqrt{4A_{-6,q} / \pi}$

Items (i-v) from above should be used in a final check to verify that the field conditions meet the quasi-linear conditions of Equation (13), and the hydrophone intensity and pressure limits as described in 6.1.6 and 6.1.7. If not, the measurement set-up should be checked. Items (vi-ix) are used to compute the **focal volume** and are used below for calculating extrapolated field intensities. .

7.2.5.3 Alternative: calculation of focal parameters using numerical projection

The parameters listed in 7.2.5.2 may alternatively be determined using the Numerical Projection Method of Annex E, by performing a raster scan at a pre-focal plane and numerically predicting the focal parameters. The criterion of Equation (13) shall be satisfied everywhere in the measurement plane at which the data is collected, so that the assumption of linear field conditions at the measurement plane are valid.

NOTE 1 If the measurement plane is significantly closer than $z = z_p$, the pressures, intensities, and nonlinearities may be lower than in the focal region. In this case the requirement of satisfying quasi-linear conditions (see Sec 7.2.5.1) and **hydrophone** pressure limits need only be met at the measurement plane. This approach also offers the advantage of driving the system under test at potentially more realistic levels. This may be useful if there is concern that the system performance at reduced driving levels may be significantly different than at normal usage levels.

If using this approach, the numerical algorithm shall be validated for the particular frequency and transducer geometry under test.

NOTE 2 One acceptable means for validation is to compare predictions of the numerical algorithm to direct measurements made according to 7.2.5.2, i.e. at driving levels where Equation (12) is satisfied at the $z = z_p$ plane. Then the numerical projection can be applied at higher levels where such comparison may not be possible.

NOTE 3 If it is not possible to perform validation according to NOTE 2, another acceptable approach is to compare to measurements made at a plane intermediate in position between the measurement plane and the $z = z_p$ plane.

NOTE 4 For non-focusing transducers, these parameters are understood to be determined at the position of the **beam maximum**.

7.2.5.4 Measurement of source aperture

The **source aperture area** is determined from the -20 dB pulse-pressure-squared integral in the **source aperture plane**. This area and the **beam area** are used in the calculation of the **local area factor**, F_a .

7.2.6 Further evaluation for sidelobes and pre-focal maxima

7.2.6.1 General

In order to assess sidelobes in the beam, it is necessary to characterize the beam throughout the three-dimensional region between the **source aperture plane** ($z = 0$) and the plane of maximum intensity ($z = z_p$). This may be done in three ways:

NOTE For non-focusing transducers, pre-focal maxima are understood to be maxima which occur at depths shallower than the position of the **beam maximum**.

7.2.6.2 Sidelobe evaluation by hydrophone scanning alone

To evaluate sidelobe levels with hydrophone scanning alone, raster scanning should be conducted in multiple planes orthogonal to the **beam axis** which lie between the entrance plane and the focal plane where $z = z_p$. The depth increment between planes should be less than λ . In each plane $I_{ta}(x,y)$ should be measured as a function of position out to at least the -20 dB level relative to the peak in that plane, or to a dB level specified by safety considerations in related standards. The spatial increment in x and y should be such that $I_{ta}(x,y)$ varies by less than 3 dB between adjacent points. For each plane $z = z_i$, the location and value of the largest secondary maximum outside of the **focal volume** should be recorded, as $I_{ta}(x_{sm}(z_i), y_{sm}(z_i), z_i)$ where $x_{sm}(z_i), y_{sm}(z_i)$ are the x - and y -coordinates in that plane. The maximum over all planes $\{z_i\}$ represents the **side-lobe peak temporal-average intensity** $I_{slpta,q}$ under **reduced quasi-linear conditions**.

7.2.6.3 Sidelobe evaluation by numerical projection

The numerical projection method, described in Annex E, is an approach that combines precise **hydrophone** measurements in a scan plane or surface with a projection algorithm to calculate the three dimensional field at other spatial locations. The validation steps given in 7.2.5 shall be followed if using this approach. In addition to this validation, a **hydrophone** measurement shall be made at the predicted position of the largest sidelobe and compared to the prediction of the projection method. The difference in the sidelobe intensity compared to the predicted value shall be evaluated and be reported for consideration with regard to the potential effects of this error on clinical usage.

7.2.6.4 Sidelobe evaluation by a combination of hydrophone scanning with other imaging methods

Other imaging methods exist which may more rapidly provide at least a qualitative assessment for the distribution of field energy, which can provide spatial coordinates of anomalous local maxima of the acoustic field. These methods include schlieren [8,9,10] and thermal mapping [11]. Upon identifying such regions and their coordinates, **hydrophone** scanning may be used further to acquire a quantitative field map of these regions only. In this manner, the amount of **hydrophone** scanning may be reduced, compared to the method of 7.2.6.3.

NOTE HITU systems which employ direct thermal measurement *in-vivo*, such as MRI thermometry, may be another way of replacing **hydrophone** scans for sidelobes [12].

7.2.6.5 Evaluation of pre-focal maxima along the z -axis

To obtain pre-focal maxima along the beam-axis, a scan along the z -axis should be made with a spatial increment of less than one-half wavelength. The value of I_{ta} at the largest maximum outside of the -6 dB focal zone of the main focus should be recorded as the **pre-focal peak temporal average intensity** I_{PFPTA} .

NOTE HITU systems which employ direct thermal measurement *in-vivo*, such as MRI thermometry, may be another way of replacing **hydrophone** scans for pre-focal maxima [12].

7.3 Considerations for scanning transducers and transducers with multiple sources

7.3.1 Automatic scanning transducers

7.3.1.1 General

Measurements on automatic scanning transducers (i.e., either mechanically scanned or electronically scanning array transducers) shall be made with the automatic scanning arrested. The measurement procedures of Clause 7 shall then be applied to the transducer in the arrested state.

7.3.1.2 Transducers with multiple sources

Multiple-source transducers fall into two classes:

- (I) those where the beams do not significantly overlap,
- (II) those where the beams significantly overlap

Class (I) transducers may be employed in order to achieve broader spatial coverage without scanning, whereas Class (II) may either be an un-intentional result of a Class (I) design, or an intentional result of trying to superpose beams to enhance the acoustic effect. Class (I) transducers may be measured by measuring the individual sources, whereas Class (II) shall require the measurement with all sources turned on.

For cases where direct measurement may be hindered by transducer geometry (such as hemispherical transducers), projection methods may be used on measurements on a single plane to predict beam properties at focal points or sidelobes.

For the purposes of this technical specification, the following criterion shall be used to distinguish between Classes (I) and (II):

If, for all points of clinical interest, there is negligible difference between the **temporal-average intensity** I_{ta} of the composite field and the sum of the time-averaged intensity of each source's field, then the transducer shall be designated as Class (I). Otherwise, it shall be designated as Class (II).

NOTE 1 The composite field is defined as the field when multiple sources are simultaneously turned on.

NOTE 2 The "sum of the time-averaged intensity of each source's field at a point" is the arithmetic sum of the intensity of each source's field at a point, when each source is acting individually.

NOTE 3 Plans for clinical usage will need to be considered to determine whether the difference is negligible.

7.4 Linear extrapolation of field values

7.4.1 General

While reliable power measurements may be made at clinical power levels, intensity measurements at these levels are problematic because of propagational nonlinearities, limited bandwidth of **hydrophones**, and concern for damaging **hydrophones**. Therefore, **hydrophone** measurements are scaled using power measurements made at clinical levels. Specifically, a scaled intensity, I_{sal} is defined in 7.4.2 and 7.4.3, and in Annex D.

7.4.2 Calculation of I_{sal}

As discussed in Annex D, I_{sal} is defined as

$$I_{\text{sal}} = P_{\text{c},6} / A_{\text{b},6,\text{q}} \quad (14)$$

where $A_{\text{b},6,\text{q}}$ is the **–6 dB beam area**, measured under quasi-linear conditions, and $P_{\text{c},6}$ is the **power within the –6 dB area at $z = z_p$ under clinical driving conditions**. $P_{\text{c},6}$ may be determined either by (i) the aperture method of Clause D.3 or (ii) by making raster scans to determine the corresponding value at quasi-linear levels $P_{\text{q},6}$ (see Annex G) and then scaling this value by the following formula:

$$P_{\text{c},6} = P_{\text{q},6} \frac{P_{\text{c}}}{P_{\text{q}}} \quad (15)$$

where

$P_{\text{c},6}$ is the **power within the –6 dB area at $z = z_p$ under clinical driving conditions**

$P_{\text{q},6}$ is the **power within the –6 dB area at $z = z_p$ under reduced quasi-linear driving conditions**

P_{c} is the **output power under clinical driving conditions**

P_{q} is the **output power under reduced driving conditions**

NOTE For the purposes of this technical specification quasi-linear conditions are defined under 7.2.5.1.

7.4.3 Scaling for sidelobes and pre-focal maxima

For purposes of estimating the amplitude of pre-focal maxima and sidelobes under **clinical driving conditions**

a) scale intensity measurements by a factor of $[P_{\text{c}} / P_{\text{q}}]$

b) scale pressure measurements by a factor of $[P_{\text{c}} / P_{\text{q}}]^{1/2}$

Thus, the **side-lobe peak temporal average intensity** is estimated as

$$I_{\text{slpta,est}} = [I_{\text{slpta,q}}] \times [P_{\text{c}} / P_{\text{q}}] \quad (16)$$

and the **pre-focal peak temporal averaged intensity** is estimated as

$$I_{\text{pfpta,est}} = [I_{\text{pfpta,q}}] \times [P_{\text{c}} / P_{\text{q}}] \quad (17)$$

NOTE An alternate method is to follow the approach of IEC/TS 61949 and measure the mean pressures close to the source at the clinical voltage U_{c} and at a lower voltage satisfying quasi-linear conditions and the pressure and intensity limits of the **hydrophone**. These results are then scaled as described in 6.2.4 of IEC/TS 61949.

7.5 Reporting

The following results shall be reported:

- total ultrasonic power at clinical driving voltage level, P_{c}
- total ultrasonic power at the quasi-linear driving voltage level at which field measurements are made, P_{q}
- axial beam scan of temporal-average intensity $I_{\text{ta}}(x = 0, y = 0, z)$
- z_p = position of peak temporal averaged intensity (I_{ta}) on the **beam axis**

