

TECHNICAL SPECIFICATION

**Ultrasonics – Field characterization – In situ exposure estimation
in finite-amplitude ultrasonic beams**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS –
FIELD CHARACTERIZATION –
IN SITU EXPOSURE ESTIMATION
IN FINITE-AMPLITUDE ULTRASONIC BEAMS**

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IEC 61949, which is a technical specification, has been prepared by IEC technical committee 87: Ultrasonics.

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

Enquiry draft	Report on voting
87/349/DTS	87/364A/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.

This publication is being issued as a technical specification (according to 3.1.1.1 of the IEC/ISO directives, Part 1) as a “prospective standard for provisional application” in the field of finite-amplitude ultrasonic beams, because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an “International Standard”. It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the IEC Central Office.

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INTRODUCTION

Acoustic waves of finite amplitude generate acoustic components at higher frequencies than the fundamental frequency. This provides a mechanism for acoustic attenuation which is not significant at lower acoustic pressure, and for which there is substantial experimental and theoretical evidence (Tables A.1 and A.2). The generation of harmonic frequency components, and their associated higher attenuation coefficient, can occur very strongly when high amplitude pulses, associated with the use of ultrasound in medical diagnostic applications, propagate through water. This fact is of importance when measurements of **acoustic pressure**, made in water, are used to estimate **acoustic pressure** in another medium, or when intensity derived from hydrophone measurements in water is used to estimate intensity within another medium. In particular, errors occur in the estimation of the **acoustic pressure** and intensity *in situ*, if it is assumed that the propagation of ultrasound through water, and through tissue, is linear.

Standards for measurement of frequency-rich pulse waveforms in water are well established (IEC 62127-1). Whilst means to quantify nonlinear behaviour of medical ultrasonic beams are specified, no procedures are given for their use. Since that time IEC 60601-2-37 and IEC 62359 have introduced “attenuated” acoustic quantities, which are derived from measurements in water and intended to enable the estimation of *in situ* exposure for safety purposes.

This Technical Specification describes means to allow “attenuated” acoustic quantities to be calculated under conditions where the associated acoustic measurements, made in water using standard procedures, may be accompanied by significant finite-amplitude effects. A number of alternative methods have been proposed (Table B.1). The approach used in this Technical Specification is aligned with the proposal of the World Federation for Ultrasound in Medicine and Biology [1]¹⁾, that “Estimates of tissue field parameters at the point of interest should be based on derated values calculated according to an appropriate specified model and be extrapolated linearly from small signal characterization of source-field relationships.”

¹⁾ Figures in square brackets refer to the Bibliography.

ULTRASONICS – FIELD CHARACTERIZATION – IN SITU EXPOSURE ESTIMATION IN FINITE-AMPLITUDE ULTRASONIC BEAMS

1 Scope

This Technical Specification establishes:

- the general concept of the limits of applicability of acoustic measurements in water resulting from finite-amplitude acoustic effects;
- a method to ensure that measurements are made under quasi-linear conditions in order to minimise finite-amplitude effects, which may be applied under the following conditions:
 - to acoustic fields in the frequency range 0,5 MHz to 15 MHz;
 - to acoustic fields generated by plane sources and focusing sources of amplitude gain up to 12;
 - at all depths for which the maximum acoustic pressure in the plane perpendicular to the acoustic axis lies on the axis;
 - to both circular and rectangular source geometries;
 - to both continuous-wave and pulsed fields;
- the definition of an acoustic quantity appropriate for establishing quasi-linear conditions;
- a threshold value for the acoustic quantity as an upper limit for quasi-linear conditions;
- a method for the estimation of attenuated acoustic quantities under conditions of nonlinear propagation in water.

2 Normative references

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

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

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

3 Terms and definitions

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

3.1

acoustic attenuation coefficient

coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point

Symbol: α

Unit: decibels per centimetre per megahertz, $\text{dB cm}^{-1} \text{MHz}^{-1}$

[IEC 62359, definition 3.1]

3.2**acoustic pressure**

pressure minus the ambient pressure at a particular instant in time and at a particular point in the acoustic field

Symbol: p

Unit: pascal, Pa

[IEC 62127-1, definition 3.33, modified]

3.3**acoustic working frequency**

arithmetic mean of the frequencies, f_1 and f_2 , at which the acoustic pressure spectrum is 3 dB below the peak value

Symbol: f_{awf}

Unit: Hertz, Hz

[IEC 62127-1, definition 3.3.2, modified]

3.4**attenuated acoustic pulse waveform**

the temporal waveform of the instantaneous acoustic pressure calculated in a specified attenuation model and at a specified point. See 3.1 of IEC 62127-1 for acoustic pulse waveform

Symbol: $p_\alpha(t)$

Unit: pascal, Pa

3.5**attenuated acoustic power**

value of the acoustic output power calculated for a specified attenuation model and at a specified point

Symbol: P_α

Unit: watt, W

[IEC 62359, definition 3.3]

3.6**attenuated peak-rarefactional acoustic pressure**

the **peak-rarefactional acoustic pressure** calculated in a specified attenuation model and at a specified point

Symbol: $p_{r, \alpha}$

Unit: pascal, Pa

[IEC 62359, definition 3.4, modified]

3.7**attenuated pulse-intensity integral**

the pulse-intensity integral calculated for a specified attenuation model and at a specified point

Symbol: $I_{pi, \alpha}$

Unit: joule per metre squared, $J\ m^{-2}$

[IEC 62359, definition 3.6, modified]

3.8

attenuated spatial-peak temporal-average intensity

the spatial-peak temporal-average intensity calculated in a specified attenuation model

Symbol: $I_{\text{spta}, \alpha}$

Unit: watt per metre squared, W m^{-2}

[IEC 62359, definition 3.7, modified]

3.9

attenuated temporal-average intensity

the temporal-average intensity calculated in a specified attenuation model and at a specified point

Symbol: $I_{\text{ta}, \alpha}$

Unit: watt per metre squared, W m^{-2}

[IEC 62359, definition 3.8, modified]

3.10

beam area

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

Symbol: A_b

Unit: metre squared, m^2

[IEC 62127-1, definition 3.7, modified]

