IEC 61846

Edition 2.0 2025-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Ultrasonics – Therapeutic focused short pressure pulse sources – Characteristics of fields

Ultrasons – Sources d'impulsions de pression courtes focalisées thérapeutiques – Caractéristiques des champs

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ULTRASONICS – THERAPEUTIC FOCUSED SHORT PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

FOREWORD

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IEC 61846 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

This second edition cancels and replaces the first edition published in 1998. This edition constitutes a technical revision.

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

a) Change of title:

"pressure pulse lithotripters" in the previous edition is changed to "therapeutic focused short pressure pulse sources" in order to take into account the development in the relevant technical and biomedical applications of such sources, which were originally used only for (kidney) lithotripsy, while recent applications include a wide range for the treatment of, for example, stone diseases, orthopaedic pain, tissue, cardiac and brain diseases.

The term "focused" was added to differentiate IEC 61846 from IEC 63045.

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The term "short" was added to align the nomenclature to IEC 63045 and to differentiate IEC 61846 from standards in the HIFU and HITU fields.

b) Clause 1 and elsewhere in the document: The term "lithotripsy" is changed to "therapy" in order to account for the wide range of applications beyond stone diseases.

c) Clause 3: The "−6 dB" parameter definitions are replaced by "$-n$ dB" to avoid misconceptions in the significance and use of these parameters and to account for newer findings in literature.

   Additional "n MPa" parameters are introduced for the same reasons.

   The definitions of "derived" parameters are aligned to those in recently published standards, for example IEC 62127-1.

   New definitions were added which describe parameters appearing in newer relevant literature, for example "momentum", "average positive acoustic pressure", "cavitation induction index", "pulse to pulse variability", "total pressure pulse energy dose".

d) Clause 6: The terms "focus hydrophone" and "field hydrophone" were removed to account for newer technical developments. New terms distinguish between "hydrophones for pressure pulse measurements" and "hydrophones for quality assurance".

e) Annexes: Descriptions, tables and figures were edited to account for newer literature and standards as well as technical developments.

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

Draft	Report on voting
87/879/FDIS	87/887/RVD

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

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

Words **in bold** in the text are defined in Clause 3.

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

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INTRODUCTION

Focused short pressure pulses were initially (since February 1980) applied clinically in lithotripsy, to break up and disrupt calcific deposits within the body, in particular, stones within the renal, biliary and salivary glands tracts. Extracorporeal pressure pulse lithotripsy has up to now been regarded as the most applied therapeutic option for treating most renal calculi [18], [23], [24].

The use of pressure pulses has been evolved to a more general use, often called "extracorporeal shock wave therapy (ESWT)" which expands its application to a broad range of musculoskeletal conditions, including plantar fasciitis, calcific tendinitis of the shoulder, lateral or medial epicondylitis of the elbow, pain treatment, non-union and delayed union of fractures [25]. Some of these are also treated using unfocused pressure pulse sources, which are specified in IEC 63045.

Several different forms of equipment for lithotripsy and for ESWT are commercially available from a number of manufacturers.

This document specifies methods of measuring and characterizing the acoustic pressure field generated by focusing pressure pulse equipment.

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ULTRASONICS – THERAPEUTIC FOCUSED SHORT PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

1 Scope

This document is applicable to:

– **therapy equipment** using extracorporeally induced focused pressure pulse waves;
– **therapy equipment** producing focused mechanical energy excluding thermal energy.

This document does not apply to percutaneous and laser **lithotripsy equipment**.

This document does not apply to:

– histotripsy or other therapeutic ultrasound bursts of longer time duration than that of the **pressure pulse**;
– non-focused pressure pulse equipment.

This document specifies:

– measurable parameters which could be used in the declaration of the acoustic output of extracorporeal **focused pressure pulse equipment**;
– methods of measurement and characterization of the pressure field generated by **focused pressure pulse equipment**.

NOTE The parameters defined in this document do not – at the present time – allow quantitative statements to be made about effectiveness and possible hazard. In particular, it is not possible to make a statement about the limits for these effects.