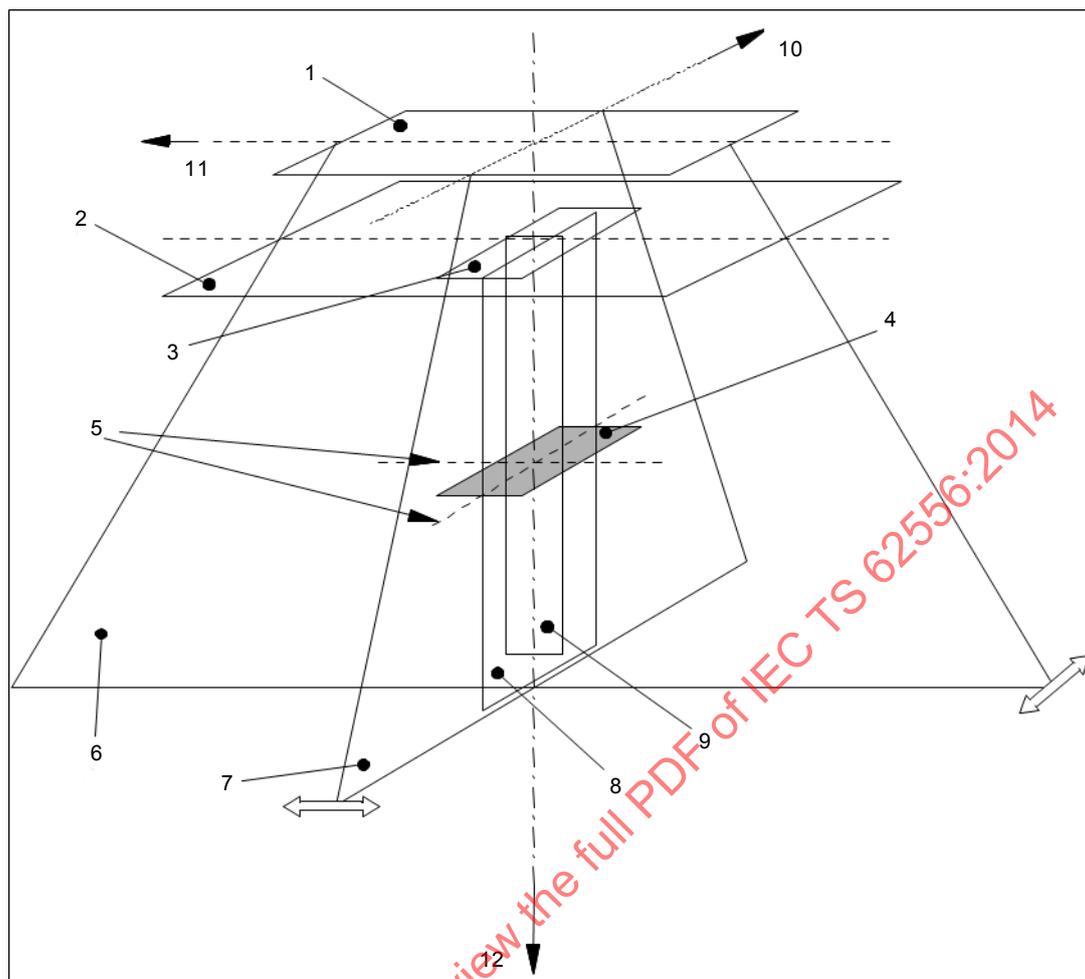
- either the **distance to the patient entry plane** (z_e) or the **offset distance**

NOTE This information is required because the measured distances are referenced to the **source aperture plane**, which may depend on the measurement setup. Reporting either of these two parameters will allow the reported measurements to be referenced to a reproducible location.

- $A_{b,6}$, -6 dB beam area at $z = z_p$
- L_{bm} , the beam maximum depth, or, equivalently, L_6 , the **focal depth**, on axis
- I_{sal}
- estimated side-lobe peak **temporal average intensity** $I_{slpta,est}$, and its position in x , y , and z
- estimated pre-focal **temporal average intensity**, $I_{pfpta,est}$ and its position in z
- relevant output settings for the **HITU equipment** corresponding to these results.

Uncertainties for the reported results shall be estimated according to Annex B and ISO Guide to the Expression of Uncertainty in Measurement [3].

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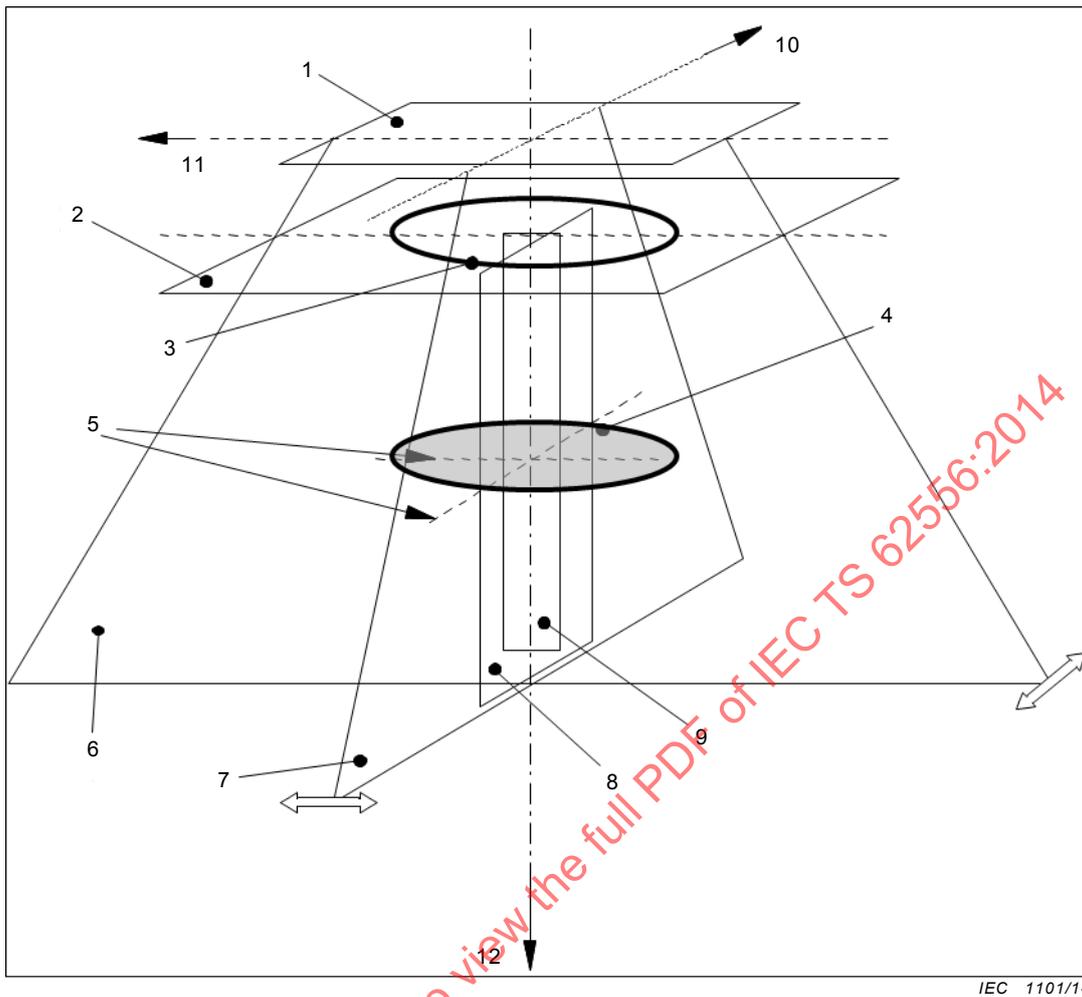


IEC 1100/14

- 1: **external transducer surface plane**
- 2: **source aperture plane** (in general, offset but parallel to **external transducer surface plane**)
- 3: **source aperture**
- 4: **beam area plane**
- 5: **beamwidth lines**
- 6: **elevation plane**
- 7: **azimuth plane, scan plane**
- 8: **principal longitudinal plane**
- 9: **longitudinal plane**
- 10: X, **azimuth axis**
- 11: Y, **elevation axis**
- 12: Z, **beam axis**

The external transducer aperture plane is physically adjacent to the ultrasonic transducer at the surface of the transducer assembly (not shown). Here the original shape of the active aperture is assumed to be rectangular in shape (see also IEC 61828).

Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field for a rectangular HITU transducer

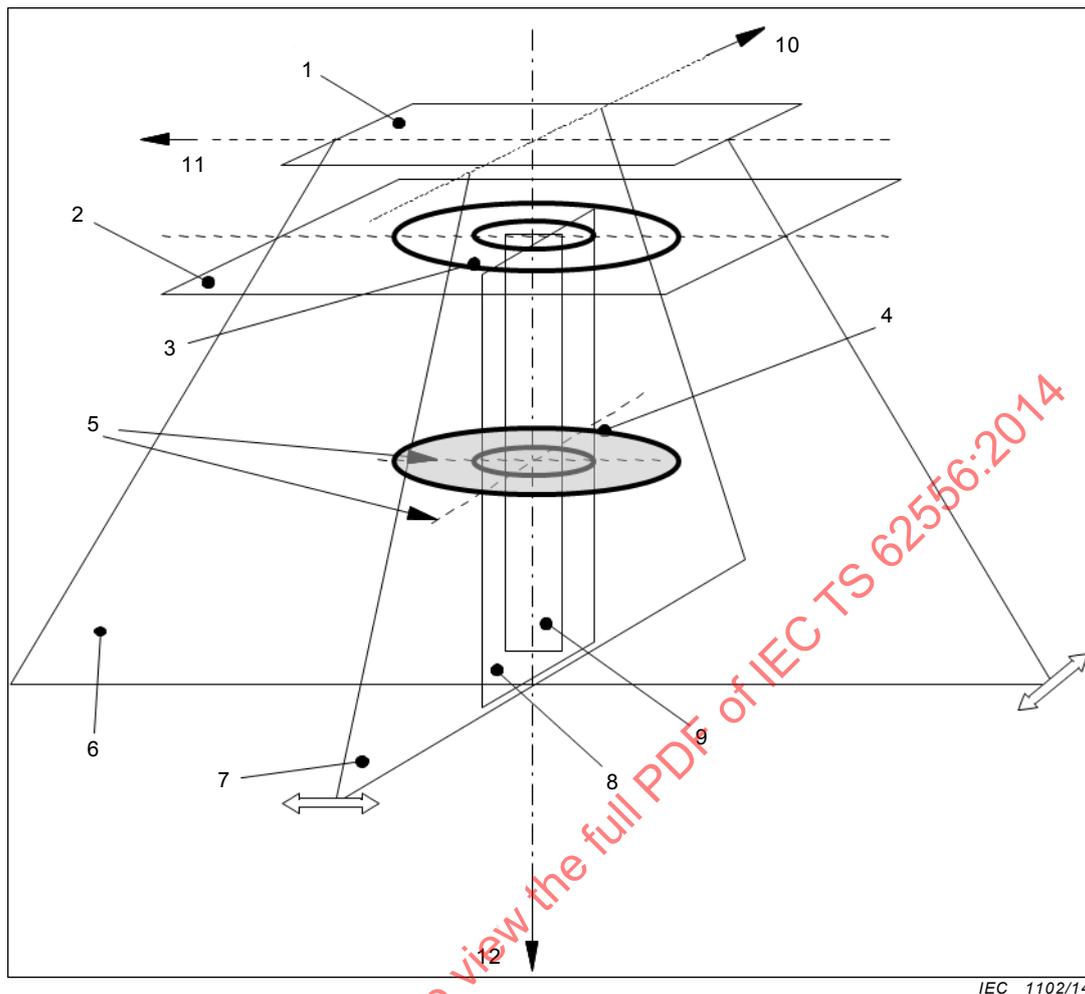


IEC 1101/14

- 1: **external transducer surface plane**
- 2: source aperture plane (in general, offset but parallel to **external transducer surface plane**)
- 3: source aperture
- 4: **beam area plane**
- 5: **beamwidth lines**
- 6: **elevation plane** (if selected)
- 7: **azimuth plane** (if selected, contains **azimuth and beam axis**)
- 8: **principal longitudinal plane**
- 9: **longitudinal plane**
- 10. X, **azimuth axis** (arbitrary because of circular symmetry)
- 11. Y, **elevation axis** (perpendicular to the **azimuth axis** and **beam axis**)
- 12. Z, **beam axis**

The external transducer surface plane is physically adjacent to the ultrasonic transducer at the surface of the transducer assembly (not shown). Here the original shape of the active aperture is assumed to be circular in shape.