3.11

local area factor

the square root of the ratio of the **source aperture** to the **beam area** at the point of interest. The relevant **beam area**, A_b , is that for which the maximum pulse-pressure-squared integral is greater than 0,135 (that is, $1/e^2$) times the maximum value in the cross-section. If the **beam area** at the -6 dB level, $A_{b,-6\text{dB}}$, is known, the **beam area** can be calculated as $A_b = A_{b,-6\text{dB}}/0,69$: ($0,69 = 3\ln(10)/10$).

$$F_a = \sqrt{\frac{0,69 A_{\text{SAeff}}}{A_{b,-6\text{dB}}}}$$

Symbol: F_a

3.12

local distortion parameter

an index which permits the prediction of nonlinear propagation effects along the axis of a focused beam. The local distortion parameter is calculated according to 6.1.1

Symbol: σ_q

3.13

mean peak acoustic pressure

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

Symbol: p_m

Unit: pascal, Pa

3.14**nonlinear threshold value**

a value of any nonlinear propagation index Y , such that for $Y \leq \tau$ the beam has quasi-linear characteristics at the selected point and for $Y > \tau$ the beam has nonlinear characteristics at the selected point

Symbol: τ

3.15**peak-rarefactional acoustic pressure**

maximum of the modulus of the negative instantaneous **acoustic pressure** in an acoustic field or in a specified plane during an acoustic repetition period. Peak-rarefactional acoustic pressure is expressed as a positive number

Symbol: p_r

Unit: pascal, Pa.

[IEC 62127-1, definition 3.44, modified]

3.16**peak-compressional acoustic pressure**

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

Symbol: p_c

Unit: pascal, Pa.

[IEC 62127-1, definition 3.45, modified]

3.17**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.

3.18**scaling factor**

the ratio between the **mean peak acoustic pressure** at a location close to the transducer to the **mean peak acoustic pressure** at the same location under **quasi-linear** conditions, where quasi-linearity is determined at the point of interest.

Symbol: S

3.19**source aperture**

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

Symbol: A_{SAeff}

Unit: metre squared, m^2

[IEC 61828, definition 4.2.65, modified]

3.20

source aperture plane

closest possible measurement plane to the external transducer aperture that is perpendicular to the beam axis

[IEC 61828, definition 4.2.67]

3.21

transducer aperture width

full width of the transducer aperture along a specified axis orthogonal to the beam axis

Symbol: L_{TA}

Unit: metre, m

[IEC 61828, definition 4.2.74, modified]

4 List of symbols

α	acoustic attenuation coefficient
A_b	beam area
A_{SAeff}	source aperture
β	nonlinearity parameter for water, $\cong 3,5$
c	speed of sound
f_{awf}	acoustic working frequency
F_a	local area factor
$I_{pi, \alpha}$	attenuated pulse-intensity integral
$I_{pi, q}$	reduced pulse-intensity integral
$I_{spta, \alpha}$	attenuated spatial-peak temporal-average intensity
$I_{spta, q}$	reduced spatial-peak temporal-average intensity
$I_{ta, \alpha}$	attenuated temporal-average intensity
$I_{ta, q}$	reduced temporal-average intensity
L	discontinuity length
L_{TA}	transducer aperture width
P	total acoustic output power
P_{α}	attenuated acoustic power
p	acoustic pressure
$p_{\alpha}(t)$	attenuated acoustic pulse waveform
$p_q(t)$	acoustic pulse waveform under quasi-linear conditions
p_c	peak-compressional acoustic pressure
$p_{c, s}$	peak-compressional acoustic pressure close to the source for scaling
$p_{c, s, m}$	pre-correction peak-compressional acoustic pressure close to the source for scaling
$p_{c, s, q}$	reduced peak-compressional acoustic pressure close to the source for scaling
p_m	mean peak acoustic pressure
p_r	peak-rarefactional acoustic pressure
$p_{r, \alpha}$	attenuated peak-rarefactional acoustic pressure
$p_{r, q}$	reduced peak-rarefactional acoustic pressure

$p_{r,s,m}$	pre-correction peak-rarefactional acoustic pressure close to the source for scaling
$p_{r,s,q}$	reduced peak-rarefactional acoustic pressure close to the source for scaling
ρ	density
S	scaling factor
σ_q	local distortion parameter
t_d	pulse duration
τ	nonlinear threshold value
τ_q	nonlinear threshold for σ_q
Y	any nonlinear index
z	axial distance of the point of interest from the transducer face

5 Equipment required

Measurements of the acoustic pulse waveform shall be carried out using hydrophones in water, as specified in IEC 62127-1.

Measurement of acoustic output power shall be made using planar scanning by means of a hydrophone. The methods described in this document do not apply to measurements of acoustic output power using a radiation force balance as specified in IEC 61161.

6 Test methods

The following method shall be used for measurement of acoustic quantities, using hydrophones in water, when these measurements are to be used for subsequent calculation of **attenuated peak-rarefactional acoustic pressure**, **attenuated pulse-intensity integral**, **attenuated temporal-average intensity**, and **attenuated acoustic power**.

6.1 Establishing quasi-linear conditions

6.1.1 The local distortion parameter

For the purpose of measurement at any axial point of interest, the **local distortion parameter**, σ_q , is calculated from the measured pulse waveform in water from the following expression

$$\sigma_q = zp_m \frac{2\pi f_{awf} \beta}{\rho_c^3} \frac{1}{\sqrt{F_a}} \quad (1)$$

where

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

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

p_c is the **peak-compressional acoustic pressure** at the point of interest

z is the axial distance of the point of interest from the transducer face

f_{awf} is the **acoustic working frequency**

β is the nonlinearity parameter for water, $\cong 3,5$

F_a is the **local area factor**

NOTE 1 For $2 < F_a < 12$, $\sigma_q \cong \sigma_m$, where σ_m is the nonlinear propagation parameter at the focus as defined in IEC 62127-1. Also see Annex C.

NOTE 2 $F_a = 2$ may be associated with an unfocussed field. In an unfocussed field from a circular source, the maximum axial **amplitude** is twice the **acoustic pressure amplitude** at the source.

NOTE 3 Alternative quantities to σ_q , that have been proposed elsewhere, are summarized in Table C.1

NOTE 4 Under some conditions, a value for the **local area factor** may not be available conveniently. Under these conditions a conservative value $F_a = 2$ may be used.