While this document has been developed for equipment intended for use in **lithotripsy**, it has been developed such that, as long as no other specific standards are available to be used for other medical applications of therapeutic extracorporeal **focused pressure pulse** equipment, this document can be used as a guideline.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-113:2011, *International Electrotechnical Vocabulary – Part. 113: Physics for electrotechnology*,

IEC TR 62781, *Ultrasonics – Conditioning water for ultrasonic measurements*

IEC 60565-1, *Underwater acoustics – Hydrophones – Calibration of hydrophones –Part 1: Procedures for free field calibration of hydrophones*

IEC 60565-2, *Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 2: Procedures for low frequency pressure calibration*

IEC 62127-1:2022, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

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IEC 62127-2:2025, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields*

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

IEC 63045:2020, *Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-13 and the following apply.

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

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

3.1 Acoustic pulse energy

3.1.1
derived acoustic pulse energy
E_R
spatial integral of the **derived pulse-intensity integral** over a circular cross-sectional area of radius R in the x-y plane which contains the **focus**

Note 1 to entry: The radius R is derived either from the largest size of a threshold value of pressure, derived pulse intensity integral, or any other quantity. This quantity is stated as a second index. The manufacturer chooses the appropriate quantity and threshold value based on their clinical significance, based on one or more of clinical significance, literature and risk analysis.

Note 2 to entry: The **derived acoustic pulse energy** is expressed in joules (J).

3.1.2
derived focal acoustic pulse energy
E_f
spatial integral of the **derived pulse-intensity integral** over the **focal cross-sectional area**

Note 1 to entry: The **derived focal acoustic pulse energy** is expressed in joules (J).

3.2
beam axis
line passing through the geometric centre of the aperture of the **pressure pulse** generator and the **focus**

Note 1 to entry: This line is taken as the z axis. See 6.1 and Clause 7.

3.3
compressional pulse duration
$t_{\mathrm{FWHM,pc}}$
time interval beginning at the first time the **instantaneous acoustic pressure** exceeds 50 % of the **peak-compressional acoustic pressure** and ending at the next time the **instantaneous acoustic pressure** has that value

SEE: Figure C.1.

Note 1 to entry: The **compressional pulse duration** is expressed in seconds (s).

Note 2 to entry: The subscript "FWHM" stands for "full width, half maximum".

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3.4
rarefactional pulse duration
t_{pr}
time interval beginning at the first time the **instantaneous acoustic pressure** is less than 10 % of the **peak-rarefactional acoustic pressure** after the decay of the **peak-compressional acoustic pressure** and ending at the next time the **instantaneous acoustic pressure** has that value

SEE: Figure C.1.

Note 1 to entry: The **rarefactional pulse duration** is expressed in seconds (s).

3.5
derived pulse-intensity integral
$PI(x,y,z)$
time integral of the **instantaneous intensity** at a particular point in a **pressure pulse** field over the **pressure pulse waveform**

Note 1 to entry: This parameter is often called "energy flux density".

Note 2 to entry: The **derived pulse-intensity integral** is expressed in units of joule per metre squared (J/m^2).

Note 3 to entry: The temporal limits for the calculation of the **derived pulse-intensity integral** are specified in the **temporal integration limits** definitions.

3.6
end-of-cable loaded sensitivity
$\underline{M}_L(f)$
<of a **hydrophone** or hydrophone assembly> quotient of the Fourier transformed **hydrophone** voltage-time signal $\mathcal{F}(u_L(t))$ at the end of any integral cable or output connector of a **hydrophone** or hydrophone assembly, when connected to a specified electric load impedance, to the Fourier transformed acoustic pulse waveform $\mathcal{F}(p(t))$ in the undisturbed free field of a plane wave in the position of the reference centre of the **hydrophone** if the **hydrophone** were removed

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

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

[SOURCE: IEC 62127-1:2022, 3.25].

3.7
focal −*n* dB cross-sectional area
$A_{f,n\,dB}$
area of the **peak-compressional acoustic pressure** contour which is in the plane, perpendicular to the **beam axis** and containing the **focus**, where all points on the contour have a pressure of $-n$ dB relative to the value at the **focus**

Note 1 to entry: The value of n is stated as subscript.

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal −*n* dB cross-sectional area** is expressed in units of metre squared (m^2).

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3.8
focal −*n* dB extent
$L_{\mathrm{f}z,n\mathrm{dB}}$
shortest distance along the z axis that connects points on the contour of **peak-compressional acoustic pressure** which have a value of $-n$ dB relative to the acoustic pressure at the **focus**

Note 1 to entry: The value of n and the axial distance z from the measurement centre point are stated as subscript.