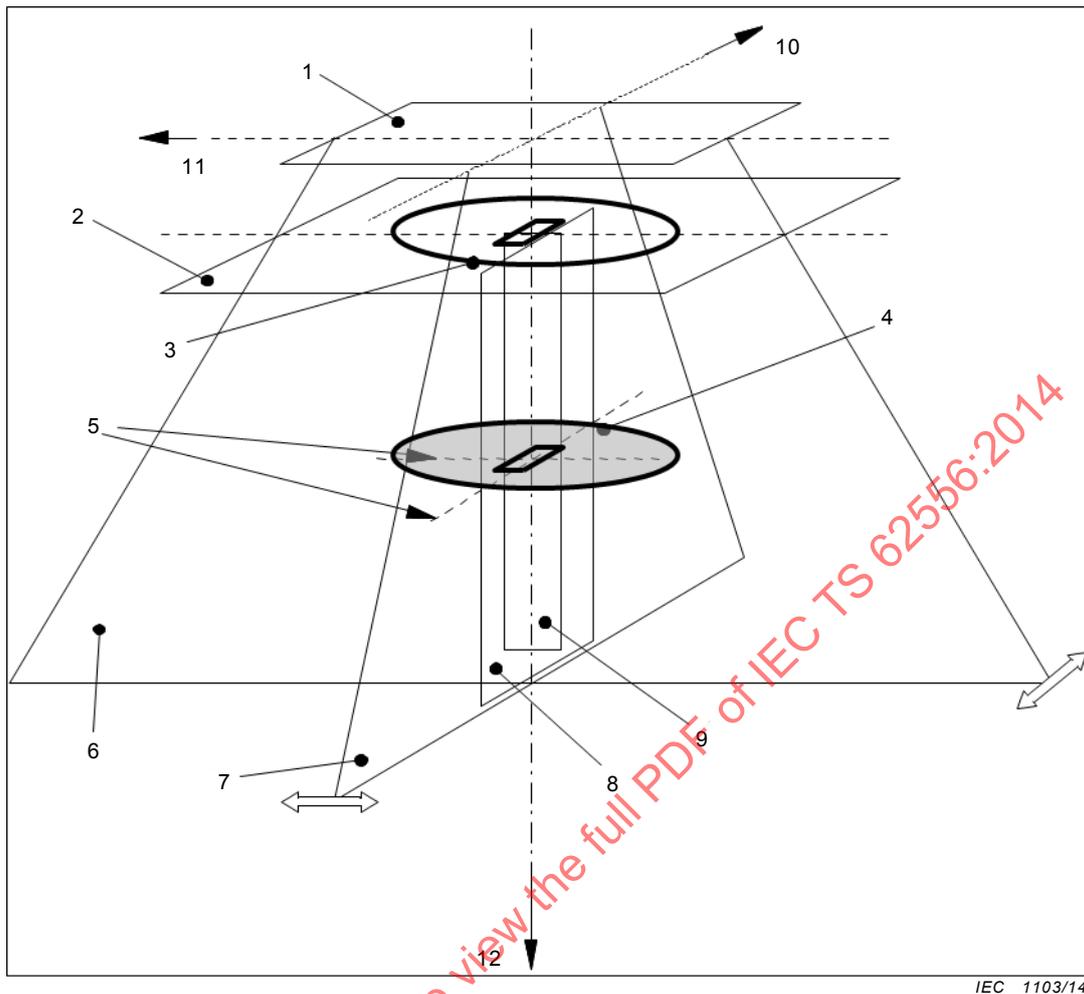
Figure 2 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer



- 1: **external transducer surface plane**
 2: **source aperture plane** (in general, offset but parallel to **external transducer surface plane**)
 3: **source aperture**
 4: **beam area plane**
 5: **beamwidth lines**
 6: **elevation plane** (if selected)
 7: **azimuth plane** (if selected, contains **azimuth axis** and **beam axis**)
 8: **principal longitudinal plane**
 9: **longitudinal plane**
 10: X, **azimuth axis** (arbitrary because of circular symmetry)
 11: Y, **elevation axis** (perpendicular to **azimuth axis** and **beam axis**)
 12: Z, **beam axis**

The external transducer surface plane is physically adjacent to the ultrasonic transducer at the surface of the transducer assembly (not shown). Here the original shape of the active aperture is assumed to be circular in shape with a hole in its center (not part of the aperture).

Figure 3 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer with a circular hole in its center

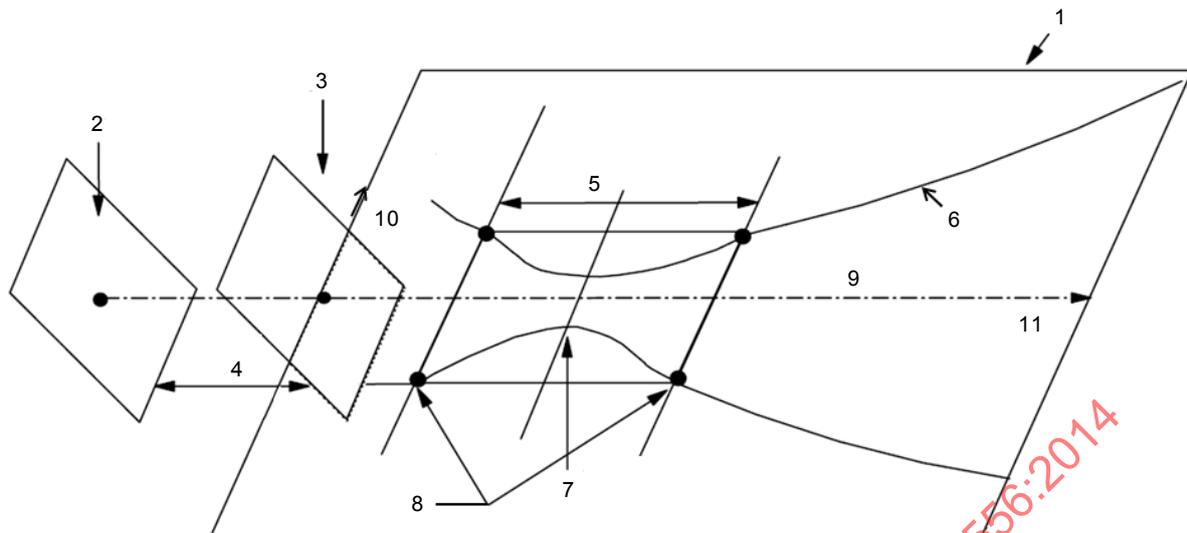


IEC 1103/14

- 1: external transducer surface plane
- 2: source aperture plane (in general, offset but parallel to external transducer surface plane)
- 3: source aperture
- 4: beam area plane
- 5: beamwidth lines
- 6: elevation plane (if selected)
- 7: azimuth plane (if selected, contains azimuth axis and beam axis)
- 8: principal longitudinal plane
- 9: longitudinal plane
- 10: X, azimuth axis (arbitrary because of circular symmetry)
- 11: Y, elevation axis (perpendicular to azimuth axis and beam axes)
- 12: Z, beam axis

The external transducer surface plane is physically adjacent to the ultrasonic transducer at the surface of the transducer assembly (not shown). Here the original shape of the active aperture is assumed to be circular in shape with a rectangular hole in its center (not part of the aperture).

Figure 4 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer with a rectangular hole in its center for a diagnostic transducer (HITU transducer azimuth axis aligned with azimuth scan axis of diagnostic transducer)



IEC 1104/14

- 1: Principle longitudinal plane
- 2: External transducer surface plane
- 3: source aperture plane (in general, offset but parallel to external transducer surface plane)
- 4: External transducer surface plane
- 5: beam maximum depth
- 6: -6 dB contour
- 7: Minimum -6 dB beamwidth
- 8: positions at which the -6 dB beamwidth is twice the minimum -6 dB beamwidth
- 9: beam axis
- 10: x-axis
- 11: z-axis (coincident with beam axis)

Figure 5 – Parameters for describing a focusing transducer of an unknown geometry (IEC 61828)

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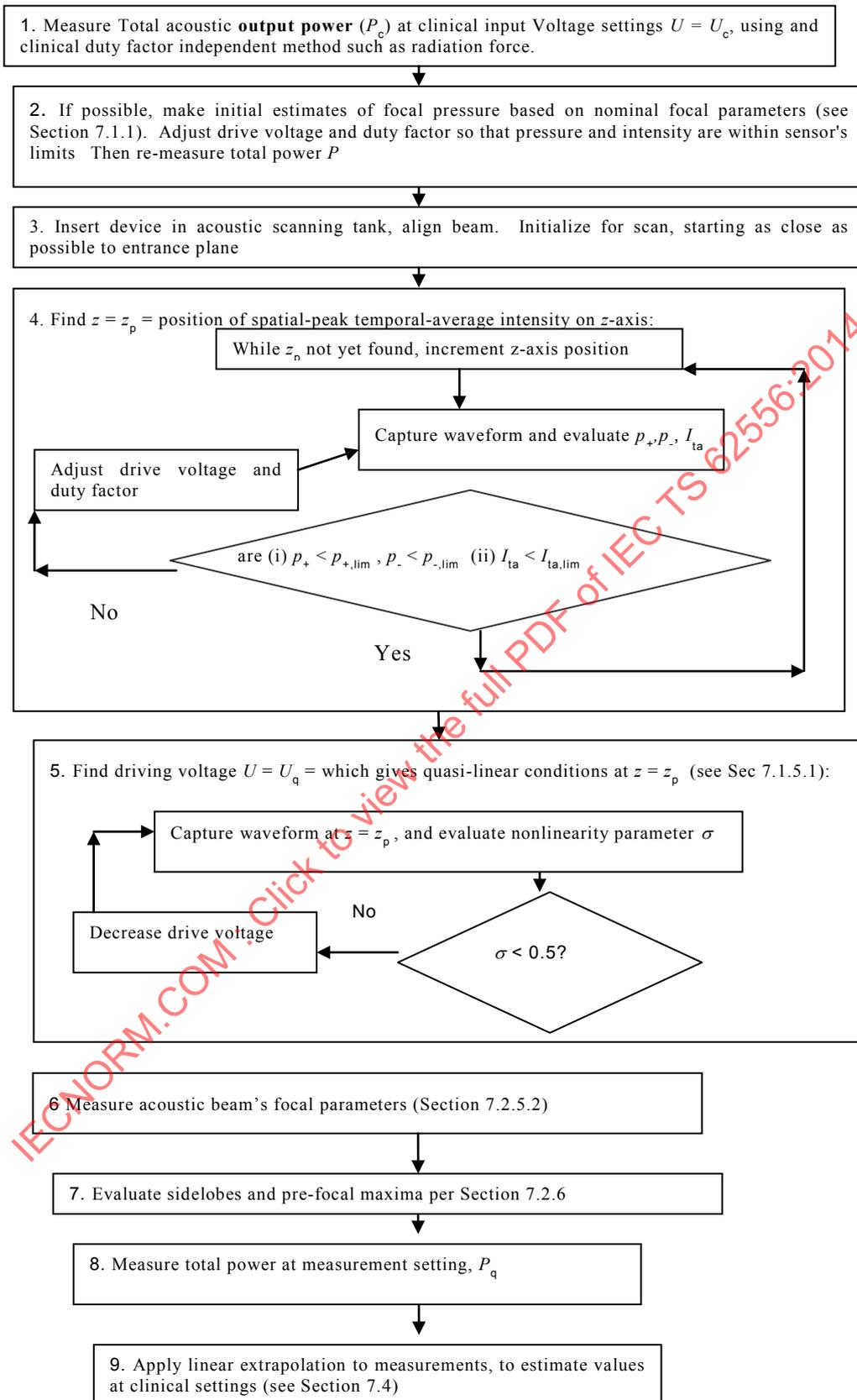


Figure 6 – Overall measurement scheme

Annex A (informative)

Rationale

A.1 General

The use of high intensity therapeutic ultrasound has advanced to the point where systems have achieved clinical approval for general use in numerous countries. Medical applications and product development are continuing rapidly. Fast development in preclinical medicine, clinical medicine, and product manufacture has created an urgent need to standardize measurements of the basic acoustic parameters and the field characteristics of HITU. In order to promote the further development of HITU and to ensure its safe and effective use, common technical specifications are required.

It can be difficult or inaccurate to apply many of the standard measurement methods to HITU fields, either due to fundamental measurement issues or to practical problems. For **hydrophone** measurements, the major problems relate to:

- Shielding by bubbles
- Thermal or cavitation damage
- Non-ideal frequency response
- Non-ideal directional response/spatial-averaging
- High pressure levels
- High harmonic content
- Off-axis measurements
- Damage to **hydrophones** may only be apparent at high pressures

Some of the causes of these difficulties and inaccuracies are introduced in the following subclauses.