6.1.2 Upper limit for quasi-linear conditions for σ_q

The field conditions shall be defined as **quasi-linear** if $\sigma_q \leq \tau_q$. τ_q is the nonlinear threshold for σ_q

For the purpose of this document, $\tau_q = 0,5$.

NOTE $\tau_q = 0,5$ is the condition for which approximately 10 % of the energy (5 % of the amplitude at the **acoustic working frequency**) has been transferred from the fundamental spectrum due to nonlinear propagation: see Annex A.

6.1.3 Range of applicability for quasi-linear conditions

The procedures to establish **quasi-linear** conditions are applicable at all depths for which the maximum **mean peak acoustic pressure** in the plane perpendicular to the acoustic axis lies on the axis. Furthermore, having established **quasi-linear** conditions at any particular axial point, together with an associated **scaling factor**, these conditions and **scaling factor** may be used for measurements at all axial positions between the transducer and the selected point. The procedures do not establish **quasi-linear** conditions for axial positions further from the transducer than the selected point.

More generally, a procedure to establish **quasi-linear** conditions for all axial points of interest in any particular field may be easily applied. This may be carried out by selecting a measurement point at an axial distance greater than those of all axial points of interest in the field under consideration. For example, for the purpose of establishing field maxima of any acoustic quantity in a spherically-focused field, a single measurement point at the focus should be sufficient. For fields with astigmatic focusing created, for example, by rectangular ultrasound sources such as those commonly used for medical diagnostic purposes, for which two focal depths exist, **quasi-linear** conditions shall be established at the focus of greater axial distance from the transducer.

6.2 Measurement procedure for estimated *in situ* exposure

Figure 1 shows the principle of the measurement procedure, which has four stages:

- identification of **quasi-linear** conditions;
- measurement under **quasi-linear** conditions;
- measurement of the **scaling factor**;
- calculation of attenuated acoustic quantities.

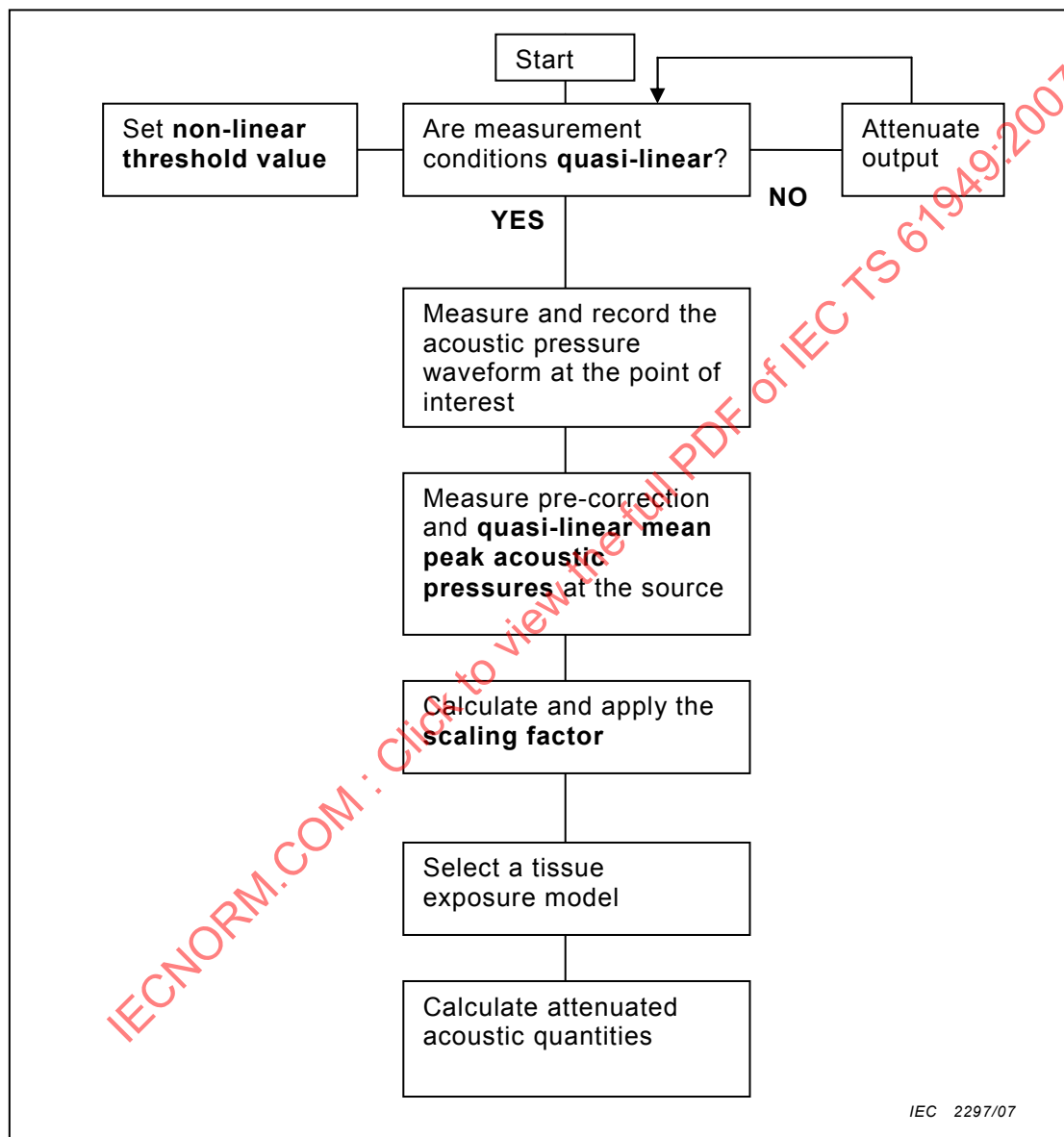


Figure 1 – Flow diagram for obtaining values of attenuated acoustic quantities

6.2.1 Identification of quasi-linear conditions

A calibrated hydrophone is positioned at the point of interest. The output from the transducer is adjusted until the calculated value of σ_q lies within the criterion set in 6.1.2.

NOTE 1 Output may be adjusted either by reducing the voltage applied to the transducer, or with appropriate acoustic attenuators [20, 21]. Where voltage control is used, the device should not alter the output by changing the number of active elements, nor the weighting applied to them. Furthermore, caution and care should be taken to check for and avoid pulser and/or nonlinear electromechanical transducer effects.