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal −*n* dB extent** is expressed in metres (m).

3.9
focal −*n* dB volume
$V_{\mathrm{f},n\mathrm{dB}}$
volume in space contained within the surface defined by the $-n$ dB (relative to the **focal pressure maximum** value) **peak-compressional acoustic pressure** contours measured around the **focus**

Note 1 to entry: It can be difficult to measure $-n$ dB points throughout the volume around the **focus**. It is reasonable in practice to approximate the **focal −*n* dB volume** from measurements taken in three orthogonal directions: the **beam axis** (*z* axis); the direction of maximum beam diameter (x axis); the axis perpendicular to the x axis (y axis), which are also orthogonal to the **beam axis.**

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal −*n* dB volume** is expressed in units of metre cubed (m^3).

Note 4 to entry: The value of n is stated as a subscript.

Note 5 to entry: See IEC 61828.

3.10
focal −*n* dB width, maximum
$L_{\mathrm{f}x,n\mathrm{dB}}$
maximum width of the $-n$ dB (relative to the **focal pressure maximum** value) contour of p_{c} around the **focus** in the x-y plane which contains the **focus**

Note 1 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 2 to entry: The focal width, maximum is expressed in metres (m).

3.11
focal −*n* dB width, orthogonal
$L_{\mathrm{f}y,n\mathrm{dB}}$
width of the $-n$ dB (relative to the **focal pressure maximum** value) contour of p_{c} around the **focus**, in the x-y plane which contains the **focus**, in the direction perpendicular to fx

Note 1 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 2 to entry: The **focal width, orthogonal** is expressed in metres (m).

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3.12
focal *n* MPa cross-sectional area
$A_{f,n\text{MPa}}$
area of the **peak-compressional acoustic pressure** contour which is in the plane, perpendicular to the **beam axis** and containing the **focus**, where all points on the contour have a pressure of n MPa

Note 1 to entry: The value of n is stated as subscript.

Note 2 to entry: a typical values of n is 5 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal *n* MPa cross-sectional area** is expressed in units of metre squared (m^2).

3.13
focal *n* MPa extent
$L_{fz,n\text{MPa}}$
shortest distance along the z axis that connects points on the contour of **peak-compressional acoustic pressure** which have a value of n MPa

Note 1 to entry: The value of n and the axial distance z from the measurement centre point are stated as subscript.

Note 2 to entry: a typical values of n is 5 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal *n* MPa extent** is expressed in metres (m).

3.14
focal *n* MPa volume
$V_{f,n\text{MPa}}$
volume in space contained within the surface defined by the $-n$ dB (relative to the **focal pressure maximum** value) **peak-compressional acoustic pressure** contours measured around the **focus**

Note 1 to entry: It is reasonable in practice to approximate the **focal *n* MPa volume** from measurements taken in three orthogonal directions: the **beam axis** (z axis); the direction of maximum beam diameter (x axis); the axis perpendicular to the x axis (y axis), which are also orthogonal to the **beam axis.**

Note 2 to entry: A typical values of n is: 5 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **focal *n* MPa volume** is expressed in units of metre cubed (m^3).

Note 4 to entry: The value of n is stated as a subscript.

Note 5 to entry: See IEC 61828 [37].

3.15
focal *n* MPa width, maximum
$L_{fx,n\text{MPa}}$
maximum width of the n MPa contour of p_c around the **focus** in the x-y plane which contains the **focus**

Note 1 to entry: A typical values of n is: 5 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 2 to entry: The **focal width, maximum** is expressed in metres (m)

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3.16
focal *n* MPa width, orthogonal
$L_{fy,n\text{MPa}}$
width of the n MPa contour of p_{c+} around the **focus**, in the x-y plane which contains the **focus**, in the direction perpendicular to fx

Note 1 to entry: A typical values of n is: 5 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 2 to entry: The **focal width, orthogonal** is expressed metres (m).

3.17
focus
location in the pressure pulse field of the maximum peak-compressional acoustic pressure

Note 1 to entry: Additional, the geometric focus can be given as point location to which all the pressure pulses are converged according to ray theory valid as frequency goes to infinite.