A.2 Detailed discussion of difficulties in HITU field measurements

A.2.1 Very high pressures

Pressures above the cavitation threshold for the measurement medium (usually water) can produce bubbles as dissolved gas is drawn out of solution. Two main problems may then arise: first, the bubbles formed may partly shield the sensor from the ultrasound field; secondly, violent bubble activity can damage or destroy the sensor. The occurrence of both of these effects can be minimised by removing dissolved gas and particulate matter from the measurement medium but it may be difficult to maintain sufficiently purity for a prolonged period.

There is also the risk of direct mechanical effects on the sensor itself due to large compressional and tensional forces. This is most likely to be a problem when there are weak points between different components of the sensor (for instance, if there is delamination of the glue layer in a bilaminar **hydrophone**).

Moreover, because of the high pressure levels involved, a proportionately large fraction of the pressure spectrum is distributed into higher harmonics, placing greater demands on **hydrophone** bandwidth and introducing errors due to the absorption of water (see A.1.4 and A.1.5).

A.2.2 Very high intensities

Energy absorbed from the ultrasound beam heats the sensor and this may affect its performance or even destroy it. For instance, the sensitivity of a membrane **hydrophone** can change if it is heated close to its Curie temperature. For pvdf, the most widely used **hydrophone** material, depolarisation occurs progressively with time at temperatures above about 70 °C and almost immediately at 110 °C. The thinness of membrane **hydrophones** will offer some protection against thermal damage because heat is very quickly lost to the surrounding medium. However, the sensitivity of pvdf **hydrophones** is temperature dependent and this change can be an additional source of uncertainty. Probe **hydrophones** may face greater risk and absorbing radiation force balance targets will certainly be damaged unless great care is taken to dissipate the absorbed energy. Heating can be reduced by generating low duty cycle toneburst ultrasound rather than continuous-wave. However, HITU transducers are generally only weakly damped and, consequently, may take many acoustic cycles for the pressure 'ring-up' at the start of the toneburst; there is an equivalent 'ring-down' at the end of the toneburst. This must be accounted for by scaling results from toneburst to the cw situation. In addition, since typically 30 % to 50 % of the electrical energy is dissipated within the transducer, its temperature and properties will change with time during operation. Using toneburst mode will reduce this self-heating and may lead to significant differences in acoustic output compared to the cw case.

A.2.3 Strong focusing

In a focused field, even more than in an unfocused field with diffraction effects, two important plane-wave assumptions become approximations. Firstly, the derived intensity may differ significantly from the true intensity [13]. Secondly, the radiation force on a target placed in the field is no longer determined solely by the properties of the target and the total ultrasound power. The geometry of the field also plays a role, especially for the widely-used conical reflecting targets; absorbing targets are preferable provided that they are not damaged by excessive heating.

There is also a third effect which relates to the directional response of a **hydrophone**. In a plane wave, the **hydrophone** can be aligned so that the wave is incident in the preferred direction for the **hydrophone** (usually perpendicular to the plane of the sensing element). In a focused field, the pressure at the **hydrophone** can be considered as the superposition of wavelets with a relative phase and an angular distribution which are determined by the transducer geometry and its distance from the **hydrophone**. An ideal **hydrophone** would respond equally to wavelets from any direction and the output signal would be proportional to the sum of the wavelets. A real **hydrophone**, on the other hand, has a sensitivity which depends on the angle of incidence of the wavefront and the output voltage therefore depends on a weighted summation of the wavelets. This means that the output voltage waveform is different in magnitude and shape from the pressure waveform. This distortion increases with the large physical apertures and short focal lengths frequently used for therapeutic applications. Furthermore, the non-ideal nature of real transducers which have amplitude and phase variations across their apertures introduces additional complexities into the measurement process. There is no information available on the measurement uncertainties in cases where the field is generated by two or more widely separated transducers, or where the point of measurement lies within or close to the volume defined by the external surface of the transducer or surfaces of transducers.

In other therapeutic applications, the transducer is nonfocusing, or it operates over short distances or it has an unusual geometry. In these cases, existing measurement standards cannot be applied.

A.2.4 Nonlinear harmonics

Hydrophones have a frequency dependent amplitude and phase response. Consequently, in any ultrasound field where the acoustic spectrum at the point of measurement contains a significant spread of frequencies, the output voltage waveform (which is the acoustic spectrum convolved with the complex frequency response of the measurement system) will differ in shape from the true pressure waveform. In general, membrane **hydrophones** have a

smoother frequency response (particularly in the low MHz region) and will give a closer representation of the pressure waveform. However, when the acoustic spectrum contains many high harmonics (as are generated by nonlinear propagation of high pressure fields), the output signal from the **hydrophone** can still be very different from the acoustic pressure waveform because the thickness resonance of the membrane typically results in a sensitivity which is 6 dB to 8 dB higher at the resonance frequency than at 1 MHz. Pulses of sufficiently high amplitude can achieve ‘full-shock’ conditions in which several hundred harmonics can be present with a relative amplitude proportional to $1/N$, where N is the harmonic number. This problem is well recognised in the measurement of diagnostic ultrasound pulses and research is being carried out on the determination of the complex frequency response of **hydrophones** and the best method for deconvolving this response. So far, it seems that deconvolution to determine temporal-average derived intensity is relatively straightforward because it requires knowledge only of the amplitude response. The problem of determining peak negative and, particularly, peak compressional pressures has not yet been solved with accuracy since it requires phase response data up to high frequencies.

A.2.5 Acoustic saturation and nonlinear loss

High amplitude acoustic pulses propagate nonlinearly in water which results in a distortion of the wave and the generation of harmonics. Since the acoustic attenuation coefficient of water is proportional to frequency squared, these harmonics are absorbed more quickly than the fundamental leading to ‘nonlinear loss’ and eventually to ‘acoustic saturation’ where any change in the acoustic pressure generated at the transducer is not seen at the measurement point in the field. For radiation force balance measurements, nonlinear loss can mean that the incident power is strongly dependent on the distance at which the measurement is made. It can also mean that there is significant streaming in the water path and this also results in a force on the target. Determining the **output power** of the transducer is therefore subject to greater uncertainties.

For **hydrophone** measurements, acoustic saturation and nonlinear loss can be problematic when making measurements in water. Unlike diagnostic pressure levels measured in water, which fall within a prescribed range, the high pressures and extended pulse lengths for therapeutics can contain a significantly more extended and higher harmonic spectrum and this places more stringent requirements on the frequency response of the measurement system. Acoustic saturation will be more pronounced at these levels. In addition, a problem arises when extrapolating from measurements in water to anticipated values in tissue, where the nonlinear properties and attenuation coefficients are significantly different. This was addressed for diagnostic ultrasound by IEC/TS 61949 which specifies a parameter and associated threshold which can be used to estimate a ‘quasi-linear’ range. To ensure quasi-linear conditions, the transducer output is reduced until nonlinear propagation processes transfer less than 10 % of the energy flux through any point in the field to the higher harmonics; it is believed that extrapolation from water values to tissue values can be better made by making measurements under these quasi-linear conditions.

A.2.6 Damage to hydrophones may only be apparent at high pressures

Exposure to HITU fields may damage **hydrophones** in ways that are not immediately detectable. For example, the effect of delaminations in internal **hydrophone** structures may only appear at combinations of high rarefactional pressures and low frequency. Also, damage may not affect the **hydrophone**'s response at the fundamental frequency, but become apparent at harmonics. Typical calibration reference sources are generally at diagnostic levels or lower. A calibrated reference source which can check relevant performance parameters may not be readily available.

A.3 Approach of this technical specification

Solutions for all of the challenges listed in 5.1.1 to 5.1.5 remain an active area of research [14]. Because no widespread consensus has yet emerged for overcoming these concerns, this specification presents a method where field characterization measurements are made after reducing the output level so that it is in a quasi-linear range, and within safe limits for the

operation of the sensor without damage or without corrupting the results. Furthermore, this document recommends confirming **hydrophone** measurements by planar scanning of the **hydrophone**, such that the derived total power may be compared to an independent measurement, such as radiation force.

Total acoustic **output power** is still measured at the full clinical output level using the method of IEC 62555. Then, the results of the field characterization at reduced levels are scaled-up to clinical output levels by using calculations. The scaling discussed in this technical specification is linear, and neglects finite-amplitude propagation effects. The justification for this is three-fold. First, as outlined in A1.4 and A1.6, this approach avoids possible damage to hydrophones, and removes the need for expensive broad-band hydrophones and/or compensation for their non-ideal frequency response when measuring nonlinear harmonics (note that this allows validation to be performed with simple hydrophones at the focus of the field when the projection method is used). Second, as outlined in A1.5, this approach allows the continued usage of water as the measurement medium, without artificial distortion of measurement results due to the particular non-linear properties of water, which may be different from tissue, as discussed in IEC/TS 61949. Finally, note that it is possible to computationally model non-linear effects to determine their significance or lack thereof, and in fact it has been shown that in many cases high degrees of non-linearity in water may not correspond to significant non-linear effects in tissue [15].

The measurement process is shown schematically in Figure 6.

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Annex B (informative)

Assessment of uncertainty in the acoustic quantities obtained by hydrophone measurements

B.1 General

To be truly meaningful, the result of a measurement should be accompanied by its associated uncertainty. 7.4 states that, in evaluating and expressing the uncertainty in the measurement, the guidance provided by ISO/IEC Guide 98-3:2008: *ISO Guide to the expression of uncertainty in measurement* (ISO GUM) shall be followed.

In general, uncertainty components are grouped according to how the values are estimated:

Type A: evaluated by statistical means;

Type B: evaluated by other means.

B.2 Overall (expanded) uncertainty

The overall uncertainty should be obtained from all uncertainty components in the manner described in the ISO GUM.

When combining uncertainty components, care should be taken when component values are expressed in decibels. Before combination, the values should ideally be expressed in linear form (e.g. in per cent or in the units of the quantity) and not in decibels. The final value of expanded uncertainty may be expressed either in the units of the quantity, in per cent or converted to decibels as required.

NOTE 1 It should be realized that the use of decibel to express uncertainties may lead to asymmetric distributions (e.g. +1,5 dB is equivalent to +19 %, but –1,5 dB is equivalent to –16 %).

NOTE 2 When each component of uncertainty is small, i.e. less than 1 dB, the overall uncertainty can be calculated using decibel.

B.3 Common sources of uncertainty

The following is a list of common sources of uncertainty using **hydrophones**. This list should not be considered exhaustive, but may be used as a guide when assessing uncertainties for a specific parameter. Depending on the parameter to be measured, some (though possibly not all) of these sources shall need assessment. For example, the errors from measuring instruments might be minimized by the use of the same measuring channel (amplifier, filter, voltmeter, etc.) for all signals and measuring only amplitude ratios. However, since this might not be the case in all implementations, components for these sources of error have been included in the list.