NOTE 2 For multi-mode conditions and for multiple focal zones, quasi-linear conditions must be identified for each separate beam.

6.2.2 Tables of limiting mean peak acoustic pressure

For practical purposes, it may be more convenient to apply a threshold to the measured **mean peak acoustic pressure**. Examples of threshold values of **mean peak acoustic pressure**, calculated using the expression for σ_q given in 6.1.1, are given, for $\sigma_q = 0,5$, in Tables D.1, D.2, D.3 and D.4. This approach is equivalent to that given in 6.2.1 for the values of acoustic field quantities given. For the purposes of this technical specification, quasi-linear conditions may be considered as being established if the measured **mean peak acoustic pressure** is equal to, or less than, the appropriate value given in these tables.

6.2.3 Measurement of acoustic quantities under quasi-linear conditions

The acoustic pulse waveform under **quasi-linear** conditions $p_q(t)$ is calculated from the hydrophone voltage waveform, measured using the methods given in IEC 62127-1. The term “reduced” and the suffix q is used to refer to measurements associated with these conditions.

For purposes of calculation, the following acoustic measures are derived from the acoustic pulse waveform under **quasi-linear** conditions, $p_q(t)$: the reduced **peak-rarefactional acoustic pressure** $p_{r,q}$, the reduced pulse-intensity integral $I_{pi,q}$, the reduced temporal-average intensity $I_{ta,q}$ and the reduced spatial-peak temporal-average intensity $I_{spta,q}$.

The reduced acoustic output power P_q is the acoustic output power under **quasi-linear** conditions.

6.2.4 Measurement of the scaling factor

A **scaling factor** S is calculated from measurements of **mean peak acoustic pressure** close to the source. The hydrophone is located within the **source aperture** approximately on the acoustic axis.

6.2.4.1 Criteria for positioning the hydrophone close to the transducer

The position of the **source aperture plane**, in which the hydrophone measurements close to the transducer are made, shall conform, as far as may be practical, to the following requirements.

- The distance between the transducer and the hydrophone shall be small enough to reduce to a minimum the effects due to non-linear propagation. An appropriate criterion, based on the discontinuity length L , is $z < 0,1 L$, where

$$L = \left(\frac{\rho_c^3}{2\pi} \right) \frac{1}{p_{r,s,m} f_{awf} \beta} \quad (2)$$

in which $p_{r,s,m}$ is the pre-correction peak-rarefactional acoustic pressure, and β is the nonlinearity parameter for water, $\approx 3,5$.

- The distance between the transducer and the hydrophone shall be large enough to prevent direct interference between the acoustically-generated hydrophone voltage and electromagnetic coupling, and also from signals created from multiply-reflected acoustic pulses. An appropriate criterion is $z > t_d c$ where t_d is the pulse duration.
- The hydrophone shall be located in a position where the spatial rate of change in the **mean peak acoustic pressure** is low in either direction perpendicular to the acoustic axis. An appropriate criterion is that movement of the hydrophone by a distance equal to its diameter shall result in a change in the peak hydrophone voltage of no more than 10 %. Such conditions exist at axial points very close to a pulsed transducer where there is no overlap in time between the edge and forward components in the wave. The range of depth, z , for which this applies is approximately

$$0 < z < \frac{(L_{TA}/2)^2 - (t_d c)^2}{2t_d c} \quad (3)$$

where L_{TA} is the shortest possible **transducer aperture width**.

NOTE For long pulse and continuous wave fields, condition (b) is not applied. In addition, whilst the general condition (c) applies, the criterion given in Equation 3 may not be applicable, and an appropriate position should be established by observation.

6.2.4.2 Measurement procedure

The procedure may be applied to any field measurement for which the criterion of 6.1.2 is not met. Values of acoustic field quantities under these conditions are referred to as pre-correction values. They may be, but are not restricted to, values measured under maximum possible output conditions.

With the hydrophone positioned as specified in 6.2.4.1, measurements of **peak-compressional acoustic pressure** and **peak-rarefactional acoustic pressure** are made under two output conditions, pre-correction and reduced.

The reduced output condition is identical to that established under 6.2.1, for which the **peak-compressional acoustic pressure** is $p_{c,s,q}$ and the **peak-rarefactional acoustic pressure** is $p_{r,s,q}$.

The pre-correction output condition is established by removing any attenuation associated with the reduced output condition, whether this has been applied by voltage control or by acoustic attenuators. All other controls shall remain unaltered. Under these conditions the **peak-compressional acoustic pressure** is $p_{c,s,m}$ and the **peak-rarefactional acoustic pressure** is $p_{r,s,m}$.

The **mean peak acoustic pressures** under reduced and pre-correction conditions are calculated as follows:

$$p_{m,s,q} = \frac{(p_{c,s,q} + p_{r,s,q})}{2} \quad (4)$$

and

$$p_{m,s,m} = \frac{(p_{c,s,m} + p_{r,s,m})}{2}. \quad (5)$$

The **scaling factor** S is calculated as follows:

$$S = \frac{p_{m,s,m}}{p_{m,s,q}}. \quad (6)$$

6.2.5 Calculation of attenuated acoustic quantities

A linear homogeneous tissue exposure model with **acoustic attenuation coefficient** α is used for the calculation of attenuated quantities.

NOTE To be aligned with other standards, the value of the **acoustic attenuation coefficient**, α , of the linear homogeneous tissue exposure model shall be $0,3 \text{ dB}(\text{cm MHz})^{-1}$. The **acoustic attenuation coefficient** of water is assumed to be negligible; this condition applies when the nonlinear effects are much greater than the absorption as estimated by the Goldberg number [25]. However, the method described is general, and any appropriate

attenuation model could, in principle, be used. For example, absorption dependent on a frequency power law [32,33] can be used where $\alpha(f_{\text{awf}}) = \alpha_0 |f_{\text{awf}}|^y$ in which α_0 is an absorption constant in $\text{dB}(\text{cm}^{-1} \cdot \text{MHz}^{-y})$ and y is an exponent usually between 1 and 2 for tissue and equal to 2 for water. To extend the equations for pressure and intensity below, $\alpha_0 f_{\text{awf}}$ can be replaced by $\alpha(f_{\text{awf}})$.