3.18
hydrophone
transducer that produces electrical signals in response to pressure fluctuations in water

[SOURCE: IEC 60050-801:2021, 801-32-26, modified – The notes to entry have been removed.]

3.19
instantaneous acoustic pressure
p
pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: In order to clarify that this parameter usually varies in time, (t) can be added in the formulae, for example $p(t)$.

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

[SOURCE: IEC 60050-802:2011, 802-01-03, modified – The definition has been rephrased, and the notes to entry added.]

3.20
derived instantaneous intensity
I
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: **Derived instantaneous intensity** is an approximation of the **instantaneous intensity**.

Note 2 to entry: **Derived instantaneous intensity** is expressed in units of watt per metre squared (W/m^2).

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Note 3 to entry: Increased **uncertainty** is expected to be taken into account for measurements very close to the transducer.

[SOURCE: IEC 62127-1:2022, 3.14, modified – The notes have been rephrased.]

3.21
lithotripsy equipment
device for disintegrating calculi and other concretions within the body

Note 1 to entry: Known applications include renal stones, gallstones, pancreatic duct stones, salivary stones, orthopaedic pain and calcification in tendons.

Note 2 to entry: Equipment for other known clinical applications such as pseudoarthrosis, cardiac applications, etc. can be termed ESWT equipment.

3.22
peak-rarefactional acoustic pressure
p_r
maximum of the modulus of the rarefactional acoustic pressure at any spatial location in the **pressure pulse** field

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

Note 2 to entry: The **peak-rarefactional acoustic pressure** is also called "peak-negative acoustic pressure".

3.23
peak-compressional acoustic pressure
p_c
maximum compressional acoustic pressure at any spatial location in the **pressure pulse** field

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

Note 2 to entry: The **peak-compressional acoustic pressure** is also called "peak-positive acoustic pressure".

3.24
average positive acoustic pressure
$p_{c,AVG}$
value calculated by averaging the **peak-compressional acoustic pressure** values over a circular cross-sectional area of radius R in the x-y plane which contains the **focus**

Note 1 to entry: The radius R is derived from the typical size of the area to be treated. This can be the typical size of a target like a kidney stone or a targeted tissue area, or the largest size of a threshold value of pressure, derived pulse intensity integral, or any other quantity. This quantity is stated as a second index. The manufacturer chooses the appropriate quantity and threshold value based on their clinical significance, based on literature or risk analysis or both.

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

3.25
momentum
vector quantity equal to the product of the mass m of a body and the velocity v of its centre of mass

Note 1 to entry: For a continuous body in a domain D, momentum is equal to the integral $\int_D \rho v \, dV = \int_D v \, dm$, where ρ is the mass density in a domain having quasi-infinitesimal volume dV and mass dm, and velocity v. For a system of bodies, it is equal to the sum of their momentums.

Note 2 to entry: If the sum of external forces is equal to zero, momentum of a body follows a law of conservation.

Note 3 to entry: The coherent SI unit of **momentum** is kilogram metre per second $kg \cdot m \cdot s^{-1}$.

Note 4 to entry: The temporal limits for the calculation of the momentum are specified in the temporal integration limits definitions.

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[SOURCE: IEC 60050-113:2001, 113-03-13, modified – The original NOTE 3 is left out, an additional Note 4 to entry was added, and the symbol p was removed.]

3.26
pressure pulse
acoustic wave emitted by the **pressure pulse** equipment, which consists of two significant wave components: one positive or negative half-cycle and one negative or positive trailing half cycle

SEE: Figure C.1.

Note 1 to entry: **Pressure pulse** sources or combinations of **pressure pulse** sources emitting signals composed of two or more **pressure pulses** which are emitted with pulse-to-pulse intervals longer than the total duration of each single **pressure pulse** as specified in the **temporal integration limits** definitions are characterized by separately documenting the parameters of each **pressure pulse**

Note 2 to entry: Depending on the properties of the **pressure pulse** source, spurious additional signals of smaller amplitude can follow the significant wave components. Only signal parts adding more than 5 % to the energy content of the wave are considered as significant. Wave components, which are for example caused by inertial motions of a mechanical applicator which is specified in IEC 63045, can appear several hundred microseconds to some milliseconds after the **pressure pulse**. These signals are outside the scope of this document. See [39] and [40].