Various potential sources of uncertainty are:

Due to alignment and waterbath

- Positioning of the **hydrophone** for maximum signal
- Misalignment, particularly at high frequencies where the **hydrophone** response may be far from omni-directional
- Interference from acoustic reflections, leading to a lack of free-field conditions;
- Acoustic scattering from the **hydrophone** mount (or vibrations picked up and conducted by the mount);

- Bubbles or air clinging to transducer and or **hydrophone** – this should be minimized by adequate wetting and soaking of transducers and **hydrophones**;
- Cavitation bubbles and dust particles in the water
- Variation in environmental conditions during the measurements (e.g. temperature, depth, mounting/rigging, etc.);
- Errors in the measurement of distances;

Errors related to signal management

- Electrical noise on the **hydrophone** signal include RF pick-up;
- Inaccuracy of any electrical loading corrections made to account for loading by extension cables and preamplifiers;
- Inaccuracy of any electrical signal attenuators used
- 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 the gains of any amplifiers, filters and digitizers used;
- Errors in measurement of the receive voltage (including the accuracy of the measuring instrumentation – voltmeter, digitizers, etc.);
- Errors due to the resolution of the digitizer
- Errors in the Time Base

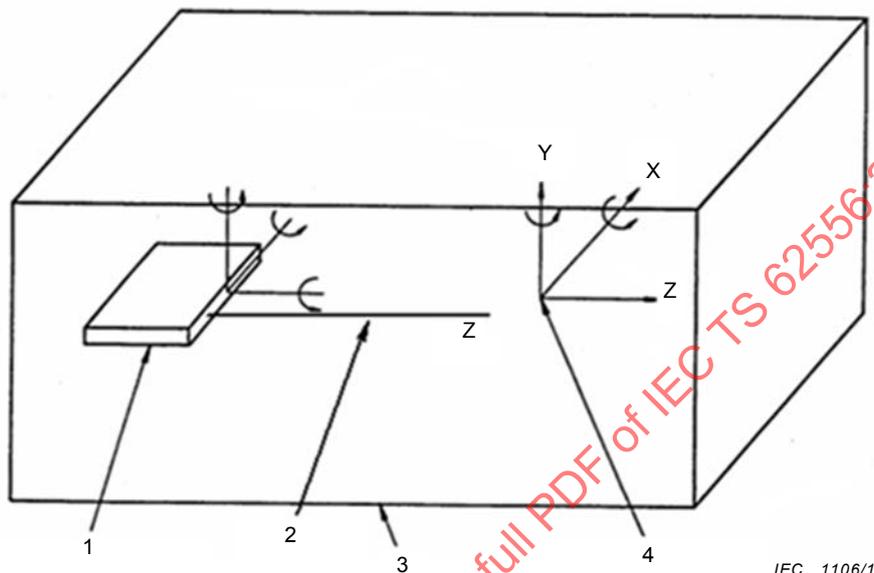
Errors related to the ultrasonic field

- Overlapping acoustic scan lines
- Variation between scan lines
- Lack of steady-state conditions
- Errors in the values for acoustic frequency
- Errors in the values for water density
- Local temperature variations between repeated measurements
- Instability of ultrasonic transducer (e.g. instability of the output or electrical drive conditions)
- Hydrophone calibration (note: absolute measurement of the field is only important in accurate measurement of the **local distortion parameter** for the purposes of this technical specification)
- Instability of the **hydrophone**
- Temperature sensitivity of the **hydrophone**
- Non-linear Distortion (note: this effect should be minimal when following this technical specification).
- The spatial averaging effects of the **hydrophones** due to their finite size

Annex C (informative)

Transducer and hydrophone positioning systems

There are numerous ways to mount the **ultrasonic transducer** and **hydrophone** such that the requirements specified in 6.2 may be met. Figure C.1 illustrates a possible system.



- 1: **ultrasonic transducer**
- 2: **beam axis**
- 3: **tank**
- 4: **hydrophone active element**

Figure C.1 – Schematic diagram of the ultrasonic transducer and hydrophone degrees of freedom. X, Y and Z denote the axis directions relative to the mounted hydrophone and ultrasonic transducer.

Annex D (informative)

Rationale for I_{sal}

D.1 General rationale

While reliable power measurements may be made at clinical power levels, intensity measurements at these levels are problematic because of propagational nonlinearities, limited bandwidth of **hydrophones**, and concern for damaging **hydrophones**. Therefore, I_{sal} was proposed [16] as a means of scaling **hydrophone** measurements made at quasi-linear conditions using results of power measurements made at clinical levels. Specifically, the general form of I_{sal} is

$$I_{\text{sal}} = P_{\text{c},6} / A_{\text{b},6,\text{q}} \quad (\text{D.1})$$

where $A_{\text{b},6,\text{q}}$ is the -6 dB beam area, measured under quasi-linear conditions and $P_{\text{c},6}$ is the power measured at clinical levels over the -6 dB area of the beam.

D.2 Determination of $P_{\text{c},6}$ using hydrophone measurements and extrapolation from linear measurements.

$P_{\text{c},6}$ may be estimated from **hydrophone** measurements via planar scanning at quasi-linear levels:

$$P_{\text{c},6} = P_{\text{q},6} \frac{P_{\text{c}}}{P_{\text{q}}} \quad (\text{D.2})$$

where

$P_{\text{c},6}$ is the **power within the -6 dB area at $z = z_p$ under clinical driving conditions**

$P_{\text{q},6}$ is the **power within the -6 dB area at $z = z_p$ under reduced quasi-linear driving conditions**

P_{c} is the **output power under clinical driving conditions**, as determined per IEC 62555

P_{q} is the **output power under reduced driving conditions**, as determined according to IEC 62555 or IEC 61161

NOTE As discussed in Annex G, in some cases P_{q} may also be determined via planar scanning, but in general uncertainties will be higher than through radiation force methods, in particular for strongly focused transducers, so the radiation force method is preferred.

D.3 Alternative determination of $P_{\text{c},6}$ using an aperture in combination with a measurement of total acoustic output power

Alternatively, $P_{\text{c},6}$ may be determined by constructing an aperture corresponding to the -6 dB beam area measured under quasi-linear conditions as in 7.2.5.2. Care should be taken to construct the aperture such that it blocks the power from the surrounding area by at least -30 dB. This aperture is placed at the position $z = z_p$ in front of the transducer, and a measurement of $P_{\text{c},6}$ is made in accord with IEC 62555. The x - and y -position of the transducer relative to the aperture should be iteratively adjusted to maximize the result of the measurement. Errors arising due to the attenuation of the water propagation path should be considered when using this method – in particular due to the losses which may arise from the attenuation of higher frequency harmonics in the signal.

D.4 Special case of uniformly vibrating spherically shaped transducers

For uniformly vibrating spherically focused transducers, an analytical solution [17] provides the following relationship:

$$P_{q,6} = 0,682 P_q \quad (D.3)$$

Combining Equations (D.1), (D.2) and (D.3) then gives

$$I_{\text{sal}} = 0,682 P_c / A_{b,6,q} = 0,868 P_c / [D_{6,q}]^2$$

where $D_{6,q} = \sqrt{4A_{b,6,q} / \pi}$

Also, using standard formulas [17] it can be shown that under linear conditions the ratio between the peak intensity and I_{sal} is given by

$$I_{\text{spta},q} / I_{\text{sal},q} = 1,79 \quad (D.4)$$

which therefore gives the following result:

$$I_{\text{spta},q} = 1,23 P_c / A_{b,6,q} = 1,56 P_c / [D_{6,q}]^2 \quad (D.5)$$

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Annex E (normative)

Propagation and back-propagation methods for field reconstruction: basic formulae and requirements

E.1 Motivation and background

In principle, the complete acoustic field at any point in space may be calculated if the complete acoustic signal is known at all points on any single plane transverse to the **beam axis**, and a suitable numerical algorithm can be employed to model the acoustic wave propagation. Suitable numerical algorithms exist in common practice for the case where linear propagation applies [18,19,20]. Algorithms to model nonlinear propagation also are in common use for axisymmetric transducers [21,22].

Thus, if the field can be measured across a plane near the transducer aperture, it can be projected to any other plane including the focal plane, under many conditions.

Potentially, the field may be sampled near the transducer aperture before focusing effects can create damage to **hydrophones** or lead to nonlinearities due to propagation effects. This information can be used to perform back-projection and determine the field on the source. Then the field at the focus may be estimated using one of the existing forward propagation methods [18-21]. In principle, the propagation may be done using a model that includes nonlinearity and tissue absorption [18-23]. However, as discussed in Clause A.3, the approach of this technical specification is to restrict the discussion to numerical projection assuming linear propagation models neglecting absorption. The more advanced propagation approaches are left to future editions of this document, and in the meantime the reader is referred to the research literature [18-23].

Also, the need to evaluate sidelobes throughout significant volumes poses a challenge for efficient measurement, because **hydrophone** scans throughout large volumes may be time-consuming. To overcome this difficulty, numerical algorithms have been employed, which calculate the field at different positions based on a thorough set of measurements (both amplitude and phase) performed on one plane transverse to the **beam axis**.

This method has the advantage of requiring only one raster scan, instead of multiple raster scans to search for sidelobes. It also has the advantage that the field may be back-projected to positions closer than practically accessible to direct measurement, such as the case with hemispherical transducers, or when electrical interference corrupts direct measurements performed close to the external transducer surface.

Care must be taken to properly assess the uncertainties in utilizing this approach. As the method relies on accurate measurement throughout a transverse plane, the step-size and the extent of the scan in the transverse dimensions influences the accuracy of the results. Also, the directivity of the **hydrophone** shall have an effect on the accuracy of data collected away from the **beam axis**. Therefore, both the phase and amplitude of the directional response of the **hydrophone** should be considered as described in Clause E.2. Finally, note that if measurements are not made at quasi-linear levels, the effects of non-linear distortion (e.g. attenuation of harmonics, and **hydrophone** bandwidth) must be considered.

E.2 Theory

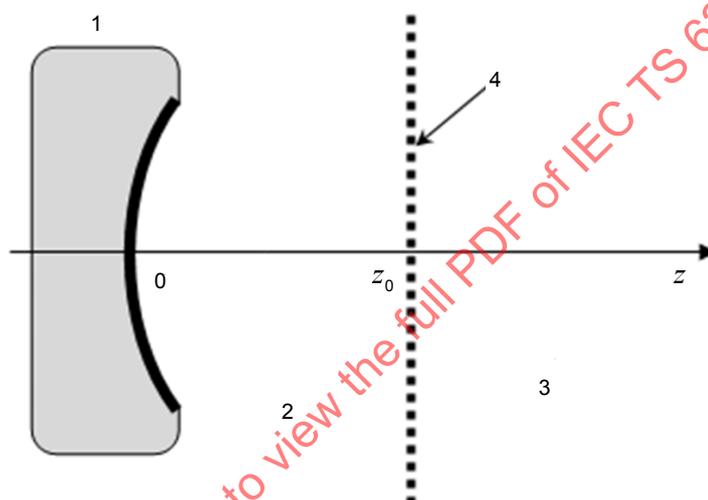
E.2.1 General

For linear propagation simulations, two methods are used frequently: an angular spectrum method (i.e., a Fourier projection) [20,24] and a Rayleigh integral method [18-19,24]. If the measurement plane surface is placed at a small (of order of a wavelength) distance from the

source to capture evanescent waves, the corresponding backward propagation procedure is called nearfield acoustic holography (NAH). Under such conditions, source vibrations can be reconstructed with a spatial resolution much smaller than a wavelength. In contrast, if the measurement surface is placed far from the source, which is usually the case for medical ultrasonic transducers, evanescent waves are not captured. Accordingly, calculation of the backward propagation is approximate and yields a spatial resolution of about a wavelength [18-19].

Both methods require complex (amplitude and phase) pressure data sampled on the flat XY plane. The angular spectrum method is typically used for projections from plane to plane, although it can also be used for curved surfaces, calculations are computationally more intensive.

For notation simplicity, we define the scanned plane to be at $z = z_0$ (Figure E.1). Here the **source aperture plane** is assumed to be at $z = 0$ and using it is a way of registering the coordinate system for computation with the location of the physical transducer.



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- 1: ultrasonic transducer
- 2: backward projection region
- 3: forward projection region
- 4: scanning plane (x', y', z_0)

Figure E.1 – Geometry of problem for forward and backward projection techniques.

Consider a source operating in cw mode (the more general transient case can be considered similarly [25]). In a cw regime, the acoustic pressure waveform p_{total} has the following form:

$$p_{\text{total}}(x, y, z, t) = A(x, y, z) \cos[\omega t - \varphi(x, y, z)] = \frac{1}{2} p(x, y, z) e^{-i\omega t} + \frac{1}{2} p^*(x, y, z) e^{i\omega t}, \quad (\text{E.1})$$

where p is the complex pressure amplitude, A is the real pressure amplitude, φ is phase, ω is the **circular frequency**, and $*$ denotes complex conjugation. Amplitude A and phase φ of the acoustic pressure at a given point are derived from the **hydrophone** output p_{total} . The complex pressure amplitude $p(x, y, z)$ is then expressed as

$$p = A e^{i\varphi}. \quad (\text{E.2})$$

Two-dimensional distribution of the complex pressure amplitude p (e.g., two 2D plots for amplitude A and phase φ) allows calculation of the acoustic field in the entire space in front of the source. Therefore, this 2D plot can be considered as the source hologram.