For consistency, it is recommended that calculations in this section use practical units of $\text{dB}(\text{cm MHz})^{-1}$ for **acoustic attenuation coefficient**, cm for the depth to the point of interest, and MHz for **acoustic working frequency**.

The **attenuated acoustic pulse waveform** $p_\alpha(t)$ at a point of interest at depth z shall be calculated as follows:

$$p_\alpha(t) = S \cdot p_q(t) 10^{(-\alpha z f_{\text{awf}} / 20)}. \quad (7)$$

The **attenuated peak-rarefactional acoustic pressure** $p_{r,\alpha}$ at a point of interest at depth z shall be calculated as follows:

$$p_{r,\alpha}(z) = S \cdot p_{r,q}(z) 10^{(-\alpha z f_{\text{awf}} / 20)}. \quad (8)$$

The **attenuated pulse-intensity integral** $I_{pi,\alpha}$ at a point of interest at depth z shall be calculated as follows:

$$I_{pi,\alpha}(z) = S^2 \cdot I_{pi,q}(z) 10^{(-\alpha z f_{\text{awf}} / 10)}. \quad (9)$$

The **attenuated temporal-average intensity** $I_{ta,\alpha}$ at a point of interest at depth z shall be calculated as follows:

$$I_{ta,\alpha}(z) = S^2 \cdot I_{ta,q}(z) 10^{(-\alpha z f_{\text{awf}} / 10)}. \quad (10)$$

The **attenuated acoustic power** P_α at a point of interest at depth z , shall be calculated as follows:

$$P_\alpha(z) = S^2 \cdot P_q 10^{(-\alpha z f_{\text{awf}} / 10)}. \quad (11)$$

NOTE If the pre-correction output power, P , has been measured close to the transducer, then the relationship $P_\alpha(z) = P \cdot 10^{(-\alpha z f_{\text{awf}} / 10)}$ is equivalent to Equation 11 and there is no need to measure P_q .

The **attenuated spatial-peak temporal-average intensity**, $I_{\text{spta},\alpha}$ at a point of interest at depth z shall be calculated as follows:

$$I_{\text{spta},\alpha}(z) = S^2 \cdot I_{\text{spta},q}(z) 10^{(-\alpha z f_{\text{awf}} / 10)}. \quad (12)$$

6.3 Uncertainties

Guidance on assessment of uncertainties associated with the use of hydrophones is given in of IEC 62127-1, and in the ISO *Guide to the expression of uncertainty in measurement*.

In calculating the value of the **local distortion parameter**, consideration shall be given to uncertainties in the measurement of **acoustic working frequency**, **mean peak acoustic pressure**, distance and **local area factor**. Greatest uncertainties may be expected to be associated with the **local area factor**. An overall uncertainty in σ_q of $\pm 50\%$ may be tolerated. For nonlinear indicators of the form $\sigma = fn(f_{\text{awf}}, z)$, such as σ_q , spectral distortion changes only

slowly in the range $\sigma < 1$. Therefore a large uncertainty is acceptable for a test for $\sigma_q = 0,5$, for the purpose of defining **quasi-linear** conditions.

Uncertainty in the measurement of the **scaling factor** depends upon the separate uncertainties in the measurements of **mean peak acoustic pressures** at the source under **quasi-linear** and pre-correction conditions. In view of the requirement to position the hydrophone close to the transducer, and the requirement to make measurements at low peak acoustic pressures, electrical noise may be of particular concern. Hydrophone noise and electrical pick-up can be evaluated by blocking the acoustic beam with a closed-cell air-filled foam or a very good absorber. For pulsed operation, coherent electrical pick-up caused by the electrical firing of the transducer should be windowed out by placing the acoustic signal at the start of the acquisition window. Errors arising from temporal stability of output between measurements should be assessed. Positioning errors may be minimized if the two measurements required to calculate the **scaling factor** are carried out without repositioning the hydrophone. Other potential sources of error are listed in Annex I of IEC 62127-1.

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Annex A (informative)

Review of evidence

A.1 Excess energy loss in water at high acoustic amplitudes

Acoustic waves of finite amplitude generate acoustic components at frequencies higher than the fundamental [2]. This provides a mechanism for acoustic attenuation that is absent from waves of low peak acoustic pressure [3,4]. The generation of harmonic frequency components, and their associated higher attenuation coefficient, can occur very strongly when high amplitude pulses associated with diagnostic ultrasound equipment propagate through water. This fact is of importance when *in situ* exposure is to be predicted from measurements made in water using hydrophones.

There is ample theoretical and experimental evidence that the propagation in water of ultrasound pulses at biomedical frequencies and pressure amplitudes has associated with it a loss of acoustic energy in excess of that from the fundamental frequency propagation. A summary of some of this evidence is given in Tables A.1 and A.2. The loss has been demonstrated by means of a reduction in the radiation force on a target as the distance between the transducer and the target is increased [5], demonstrating a loss in acoustic power with distance. Similarly, the axial profile in water is dependent on pulse amplitude, and the comparison of profiles at high and low pulse amplitude has been used to demonstrate the depth at which excess attenuation commences [6,7]. Beams generated by modern clinical scanners are focused astigmatically, and these focusing regimes add a further cause of difference between high and low-amplitude beams [8]. Under some circumstances, the low amplitude beam reaches its highest value at the deeper of the two focal depths, whilst at high amplitudes it is the shallower peak which has the greatest amplitude [7]. A reduction in temperature rise in a simple thermal test object can be related directly to the loss of beam intensity due to nonlinear propagation [9].

Surveys of exposure from diagnostic ultrasound scanners suggest operation at levels associated with severe nonlinear effects. Modern scanners generate peak **acoustic pressures** which may exceed 2 MPa at the source [7]. Estimates of the degree of nonlinearity at the focus have been made using the acoustic propagation parameter σ_m [10 and IEC 62127-1]. Starritt & Duck, [11] estimated the shock parameter at the focus, σ_f , from measurements of σ_m , scaling from measurements at the source [12]. For 11 out of 36 beams, σ_f exceeded 3.0. As remarked below, $\sigma > 3$ is associated with significant excess transmission loss due to the propagation of an acoustic shock.