Note 3 to entry: Typical applications of **pressure pulses** are given in Annex A.

3.27
pressure pulse waveform
temporal waveform of the **instantaneous acoustic pressure** at a specified position in a pressure pulse field and displayed over a period sufficiently long to include all significant acoustic information in the **pressure pulse**

Note 1 to entry: The time durations of the pressure pulse waveform and parts thereof are specified in the **temporal integration limits** definitions.

3.28
pulse-pressure-squared integral
ppsi
time integral of the square of the **instantaneous acoustic pressure** over the **pressure pulse waveform**

Note 1 to entry: The **pulse-pressure-squared integral** is expressed in units of pascal squared times second (Pa^2s).

Note 2 to entry: The temporal limits for the calculation of the **pulse-pressure-squared integral** are specified in the **temporal integration limits** definitions.

[SOURCE: IEC 62127-1: 2022, 3.56, modified – The definition has been rephrased.]

3.29
rise time
t_r
in a **pressure pulse waveform**, time taken for the **instantaneous acoustic pressure** to increase from 10 % to 90 % of the **peak-compressional acoustic pressure**

SEE: Figure C.1.

Note 1 to entry: The **rise time** is expressed in seconds (s).

3.30
target location
V_t
location in space where the manufacturer intends the user to locate the calculi or other biological tissue to be treated, given as a three-dimensional position vector (x_t, y_t, z_t)

Note 1 to entry: For different applications, the **target locations** can differ.

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Note 2 to entry: The **target location** is expressed in metres (m).

3.31
temporal integration limits
time durations of significant parts of the **pressure-pulse waveform**

Note 1 to entry: Depending on the properties of the **pressure pulse** source, spurious additional signals of smaller amplitude can follow the significant wave components. Only signal parts adding more than 5 % to the energy content of the wave are considered as significant. Wave components, which are for example caused by inertial motions of a mechanical **applicator**, or from bubble collapse of an electrohydraulic or laser source, can appear several hundred microseconds to some milliseconds after the **pressure pulse**. These signals are outside the scope of this document. See [39] and [40].

3.31.1
positive temporal integration limits
$t_{Pt,lim}$
times between which the compressional acoustic **pressure pulse waveform** first exceeds 10 % of its **peak-compressional acoustic pressure** value and first it reduces below 10 % of its **peak- compressional acoustic pressure** value

Note 1 to entry: The **positive temporal integration limits** are expressed in seconds (s).

3.31.2
total temporal integration limits
$t_{Tot,lim}$
times between which the absolute value (modulus) of **pressure pulse** waveform first exceeds 10 % of its maximum value and last it reduces below 10 % of its maximum value

Note 1 to entry: The **total temporal integration limits** are expressed in seconds (s).

3.31.3
total temporal MPa threshold integration limits
$t_{Tot,n MPa,lim}$
times between which the **pressure pulse waveform** first exceeds a value of n MPa and last it falls below the n MPa value

Note 1 to entry: The value of n is stated as a subscript.

Note 2 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **total temporal MPa threshold integration limits** are expressed in seconds (s).

3.32
focusing transducer
electro-acoustic device that produces a −6 dB beamwidth in a longitudinal plane that is less than that of a flat transducer with the same source aperture size (and apodization, if any) and same excitation at a distance less than the transition distance from the source aperture plane

Note 1 to entry: IEC 61828:2020, Clause 3 and Figure B.6 give more information on different types of transducers.

Note 2 to entry: Examples of different types of pressure pulse transducers are given in Annex B.

3.33
pulse repetition frequency
f_{PRF}
number of acoustic pressure pulses generated per second

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

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3.34
cavitation induction index
C_{II}
indicator of the likelihood of cavitation occurrence caused by pressure pulses, which can cause bioeffects

$$C_{\mathrm{II}}(x,y,z) = C_{\mathrm{M}} \times \left| p_{\mathrm{r}}(x,y,z) \right| \times \sqrt{2t_{\mathrm{pr}}(x,y,z)} \tag{2}$$

where $C_{\mathrm{M}} = \left(1\,\mathrm{MPa} \times \sqrt{1\,\mu\mathrm{s}}\right)^{-1}$ is a normalization constant, p_{r} is the **peak rarefactional pressure** and t_{pr} is the **rarefactional acoustic pulse duration**

Note 1 to entry: C_{II} is expressed in units of 1.