E.2.2 Fourier projection approach

E.2.2.1 General

Calculation of acoustic pressures by Fourier projection comprises two steps [20, 24]:

- 1) Fourier transform of the complex acoustic pressure amplitude over the scanning plane $z = z_0$ (Figure E.1):

$$F(k_x, k_y) = \iint p(x', y', z_0) e^{-i(k_x x' + k_y y')} dx' dy' \quad (\text{E.3})$$

Inverse Fourier transform to get the complex pressure amplitude at desired points (x, y, z) in the forward or backward direction:

$$p(x, y, z) = \frac{1}{(2\pi)^2} \iint F(k_x, k_y) e^{ik_z(z-z_0)} e^{i(k_x x + k_y y)} dk_x dk_y \quad (\text{E.4})$$

where $k = 2\pi / \lambda$ is the circular wave number and k_x and k_y are the **wave vector components along the x- and y-axes**, respectively.

NOTE It is assumed that the complex acoustic pressure amplitude $p(x', y', z_0)$ is determined from **hydrophone** measurements in the scanning plane (see 6.1.1).

E.2.2.2 Fourier projection computation

In practical implementations, the integration is restricted to a limited scanning region for measurements. Usually measurements are performed using a raster scan with discrete step sizes Δx and Δy to fill a rectangular shape of size $L_x \times L_y$. Scans are commonly identical in the x - and y -directions, forming a square region with $L_x = L_y = L$ and incremental step sizes $\Delta x = \Delta y = h$. Fourier integrals can then be discretized:

$$F(k_x, k_y) = h^2 \sum_{x', y'} p(x', y', z_0) e^{-i(k_x x' + k_y y')} \quad (\text{E.5})$$

$$p(x, y, z) = L^{-2} \sum_{k_x, k_y} F(k_x, k_y) e^{ik_z(z-z_0)} e^{i(k_x x + k_y y)} \quad (\text{E.6})$$

Here x' and y' are summed over the scanned data in the measurement plane, while k_x and k_y run from $-\pi/h$ to π/h with step $2\pi/L$.

To project the 2D pressure distribution measured on the plane $z = z_0$ to another plane $z = z_1$, a computationally efficient FFT algorithm may be used. This computational efficiency is an advantage of the Fourier approach. Each pressure value used as an input or output of the calculation should be interpreted as a point sample of the acoustic field.

Fourier projection preserves energy and momentum exactly. So, the total power $P(z)$ flowing through each output plane (vector Poynting integral) is equal to the input plane flux [22]:

$$P(z) = \frac{h^2}{2} \sum_{x,y} \operatorname{Re} [v_z(x, y, z) p^*(x, y, z)] \quad (\text{E.7})$$

where $v_z(x, y, z) = (kZ_a L^2)^{-1} \sum_{k_x, k_y} k_z F(k_x, k_y) e^{ik_z(z-z_0)} e^{i(k_x x + k_y y)}$ is the z -component of the particle velocity and $Z_a = \rho c$ is the characteristic acoustic impedance.

For Fourier projections, the sampling resolution h , the size L of the measurement window, and the size of the projected output window are all highly important.

E.2.2.3 Resolution (sampling) issues

For practical purposes, good reconstruction quality of the focal region can be achieved if the scanning resolution of measurements meets or exceeds the Nyquist limit:

$$h < \frac{\pi}{k_{\max}} \approx \lambda N \quad (\text{E.8})$$

where

- i) k_{\max} is defined from the requirement that $F(k_x > k_{\max}, k_y > k_{\max})$ be negligible (i.e., there is no significant angular spectrum for higher wavenumbers and)
- ii) λ is the ultrasound wavelength
- iii) $N = \text{Focal Distance} / \text{Transducer Diameter}$ is the transducer's F-number

For high steering angles and reconstruction of distant side lobes, a finer sampling of less than one-half wavelength is preferred:

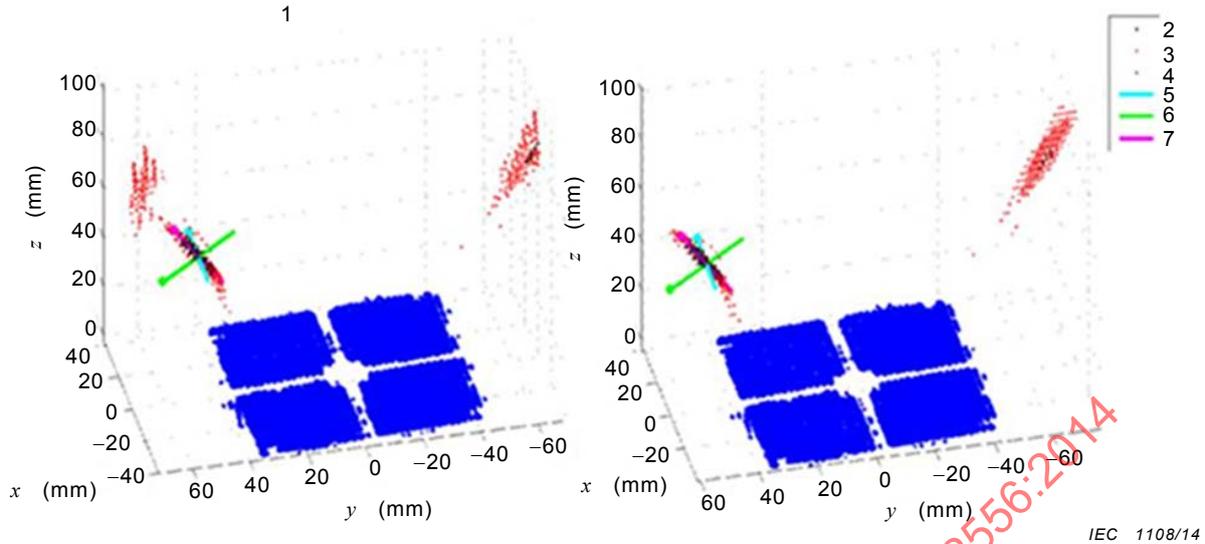
$$h < \lambda/2 \quad (\text{E.9})$$

NOTE Equation (E.9) specifies only the spatial sampling for the raster scan, not the hydrophone size. In general, the requirements for the **effective hydrophone radius** are given in 6.1.5, which is applicable for the projection method as well as direct measurement. In general, it is expected that the **effective hydrophone radius**, will be smaller than half the step-size h ; if not, the effective sampling will be larger than the step-size and the impact of this on measurement uncertainty needs to be considered.

The spatial resolution used along the surface of the reconstructed transducer is important only for visualization purposes and may be changed “on the fly” by zero padding in the Fourier space.

E.2.2.4 Window size issues

A discrete Fourier transform is intrinsically periodic with the window size period. Thus any field pattern or side lobe that enters the input window but appears to miss the projected output window shall actually be periodically replicated back into the output window. This computational artefact can be considered as a safety feature: if potentially dangerous side lobes exist, they shall be detected in any calculated forward projection along the **beam axis** from the **external transducer surface plane**. See Figure E.2.



- 1: results with too small a window (results with larger window in right)
- 2: portion of beam within –6 dB of focal intensity
- 3: portion of beam within –10 dB of focal intensity
- 4: surface of **ultrasonic transducer**
- 5: **azimuth axis**
- 6: **elevation axis**
- 7: **beam axis**

Window size is too small to include side lobe (left side picture). Part of it replicates periodically to opposite side of the window. Simulation artefact is removed by enlarging the window (right side picture). The Transducer plane surface is depicted by blue dots.

Figure E.2 – Transducer focused at –15mm, y = 48,16 mm, z = 56,85 mm

Another consequence of this artefact is the possible presence of “reflection” ripple on the output field. The way to remove it is to enlarge the input window by zero padding. The region of interest may be also shifted “on the fly” in that the output window can be centred through phase shifts in the Fourier space: $F(k_x, k_y) \Rightarrow F(k_x, k_y) \exp[i(k_x x_{shift} + k_y y_{shift})]$.

E.2.2.5 Filtering

Fourier projection works in the eigenstates basis of the acoustic field (plane waves). Unphysical, non-propagating harmonics $\sqrt{k_x^2 + k_y^2} > k = 2\pi/\lambda$ may be set to zero in the Fourier space. For these harmonics, $k_z = \sqrt{k^2 - k_x^2 - k_y^2} = i|k_z|$ is purely imaginary so that the factor $e^{ik_z(z-z_0)}$ in (E6) decays with distance for calculated forward projections ($z > z_0$), and grows exponentially for calculated backward projections ($z < z_0$). Considering only harmonics with $\sqrt{k_x^2 + k_y^2} < k$ reduces measurement noise and avoids exponential divergence of evanescent waves being back-projected. Such filtering smoothes the pressure distribution during projections in that pressure-field details smaller than a wavelength are lost. This loss corresponds to the classical diffraction resolution limit and does not influence the accuracy of field projections because evanescent waves are present only in a narrow wavelength in the immediate vicinity of ultrasound sources.

E.2.3 Rayleigh integral approach

E.2.3.1 General

Contrary to angular-spectrum projections, the Rayleigh integral can be evaluated not only on flat surfaces, but also on smoothly curved surfaces. As such, the Rayleigh integral allows computation of the acoustic field generated by a distribution of normal velocities or acoustic pressure on a curved transducer surface [17, 26]. The Rayleigh method is therefore more flexible and universal; however, Fourier projections are more computationally efficient, which may be important for large reconstructions. Both methods are mathematically equivalent [26] for the case in which infinite, flat planes are sampled continuously. Accordingly, proper implementation of either the Rayleigh or the Fourier approach should yield the same results.

There are several Rayleigh-type integrals. Acoustic pressure at a given point can be derived from either a normal velocity distribution or an acoustic pressure distribution on some surface (e.g., the **source aperture** plane). The corresponding expressions are called first and second Rayleigh integrals, respectively. Particle velocity components can also be expressed from surface pressure or normal velocity by Rayleigh-type integrals [20]. For the purpose of forward projection ($z > z_0$) it is possible to use the Rayleigh second integral over the scanning plane [26]:

$$p(x, y, z > z_0) = -\frac{1}{2\pi} \iint p(x', y', z_0) \frac{\partial}{\partial n} \left(\frac{e^{ikR}}{R} \right) dx' dy' \quad (\text{E.10})$$

where n is the local outward normal to the measurement surface and $R = \sqrt{(x - x')^2 + (y - y')^2 + (z - z_0)^2}$. When the integration is performed over the entire plane, the formula (E10) gives exact expression for acoustic pressure at $z > z_0$. A similar expression can be used for the calculated backward projection ($z < z_0$) [18]:

$$p(x, y, z < z_0) = -\frac{1}{2\pi} \iint p(x', y', z_0) \frac{\partial}{\partial n'} \left(\frac{e^{-ikR}}{R} \right) dx' dy' \quad (\text{E.11})$$

where n' is the local inward normal to the measurement surface. Note the negative sign in the exponent, in contrast to Equation (E.10). With this equation, back-propagation calculations are not rigorously exact, as they do not account for evanescent waves. Similar to the filtering of harmonics in the angular spectrum approach (i.e., $\sqrt{k_x^2 + k_y^2} > k$), the expression (E11) smoothes out details that are smaller than a wavelength. Therefore, it provides a practical and sufficiently precise method for performing back-projection calculations.