The changes which take place due to finite amplitude propagation in a plane wave can be characterised by the plane-wave shock parameter $\sigma = \beta \epsilon k z$. β is the nonlinear propagation parameter of the medium, ϵ is the acoustic Mach number (the ratio of particle velocity at the source to the speed of sound), $k = 2\pi/\lambda$ is the wave number and z is the propagation distance. Formal acoustic analysis has considered three nonlinear regions: that for which $\sigma < 1$, that for which $\sigma > 3$ and a transition region between [2]. For this special case of a pure sinusoid it is convenient to define the plane-wave discontinuity length L as the distance for which $\sigma = 1$: $L = 1/\beta \epsilon k$. In a practical situation, however, the distance required to form a shock may differ slightly from the theoretical value for discontinuity length [[2], page 73].

For a plane wave at $\sigma > 3$, a sawtooth wave has formed, and significant excess energy loss occurs. For any value of σ , a reciprocal relationship exists between source amplitude and propagation distance. This means that the distance at which a $\sigma = 3$ shock is reached decreases inversely with source amplitude. Furthermore, at any field position for which σ exceeds 3, the fraction of the propagation distance which is lossy becomes progressively

greater as the source amplitude increases. Ultimately the incremental transmission loss closely approximates to the incremental increase in source intensity, leading to a condition known as acoustic saturation at a particular field point. Under these conditions variations in the source pressure remain hidden from the field point [2,13].

IEC 62127-1, 7.2.4 gives useful practical ranges for the nonlinear propagation parameter, σ_m . This parameter was developed to quantify the nonlinearity at the focus of a spherically converging field. For $\sigma_m < 0,5$, little nonlinear distortion has occurred, and the amplitude at the fundamental differs by less than 5 % from the value in the absence of nonlinear effects. For $0,5 < \sigma_m < 1,5$, considerable distortion has occurred, and at $\sigma_m = 1,5$ the amplitude in a one half octave band centred at the **acoustic working frequency** differs by 25 % from its value in the absence of nonlinear effects. For $\sigma_m > 1,5$, considerable nonlinear distortion and attenuation occurs at the **acoustic working frequency**. According to 6.4.c.5 of IEC 61828, $\sigma_m < 0,2$ may be considered as being in the linear range. The threshold for σ_q used in the present document to define the boundary below which **quasi-linear** conditions apply is $\sigma_q < 0,5$, a condition for which the amplitude at the fundamental differs by less than 5 % from that in the absence of nonlinear effects. More stringent conditions were considered to be unwarranted for the purposes of this technical specification.

Table A.1 – Experimental evidence of nonlinear loss associated with the propagation of ultrasound pulses under diagnostic conditions in water

Experimental study	Reference
Excess attenuation of acoustic power in water	[5]
Excess attenuation of axial pulse intensity integral in water	[6]
Up to 80% reduction in estimated p_r in gels using linear “derating”	[12]
Shift of intensity maximum between focal peaks in water	[7]
Many diagnostic beams have $\sigma > 3$ at focus	[11]
Thermal effects attenuated by excess propagation loss	[9]

Table A.2 – Theoretical evidence of nonlinear loss associated with the propagation of ultrasound pulses under diagnostic conditions in water

Theoretical study	Reference
Excess on-axis energy loss: circular transducer	[14]
Excess off-axis energy loss: circular transducer	[15]
Excess energy loss: rectangular transducer	[8]
Errors in estimating MI	[16;17;18]
Finite-amplitude effects and heating	[4]
Effects on safety indices	[19]

A.2 The effect of nonlinear propagation loss on estimates of *in situ* exposure quantities using linear assumptions.

The experimental evidence, some of which has been presented above, together with detailed theoretical predictions of nonlinear propagation in diagnostic fields give together very strong grounds to challenge the validity of present procedures for calculating *in situ* exposure. The exposure quantity receiving most attention has been the Mechanical Index [16,17,18]. Excess attenuation of rarefaction pressure in water causes calculated values of MI to be underestimates of true *in situ* values. MI is one of the exposure quantities included in IEC 60601-2-37. In addition, both the position and the value of attenuated (de-rated) peak pulse intensity integral and peak time average intensity can be affected [7]. In addition the **acoustic working frequency** also may vary slightly with pulse amplitude. As a result, other

quantities defined within IEC 60601-2-37 may be affected, including the soft tissue thermal index and the bone thermal index in non-scanning mode. Thermal index in scanning mode is primarily dependent on output acoustic power, but its dependence on centre frequency means that its values may also alter slightly in the presence of nonlinear effects. More generally, the ability to predict *in situ* exposure at any specified point of interest, is compromised by the use of linear attenuation factors for any quantity which is calculated from exposure measurement rather than being measured.

The errors in estimating attenuated exposures by using linear attenuation correction may be as great as 80 % [12]. Comparisons are difficult, however, since the defined position at which the *in situ* exposure is to be estimated alters its estimated value [18]. Nevertheless, in principle the errors can be very high as the limit set by the acoustic saturation pressure at any point in the field is approached. A theoretical study of saturation pressures has predicted that some present regulatory limits are ineffective, since they are based on linear estimates of *in situ* exposure [13]. This lack of effective acoustic output control is associated with higher frequencies and longer focal depths.

The propagation of high-amplitude pressure waves through tissue is also a non-linear process. The harmonic generation associated with this propagation is exploited in medical ultrasound imaging systems. At diagnostic frequencies and amplitudes, however, the Goldberg number, Γ , for soft tissue is about two orders of magnitude smaller than that for water [30]. Γ is the ratio of two characteristic distances, the absorption length and the discontinuity length, and so quantifies the competing effects of non-linear propagation and acoustic absorption. It is appropriate therefore to consider as a priority the non-linear propagation effects in water, and this is the concern of this document. The linear tissue exposure model used in this document is an acceptable and pragmatic first approximation. Nevertheless, it does not prevent the use of more complex tissue models to be used, including those which invoke nonlinear propagation effects in the tissue (see Figure 1).

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Annex B (informative)

Review of alternative methods for managing finite-amplitude effects during field measurement

A number of methods have been proposed for the management of nonlinear loss during *in situ* exposure estimation. These are given in outline in the Table B.1, and summarized in this Annex

B.1 Methods which use water as the measurement medium.