Note 2 to entry: See [35].

3.35
pulse to pulse variability
$S_{\mathrm{FI}}(x,y,z)$
percentage variability in the acoustic parameters (p_{c}, p_{r}, f_{o}, etc) of the at least 15 consecutive pressure pulses produced under the given settings of the control parameters such as electrical power or charging voltage, pulse repetition frequency

Note 1 to entry: The pulse to pulse **variability** is expressed as a percentage.

3.36
total pressure pulse energy dose
SED_{E}
total amount of energy applied to the patient during the complete course of the pressure pulse treatment, expressed by the derived focal acoustic energy multiplied by the number of applied pressure pulses

Note 1 to entry: The defined energy quantity (e.g. based on a $-n$ dB or a n MPa boundary and the integration time duration used) is stated as a subscript.

Note 2 to entry: Reasonable values of E for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **total pressure pulse energy dose** is expressed in joules (J).

3.37
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 document 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 units of watt per metre squared ($\mathrm{W/m^2}$).

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4 List of symbols

$A_{\mathrm{f},n\mathrm{dB}}$	**focal −*n* dB cross-sectional area**
$A_{\mathrm{f},n\mathrm{MPa}}$	**focal *n* MPa cross-sectional area**
C_{II}	**cavitation induction index**
E_{f}	**derived focal acoustic pulse energy**
E_R	**derived acoustic pulse energy**
f_{PRF}	**pulse repetition frequency**
$L_{\mathrm{f}x,n\mathrm{dB}}$	**focal −*n* dB width, maximum**
$L_{\mathrm{f}x,n\mathrm{MPa}}$	**focal *n* MPa width, maximum**
$L_{\mathrm{f}y,n\mathrm{dB}}$	**focal −*n* dB width, orthogonal**
$L_{\mathrm{f}y,n\mathrm{MPa}}$	**focal *n* MPa width, orthogonal**
$L_{\mathrm{f}z,n\mathrm{dB}}$	**focal −*n* dB extent**
$L_{\mathrm{f}z,n\mathrm{MPa}}$	**focal *n* MPa extent**
I	**derived instantaneous intensity**
M	**scalar magnitude of momentum**
M_{L}	**end-of-cable loaded sensitivity of the hydrophone**
p	**instantaneous acoustic pressure**
p_{r}	**peak-rarefactional acoustic pressure**
p_{c}	**peak-compressional acoustic pressure**
$p_{\mathrm{c,AVG}}$	**average positive acoustic pressure**
$ppsi$	**pulse-pressure-squared integral**
$PII\ (x,y,z)$	**derived pulse-intensity integral**
$S_{\mathrm{FI}}(x,y,z)$	**pulse to pulse variability**
SED_{E}	**total pressure pulse energy dose**
t_{r}	**rise time**
$t_{\mathrm{FWHM,pc}}$	**compressional pulse duration**
t_{pr}	**rarefactional pulse duration**
$t_{\mathrm{Pt,lim}}$	**positive temporal integration limits**
$t_{\mathrm{Tot,lim}}$	**total temporal integration limits**
$t_{\mathrm{Tot},n\mathrm{MPa,lim}}$	**total temporal MPa threshold integration limits**
$V_{\mathrm{f},n\mathrm{dB}}$	**focal −*n* dB volume**
$V_{\mathrm{f},n\mathrm{MPa}}$	**focal *n* MPa volume**
V_{t}	**target location**
Z	**characteristic acoustic impedance of the medium**

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5 Conditions of measurement

Measurements shall be performed in a situation approximating conditions of actual operation. Parameters to be considered include:

– **pressure pulse** generator drive level;
– rate of **pressure pulse** release;
– ambient temperature;
– electrical conductivity of water in the measuring tank;
– temperature and oxygen content of water in the measuring tank.

The values of these parameters at which the measurements are made shall be noted. Degassed water (see IEC TR 62781 for recommendations) at 20 °C to 40 °C should be used in the measuring tank (test chamber) which shall be large enough to allow the measurement environment to approximate free-field conditions. If degassed water is not used bubbles shall be removed if they are collecting on the **hydrophone** or anywhere in the beam path. The time between consecutive pulses shall be long enough to allow for complete dissolution of cavitation bubbles in the path of the sound field up to the measurement position.