E.2.3.2 Rayleigh integral projection computation

For numerical implementation, the Rayleigh integral is replaced by a finite sum over a discrete number of sample points. If acoustic pressure is measured by a raster scan with equal steps in two directions ($\Delta x = \Delta y = h$), the outward normal $\partial / \partial n$ is replaced by $\partial / \partial z$ and the inward normal $\partial / \partial n'$ is replaced by $-\partial / \partial z$, then (E10) and (E11) are replaced by

$$p(x, y, z) = \mp \frac{h^2}{2\pi} \sum_{x', y'} p(x', y', z_0) \frac{\partial}{\partial z} \left(\frac{e^{\pm ikR}}{R} \right) \quad (\text{E.12})$$

where the negative/positive multiplier and the positive/negative sign in the exponent corresponds to forward/backward projection. Physically, the reconstructed acoustic field is equivalent to the field emitted from a superposition of point sources located at each of the sample point locations. If the step h is not sufficiently small, Equation (E.12) leads to some overestimation in reconstructed field values especially at high steering angles or for side lobes. For most purposes, half-wavelength sampling is sufficient, i.e. formulas (E.8) or (E.9) are applied in this case as well. If one needs even more accurate results, original data may be resampled by Fourier or spline interpolation before feeding it into the Rayleigh sum.

E.3 Implementation

E.3.1 General

Scanned measurements are most often taken in a plane close to the transducer to catch most of the radiated acoustic energy within a relatively limited scanning window (Figures 1 and 2). Measurement considerations can be found in Clause 6, see also [18-20].

E.3.2 Recommendations for hydrophone

Most often, to avoid parasitic reverberation between the source and the receiver during measurements close to the source, needle **hydrophones** are used. To avoid nonlinear distortion of the waveform, measurements are performed in a linear regime (i.e., at low intensity levels). With appropriate scan parameters (window size and resolution), the reconstructed field will predict exactly the same signal values that could be measured by the same **hydrophone** placed physically at the reconstructed positions. Thus, **hydrophone** parameters for the numerical field reconstruction are of the same importance as for any other **hydrophone** quasi-cw measurements.

Hydrophone directivity can be measured as a response (amplitude and phase) to plane waves coming from different directions. If such data are available, they provide full **hydrophone** calibration. For characterization of the focus, it is sufficient to have uniform (<3 dB) directivity within the angle defined by the transducer's numerical aperture. For quantitative measurements of high angle side lobes, **hydrophone** directivity should be sufficiently wide to include these high-angle incident directions.

As an additional advantage of numerical reconstruction methods, the output field may be corrected for **hydrophone** directivity. In this case, the Fourier image of the scanned field should be replaced by

$$F(k_x, k_y) = \frac{F_{scan}(k_x, k_y)}{D(k_x, k_y)} \tag{E.13}$$

where $D(k_x, k_y)$ is the **hydrophone** directivity.

NOTE The directivity of the **hydrophone** may be estimated as

$$D(k_x, k_y) = \frac{2J_1[ka_e \sin(\theta)]}{ka_e \sin(\theta)} \tag{E.14}$$

where $\theta = \arctan\left[\sqrt{k_x^2 + k_y^2} / k\right]$ and where a_e is the effective radius of the **hydrophone**, as determined using the procedures of 5.6 of IEC 62127-1:2007.

E.3.3 Recommendation for planar scan parameters

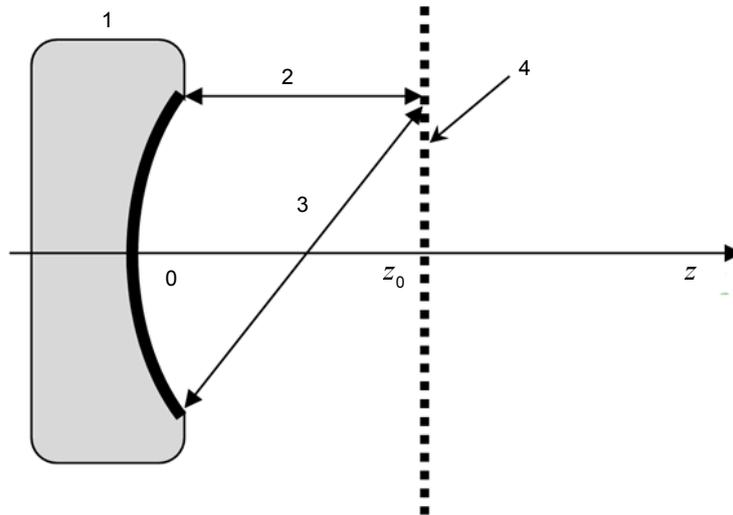
E.3.3.1 Waveform acquisition window

The preceding discussion has assumed that the waveforms are acquired under cw operating conditions. In practice, hydrophone measurements are carried out under toneburst conditions to avoid acoustic reflections and interference, so it is necessary to select a period of time after the start of a toneburst during which the acquired waveforms are representative of the field which would exist at the same location under cw operation in free-field conditions.

The selection of the preferred acquisition window is often a compromise taking into consideration at least the following:

- a) The ring-up time of the transducer – this can be measured at the focus or at the last axial maximum (for an unfocused transducer).
- b) The time of flight between measurement points and all points on the transducer surface – continuous wave conditions can only be established after waves from all parts of the radiating surface have reached the measurement point.
- c) Reflections from the hydrophone mount, water surface and tank walls – if the toneburst is long enough, reflections can interfere with the direct wave; it can be helpful to cover parts of the surfaces with acoustic absorber.
- d) Multiple reflections between the hydrophone and transducer – these can start after $3 z_{\min}/c$ where z_{\min} is the shortest distance between the hydrophone and the transducer surface.
- e) Internal reflections within the transducer – amplitude variations at the beginning and end of the toneburst resulting from internal reflections can sometimes be seen.

In selecting the preferred acquisition window, it can be instructive to excite the transducer with a short burst (1 to 3 cycles) to identify individual sources of reflection. A convenient compromise for a focused transducer is to consider a point in the scanning plane which is opposite one edge of the radiating surface (Figure E-3). The acquisition window should ideally start at least $t_{\text{ring}} + z_{\text{max}}/c$ after the start of electrical excitation and finish less than $3 z_{\min}/c$ after the start of excitation (where t_{ring} is the ring-up time of the transducer). If the scanning plane is sufficiently far from the transducer, then z_{max} is approximately equal to z_{\min} and a suitable window can usually be identified easily. However, as the scanning plane approaches the transducer rim, there will be a minimum value of z_0 below which no window meets these criteria. A decision then needs to be made either to increase z_0 or to accept that additional uncertainty may be introduced due to reflections or to the inability to establish full cw conditions over the whole scanning plane. Note that cw conditions may still be established over the central part of the scanning plane; note also that meeting these two criteria does not necessarily establish cw conditions on the more distant parts of the scanning plane which lie outside the projection of the transducer onto the plane.



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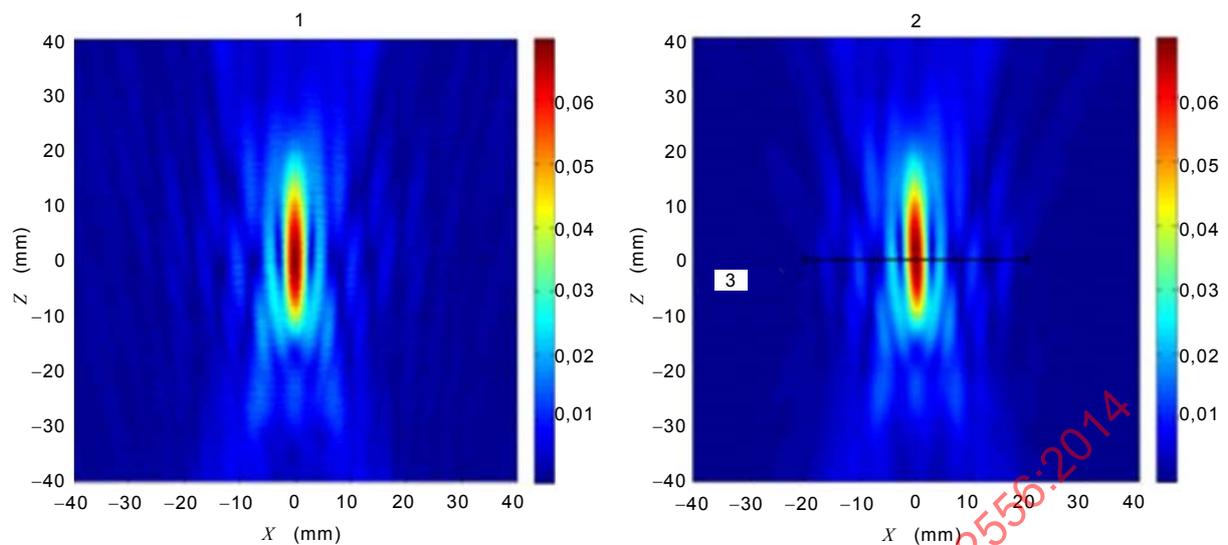
- 1: ultrasonic transducer
- 2: z_{\min}
- 3: z_{\max}
- 4: scanning plane (x', y', z_0)

Figure E.3 – Selection of acquisition window

E.3.3.2 Scanning window size and sampling

All relevant acoustic energy or/and side lobes should pass through the scanning window. Energy that passes outside the window cannot be reconstructed by any numerical simulation. For focal characterization, it is generally sufficient to scan in a small focal plane that includes main side lobes (Figure E.4). But for full transducer characterization, it is better to scan close to the transducer surface so that the scan window contains all energy transmitted to the human body. Scanning resolution (sampling) has been discussed in E.2.1, see Equations (E.8) and (E.9).

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- 1: hydrophone measurement
 2: numerical reconstruction
 3: range of scanning used to provide input to numerical algorithm

Acoustic cw field of 590 kHz frequency was raster-scanned with 0,25 mm step within a 40 mm × 40 mm window in the focal XY plane (intersection with the XZ plane shown by the black bar on right), zero padded and reconstructed by Fourier projection forward and backward from the scanning plane. Hydrophone used: PZT-type, 0,4 mm sensor size. Reconstruction result in the XZ plane (at right) is compared to the direct scan measurement (at left). It is seen that lobes that intersected the scanning window are reconstructed and propagated (or back-propagated) very well, whereas the side lobes that did not intersect the scanning window are missed in the reconstruction.

Figure E.4 – Scanned field compared to its reconstruction from a finite window

E.4 Assessment of uncertainties

Sources of uncertainty may include:

- a) Hydrophone directivity. The effect of **hydrophone** directivity on measurement uncertainty should be simulated.
- b) Sampling position errors. There are different kinds of mechanical errors in scanner, that may affect correct field reconstruction:
 - 1) random position error due to vibrations or mechanical freedom;
 - 2) scaling position error;
 - 3) non-perpendicular axis alignment error;
 - 4) scanning backlash.
- c) The effect of these sources of error on the uncertainty should be assessed in simulation. The setup should be validated. It may be done by scanning different planes to compare them with the predictions of the numerical reconstruction. Validation criteria may be:
 - 1) The **spatial-peak temporal average intensity** error should be less than 20 % when comparing the measured results to simulations of the derived intensity. The comparison should be done at safe quasi-linear levels at the focal point, as described in 7.2.5.3.

It is recommended that comparisons between the results of numerical projection and the results of direct measurements be made with the same hydrophone—i.e., the same hydrophone is used for the input to the projection algorithm and for measurements at

the focus. This will eliminate the effect of uncertainty in the absolute calibration of the hydrophone.

- 2) Comparison of side-lobe intensity levels, as discussed in 7.2.6.3.