Water has significant advantages over any other liquid as the medium in which to make standard acoustic measurements. It is widely available in large quantities. It is non-toxic and measurement tanks may be refilled at very little expense. Its acoustic and mechanical properties are very well documented. For these reasons there is a great incentive to retain water as the medium for measurement.

B.1.1 Measurements under quasi-linear conditions

All measurements are made with the wave amplitude attenuated such that propagation is **quasi-linear**. This may be achieved in principle through electronic attenuation of the output drive level. Alternatively acoustic attenuation may be applied, using calibrated plastic attenuators [20, 21].

B.1.2 Measurements at highest amplitudes

Measurements are made at highest amplitudes, and a correction applied to compensate for the estimated excess loss of energy [12]. The beam may be numerically modeled using an appropriate computational approach. Several numerical methods exist [8, 15, 22, 23]. This approach has been demonstrated and validated for a circular focused source using a numeric implementation of the Khokhlov-Zablotskaya-Kuznetsov (KZK) equation (14). One suggested method [12] uses two alternative algorithms depending on whether σ is less than or greater than 2,0. Each beam would apparently require unique modeling, challenging the numeric methods currently available. Accurate knowledge of the amplitude and phase distribution across the transducer is required. A practical approach could be the generation of tables of loss factors for sample fields which might be taken to sufficiently approximate any selected field to give confidence in the correction.

B.2 Methods which use a liquid other than water, or a solid.

An alternative strategy is to use a liquid other than water as the propagation medium. These liquids broadly fall into two categories. Most effort has been placed in developing a liquid whose attenuation coefficient is carefully set as being $0,3 \text{ dB}(\text{cm} \cdot \text{MHz})^{-1}$, with the additional controls that both speed of sound and B/A should be appropriate [24]. B/A is the coefficient of nonlinearity of the material [2]. Alternatively any liquid could be selected for which the acoustic properties are well characterized and stable, and within which the excess attenuation associated with nonlinear propagation does not occur at the pulse amplitudes in use. Solids with tissue-equivalent properties have also been suggested [25].

Table B.1 – Methods for estimation of *in-situ* exposure in nonlinear beams

Measurement medium	Output beam conditions	Method	Refs	Tissue models
Water	Maximum	Apply theoretical factor to correct for nonlinear loss	[14,12]	Linear or nonlinear
Water	Quasi-linear using electronic attenuation	Apply scaling factor from measurements at source	[7,19]	Linear or nonlinear
Water	Quasi-linear using acoustic attenuators	Apply scaling factor from attenuator calibration	[20]	Linear or nonlinear
Tissue mimic (liquid)	Maximum	$\alpha=0,3 \text{ dB (cm} \cdot \text{MHz)}^{-1}$	[24]	Tissue mimic properties
Tissue mimic (liquid)	Maximum	Any known properties sufficient to linearize exposure	[31]	Linear or nonlinear
Tissue mimic (gel/solid)	Maximum	Known properties	[25]	Tissue mimic properties

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Annex C (informative)

Parameters to quantify nonlinearity

C.1 List of symbols used only in Annex C

f_a	upper frequency bound of a linear pulse spectrum, used in the definition of spectral index
G_F	amplitude gain at the focal point
$P_f df$	output acoustic power increment at frequency f
p_{rms}	root-mean-square acoustic pressure
z_F	axial distance to the focal point
σ_m	nonlinear propagation parameter
σ_s	Ostrovskii/Sutin propagation parameter
σ_z	field sigma

C.2 Summary of parameters describing propagation nonlinearity

A substantial number of parameters have been defined with the purpose of specifying the nonlinear conditions in pulsed ultrasound beams used for medical diagnostic purposes. The most significant of these are listed in Table C.1.

Table C.1 – Parameters for quantification of nonlinearity in an ultrasonic field

Parameter	Expression	For	Against
Acoustic propagation parameter, σ_m IEC 62127-1, [10]	$z_F p_m \frac{2\pi f_{awf} \beta}{\rho c^3} \frac{\ln(G_F + \sqrt{G_F^2 - 1})}{\sqrt{G_F^2 - 1}}$	Established in IEC and AIUM standards Developed theory	Theory is for single frequency excitation, and Gaussian profiles, at the focus. Requires measurement of focal gain. Several potential sources of measurement error
Local distortion parameter, σ_q [26]	$z p \frac{2\pi f_{awf} \beta}{\rho c^3} \frac{1}{\sqrt{F_a}}$	Modeling demonstrates robustness over a wide range of conditions, and distances. For $2 < F_a < 12$, $\sigma_q \approx \sigma_m$	Empirical Requires measurement of F_a
Ostrovskii/Sutin propagation parameter, σ_s [27]	$\frac{(p_c - p_r)}{(p_c + p_r)}$	Potentially simple expression	Valid at focus Uncertain behaviour for non-spherical focusing
Field sigma σ_z [25]	$z p \frac{2\pi f_{awf} \beta}{\rho c^3}$	Valid definition at all points in field Derived directly from pressure waveform	Does not represent actual nonlinearity at the field position

Table C.1 (continued)

Parameter	Expression	For	Against
Spectral index [7]	$\frac{\int_{f_a}^{\infty} P_f \cdot df}{\int_0^{\infty} P_f \cdot df}$	Valid at any field point Derived directly from pulse spectrum	Indefinite value for low degrees of nonlinearity. Depends on initial wave shape. Requires selection of threshold frequency
Second harmonic ratio [25]	$\frac{p_2}{p_1}$	Valid at any field point Derived directly from pulse spectrum	Requires consideration of definition of centre frequency and selection of harmonic frequency
Acoustic pulse crest factor IEC 61102 ²⁾	$\frac{p_c}{p_{rms}}, p_c > p_r$	Derived directly from pressure waveform	Value depends on diffraction
Asymmetric ratio [27]	$\frac{p_c}{p_r}$	Derived directly from pressure waveform	Value depends on diffraction

The parameters fall into the following categories.

- a) Parameters which are calculated from a measurement of acoustic pressure.
 - 1) Parameters which quantify pulse asymmetry from measurements of peak- rarefactional acoustic pressure and peak-compressional acoustic pressure (acoustic crest factor, asymmetric ratio, Ostrovskii/Sutin propagation parameter).
 - 2) Parameters which quantify nonlinearity from measurements of **mean peak acoustic pressure**, propagation distance, acoustic working frequency and focal conditions (acoustic propagation parameter, field sigma, local distortion parameter, Ostrovskii/Sutin propagation parameter).
- b) Parameters which are calculated from the pulse spectrum.
 - 1) Parameters which select measurements at specified frequencies (second harmonic ratio).
 - 2) Parameters which use the complete spectrum of frequencies (spectral index).