The conductivity of the water shall be suitable for the **hydrophone** being used. The calibration of the **hydrophone** shall be known at the temperature of the water in the measuring tank.

NOTE Depending on the rarefactional amplitude p_r of the **pressure pulses**, ultrapure water can be used to reduce the occurrence of cavitation nuclei.

6 Test equipment

6.1 Test chamber

The test chamber shall be a water tank constructed in a form that can be securely fixed to the **pressure pulse** generator so that the acoustic output from the **pressure pulse** generator is coupled into a volume of water. The chamber shall be sufficiently large to allow the expected position of the **focus** to be several centimetres away from any reflective boundary, in particular the water surface. The distance between the focus and reflective boundaries shall be chosen such that no spurious or multiple reflections of the **pressure pulse** interfere with the measurements.

There shall be a suitable mechanical holder for the **hydrophone** which shall be mounted on a coordinate positioning system to allow adjustment and measurement of the position of the **hydrophone** in three orthogonal directions relative to the **focus**. One axis (z axis) of the co-ordinate positioning system shall be collinear with the **beam axis**. The relative position of the **hydrophone** shall be measurable with a precision of 0,5 mm or better.

Any coupling membranes or other interfaces in the pressure pulse path shall not influence the measurements. The coupling media shall be as specified by the manufacturer.

6.2 Hydrophone

6.2.1 General

The **hydrophone** shall have characteristics complying with IEC 62127-1, IEC 62127-2 and IEC 62127-3.

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The **hydrophone** should have a frequency range from less than 10 kHz to at least f_{max}, where f_{max} is calculated according to Formula (1); see IEC 63045:2020, 6.1.2:

$$f_{max} = 5 / t_r \quad (1)$$

Calibration shall be performed in the frequency range of $1/(2\ t_{FWHMpC})$ to 5 MHz in accordance with the requirements of IEC 62127-2, IEC 60565-1 and IEC 60565-2. If used without deconvolution, the hydrophone's frequency response shall not vary by more than 6 dB over the calibrated frequency range. The effective diameter of the **hydrophone** should be as small as possible, and its value shall be stated. If necessary, deconvolution is described in IEC 62127-1.

Calibration of hydrophones should follow the procedures established in IEC 62127-2 and IEC 60565-1.

NOTE 1 The upper frequency limit of the **hydrophone** as defined here is sufficient as long as no significant non-linear steepening of the signals occurs in the **pressure pulse** field.

NOTE 2 It is ideal that the hydrophone system has a flat frequency response upward to a high frequency which allows it to sense a shock front. The cable loaded hydrophone or hydrophone-amplifier combination are sensitive to be measurable over a frequency range extending from lower than a half of f_c upward to higher than $2/t_r$.

6.2.2 Hydrophone for pressure pulse measurements

Examples for appropriate **hydrophones** for **pressure pulse** measurements are listed in Table C.1. The frequency response of the **hydrophones** for **pressure pulse** measurements shall both cover low frequencies of 10 kHz and less and high frequencies of 20 MHz and higher, depending on the **rise time** and the **duration** of the **pressure pulse** signals. To compensate for the hydrophone's intrinsic response over the whole range, post processing of the pressure pulse signals by using deconvolution as described in IEC 62127-1:2022, Annex D shall be applied.

NOTE On the importance of a sufficient low frequency response, see [42].

Measurements undertaken using the **hydrophone** should not vary by more than ±10 % over the duration of the measurements. If they do, additional investigative studies should be carried to establish whether the variation is due to the variations in source output or a change in sensitivity of the **hydrophone** employed. This might involve using an alternative **hydrophone** or changing the experimental conditions. Regular re-calibration of the sensitivity is advisable (see IEC 62127-2:2025, 5.4).

6.2.3 Hydrophones for quality assurance

For quality assurance, consistency checks can be required for periodic measurements of the **pressure pulse** source in order to assure that the device remains inside the specifications. These consistency checks can be required at regular intervals, for example each year, and additionally after servicing and repair. The **hydrophone** for quality assurance purposes shall have a robust construction and shall have a frequency response which does not vary by more than 6 dB per octave over the frequency range from 0,5 MHz to 5 MHz. If that is not the case, In order to achieve a flat frequency response over the whole range, post processing of the pressure pulse signals by using deconvolution as described in IEC 62127-1:2022, Annex D, can be applied.