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Annex F (informative)

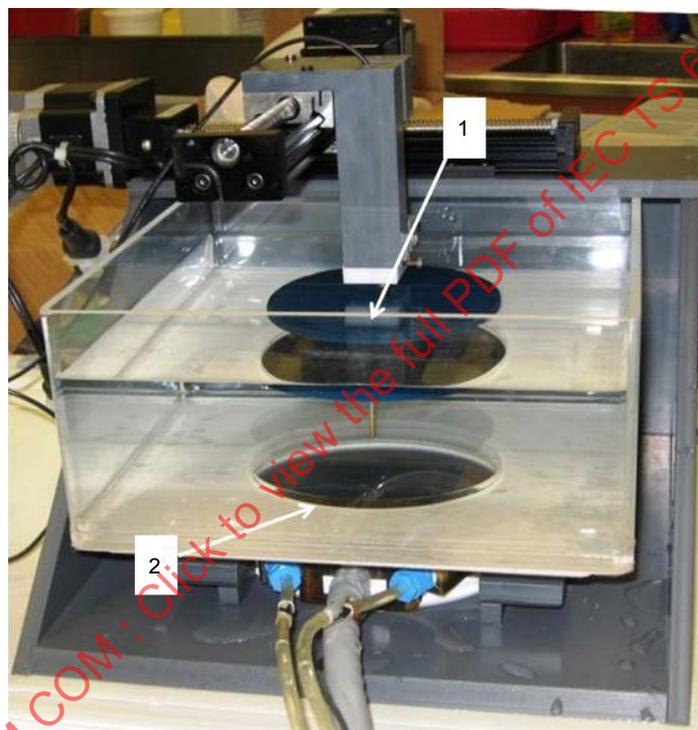
Propagation and back-propagation methods for field reconstruction: examples and uses

F.1 Examples

F.1.1 Fourier projection example

Scanning test equipment developed is shown in Figure F.1:

- 1) A focusing transducer (flat rectangular array 8 cm × 8 cm in size) driven by a commercial clinical system is mounted in the bottom of a tank that is fitted with a scanner (Figure F.1).



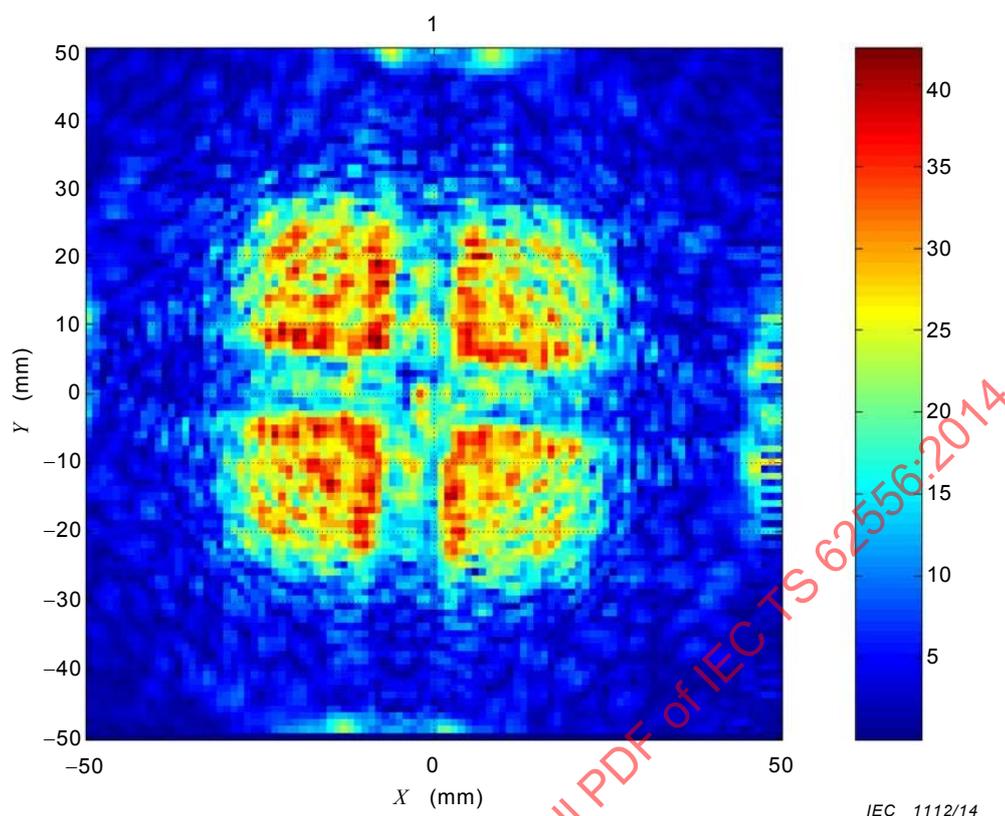
1: hydrophone

2: ultrasonic transducer

Working frequency 550 kHz. Hydrophone has a 0,5 mm aperture. Hydrophone equipped with absorbing disk to prevent reflections from water surface.

Figure F.1 – Transducer inside 2-axis scanner setup

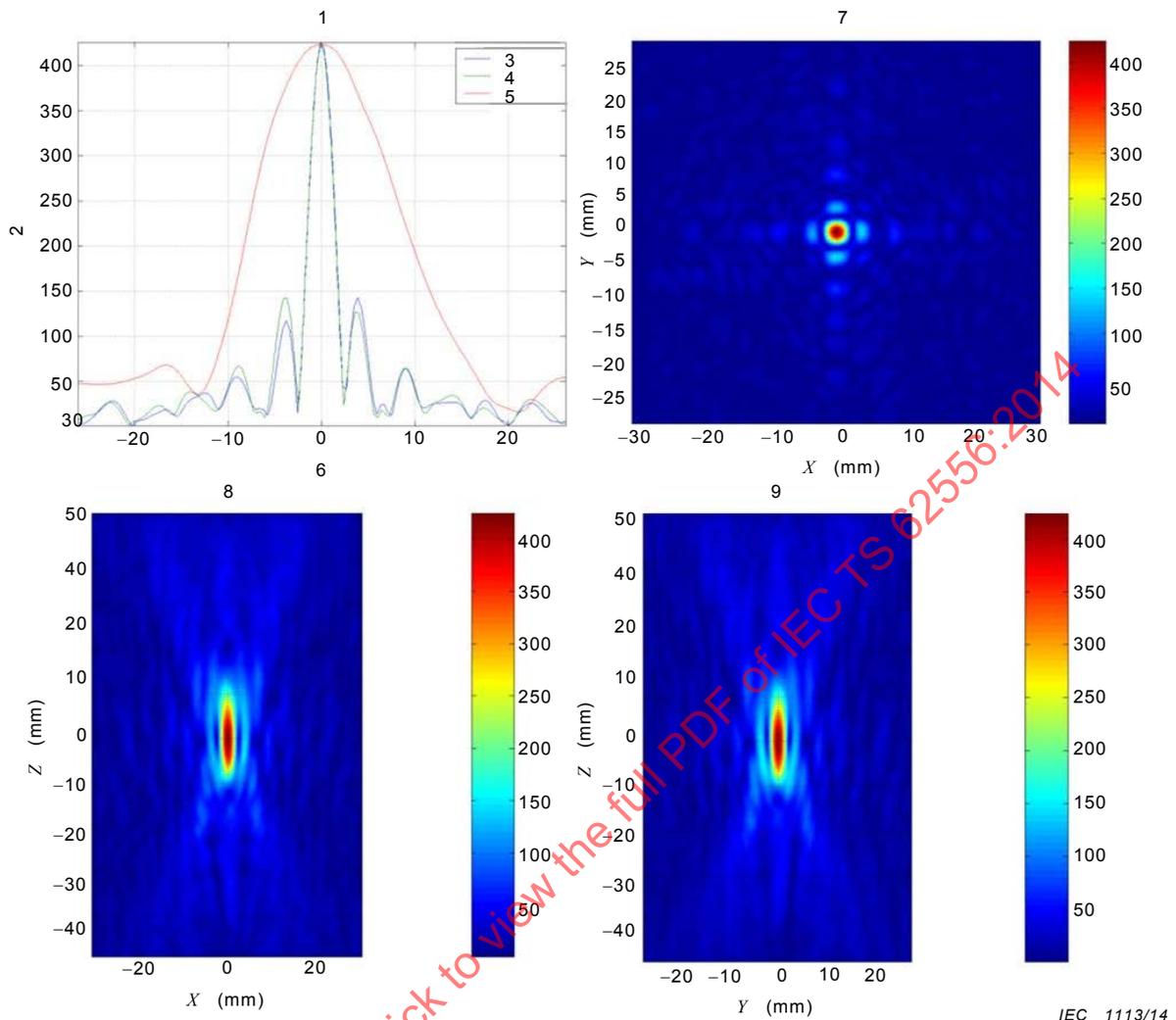
- 2) The transducer is driven to focus at a predefined position: $X = 0$, $Y = 0$, $Z = 60$ mm above its external surface. The ultrasound frequency is 550 kHz.
- 3) A scan was performed 20 mm above the transducer surface. The window size was 100 mm × 100 mm and the step size was 1 mm (0,37 wavelength). Measured pressure amplitudes are shown in Figure F.2.



1: hydrophone measurement

Figure F.2 – Pressure amplitude as scanned

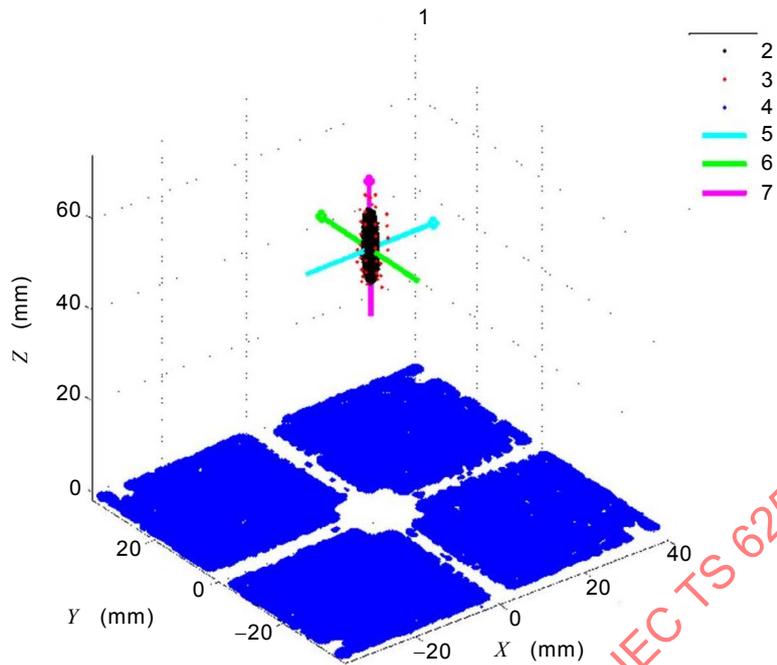
Acoustic pressure was reconstructed by a Fourier projection throughout a $300\text{ mm} \times 300\text{ mm} \times 150\text{ mm}$ volume. The original scan was zero-padded to achieve half-wavelength resolution in the projection. The results for XY , XZ , and YZ planes are shown in Figure F.3.



- 1: beam plot
 2: pressure (kPa)
 3: color for plot along **azimuth axis** (blue)
 4: color for plot along **elevation axis** (green)
 5: color for plot along **beam axis** (red)
 6: position along axis, in mm
 7: pressure map in *xy*-plane
 8: pressure map in *xz*-plane
 9: pressure map in *yz*-plane

Figure F.3 – Reconstructed pressure amplitude distribution in 3 orthogonal planes that contain the focal point

The entire volume was searched for intensities above -6 dB and -10 dB thresholds relative to maximal detected value. Results are depicted in Figure F.4 as a 3D plot in which dangerous hot region margins are marked (in this case, only the focal region, but in general these may be determined from volume reconstruction).



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- 1: focus and hot spots
- 2: portion of beam within -6 dB of focal intensity
- 3: portion of beam within -10 dB of focal intensity
- 4: surface of **ultrasonic transducer**
- 5: **azimuth axis**
- 6: **elevation axis**
- 7: **beam axis**

Black and red boundaries show regions with intensities above -6 dB and -10 dB thresholds. Focal axes are defined algorithmically from beam analysis. The blue region indicates locations on transducer aperture plane where pressures exceed some predefined threshold. The scan was performed at a height of $Z = 20$ mm.

Figure F.4 – 3D representation of the focal beam for nominal focus at $x = -0,85$ mm, $y = -0,25$ mm, $z = 58,95$ mm

The pressure field was back-projected onto the source surface with a calculation step size of $1/6$ wavelength (Figure F.5). Such a plot can be used for detecting major transducer malfunctions.