In addition, some parameters have validity only at the focus (acoustic propagation parameter, Ostrovskii/Sutin propagation parameter).

C.3 Criteria for selection of an appropriate parameter

In order to operate successfully for the purposes of this technical specification, the following criteria for parameter selection have been applied.

- a) The parameter should have validity at all points of interest in the field at which it is required to estimate *in situ* exposure.
- b) The parameter should be valid irrespective of the initial pulse waveform and pulse spectrum.
- c) The parameter should be valid irrespective of the conditions of focusing.
- d) A defined threshold value for the parameter should enable nonlinear conditions to be identified in all cases.

2) IEC 61102, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz* (withdrawn and replaced by IEC 62127-1, IEC 62127-2 and IEC 62127-3 in 2007).

- e) The parameter should be simple to measure.
- f) Measurement errors associated with the parameter should be as small as possible, particularly when the value of the parameter is close to the defined threshold value.

None of the listed parameters rigorously meet all criteria. Parameters using pulse asymmetry are simple to measure, but fail to operate over all conditions of focusing and pulse waveform. Similarly, the second harmonic ratio is simple to measure, but its value may depend strongly on the linear spectral shape.

To underpin the preparation of this technical specification, a software solution to the KZK equation, implemented as the so-called “Bergen” code [28, 29], was used to explore the behaviour of the alternative parameters under a range of conditions. These included estimates along the acoustic axis with both circular and rectangular sources, astigmatic foci, a range of acoustic working frequencies, and pulse shapes [26]. From this study, it was shown that the empirical parameter σ_q was the most robust parameter over all conditions.

C.4 Absolute and relative measures of nonlinearity

The rationale used here assumes that it is possible to quantify the degree of nonlinearity at the point of interest from a single measurement. It is also possible to quantify nonlinear propagation effects by carrying out multiple field measurements at a specific location, over a range of drive levels. Inspection of any nonlinearity between measured **mean peak acoustic pressure** at the source and measured mean peak **acoustic pressure** at the field point may be used to define a threshold for nonlinear behaviour. Whilst such an approach has merit, it has not been used in this technical specification, because of the criterion to simplify the measurement procedure. Furthermore the procedure depends on the ability to make many measurements within the **quasi-linear** range, which may be difficult to implement generally in practice.

Annex D (informative)

Tables of upper limits for mean peak acoustic pressure for quasi-linear conditions

In practice, it may be convenient to apply a threshold to the measured **mean peak acoustic pressure**. This annex includes four tables (Tables D.1, D.2, D.3 and D.4) as examples, in which the upper limits for **mean peak acoustic pressure** associated with **quasi-linear** conditions in water are presented, for acoustic working frequencies $f_{awf} = 2,0$ MHz, 3,5 MHz, 5,0 MHz and 7,0 MHz. Threshold **mean peak acoustic pressures** are presented for values of local area factor, F_a , between 2 and 12, and for depths from 1 cm to 20 cm in each case. The values have been calculated using the expression for σ_q given in paragraph 6.1.1, for $\sigma_q = 0,5$. Values for the other variables were: speed of sound 1 480 m s⁻¹; density 1 000 kg m⁻³; nonlinear parameter 3,5. This expression can be used to create further tables as required.

Table D.1 – The upper limit for mean peak acoustic pressure (MPa) associated with quasi-linear conditions, $\sigma_q \leq 0,5$; acoustic working frequency, $f_{awf} = 2,0$ MHz

Depth cm	Local area factor, F_a										
	2	3	4	5	6	7	8	9	10	11	12
1	5,21	6,38	7,37	8,24	9,03	9,75	10,42	11,06	11,65	12,22	12,77
2	2,61	3,19	3,69	4,12	4,51	4,88	5,21	5,53	5,83	6,11	6,38
3	1,74	2,13	2,46	2,75	3,01	3,25	3,47	3,69	3,88	4,07	4,26
4	1,30	1,60	1,84	2,06	2,26	2,44	2,61	2,76	2,91	3,06	3,19
5	1,04	1,28	1,47	1,65	1,81	1,95	2,09	2,21	2,33	2,44	2,55
6	0,87	1,06	1,23	1,37	1,50	1,63	1,74	1,84	1,94	2,04	2,13
7	0,74	0,91	1,05	1,18	1,29	1,39	1,49	1,58	1,67	1,75	1,82
8	0,65	0,80	0,92	1,03	1,13	1,22	1,30	1,38	1,46	1,53	1,60
9	0,58	0,71	0,82	0,92	1,00	1,08	1,16	1,23	1,30	1,36	1,42
10	0,52	0,64	0,74	0,82	0,91	0,98	1,04	1,11	1,17	1,22	1,28
11	0,47	0,58	0,67	0,75	0,82	0,89	0,95	1,01	1,06	1,11	1,16
12	0,43	0,53	0,61	0,69	0,75	0,81	0,87	0,92	0,97	1,02	1,06
13	0,40	0,49	0,57	0,63	0,69	0,75	0,80	0,85	0,90	0,94	0,98
14	0,37	0,46	0,53	0,60	0,65	0,70	0,74	0,79	0,83	0,87	0,91
15	0,35	0,43	0,49	0,55	0,60	0,65	0,70	0,74	0,78	0,82	0,85
16	0,33	0,40	0,46	0,52	0,56	0,61	0,65	0,69	0,73	0,76	0,80
17	0,31	0,38	0,43	0,49	0,53	0,57	0,61	0,65	0,69	0,72	0,75
18	0,29	0,36	0,41	0,46	0,50	0,54	0,58	0,61	0,65	0,68	0,71
19	0,27	0,34	0,39	0,43	0,48	0,51	0,55	0,58	0,61	0,64	0,67
20	0,26	0,32	0,37	0,41	0,45	0,49	0,52	0,55	0,58	0,61	0,64

For **mean peak acoustic pressures** equal to or below those given in this table, quasi-linear conditions may be assumed to exist at the depth specified.