The effective diameter of the **hydrophone** should be as small as possible, it shall not exceed the **source aperture** and its value shall be stated. See Table C.2 for examples.

Data measured with the **hydrophone for quality assurance** purposes shall not be published as absolute values for the characterization of a **pressure pulse** source.

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Examples for appropriate **hydrophones** for quality assurance measurements are listed in Table C.2.

Two different **hydrophones** are permitted because many of those suitable for measurements at close distances to the **source aperture**, in particular on the z axis, are very fragile. A more robust, less highly specified device is therefore permitted for general field measurements and for use in the dry test bench.

When selecting a more robust **hydrophone** a type which will provide the needed linearity and **peak-negative acoustic pressure** values of the high acoustic pressures encountered shall be selected.

If only measurements at the **beam axis** are done, for example in the dry test bench, then the effective diameter of the **hydrophone** can be larger but shall not exceed the **source aperture**.

6.3 Voltage measurement

6.3.1 Oscilloscope or transient recorder

In order to secure that the device used to observe and measure the **hydrophone** output signal is appropriate its frequency response and input capacitance and resistive impedance shall be reported. A digital oscilloscope with a sampling frequency greater than 100 MHz is the preferred option, although a transient recorder and digital storage for subsequent computer display can be satisfactory.

The **end-of-cable loaded sensitivity of the hydrophone** shall be determined as specified in IEC 62127-1:2022, 5.1.2. This value shall then be used to calculate the incident acoustic pressures from the observed **hydrophone** output voltages.

6.3.2 Pressure-pulse-waveform recording

The output voltage waveform from the hydrophone shall be recorded in such a way as to allow the measurement or calculation of:

– **instantaneous acoustic pressure**, $p(t)$;
– **peak-rarefactional acoustic pressure**, p_r;
– **peak-compressional acoustic pressure**, p_c;
– **rise time**, t_r;
– **compressional pulse duration**, $t_{FWHM,pc}$;
– **rarefactional pulse duration**, t_{pr};
– **instantaneous intensity**, I;
– **cavitation induction index**, $C_{II}(x,y,z)$;
– **total temporal integration limits**, $t_{Tot,lim}$.

NOTE If measurements in regions outside the focus zone are made, the signals can be polluted by noise depending on properties of the hydrophone, the amplifier or both. In this case, it is possible to:

a) use a more sensitive hydrophone and a low noise preamplifier if applicable; or

b) in order to reduce noise from the instantaneous acoustic pressure signals, acquire several (e.g. 10 to 20) signals at the same position by triggering at the onset of the acoustic pressure pulses and average these signals on a sample-by-sample basis; or

c) average the following parameters of several (e.g. 10) signals: **peak compressional acoustic pressure**, **peak-rarefactional acoustic pressure**, **rise time**, **compressional pulse duration**, **rarefactional pulse duration**.

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7 Measurement procedure

7.1 General

The measurements shall be made at least at one clinical setting for each clinical application as specified by the manufacturer. If only one setting is used, this setting shall be the maximum available for clinical application. The settings used shall be documented.

Using the x-y-z coordinate positioning system, with the z direction being the **beam axis**, the following measurements shall be made to define the spatial characteristics of the beam.

The x axis shall be taken as the direction of the maximum beam width in the x-y plane which contains the **focus**. The distance between the **focus** and the **target location** shall be documented. If **the peak-compressional acoustic pressure** p_c in the **target location** does not differ by more than 10 % of p_c in the **focus**, it is feasible to do the measurements in the x-y plane at the z position indicated by the **target location**.

If the pressure pulse source is specified to produce a focus only in one plane along the z axis (e.g. line sources), the parameters specified in IEC 63045 shall be used to describe the pressure pulse field in the non-focusing planes.

7.2 Spatial measurements

7.2.1 General

The spatial distribution of acoustic pressure shall be measured in the test chamber.

The maximum sampling interval shall be the lesser of 1 mm or one fifth of the minimum width of the −6 dB isobar in the x-y plane. It shall be the lesser of 2 mm or one fifth of the maximum dimension of the −6 dB isobar in the x-z plane. If the values of p_c from sampling point to sampling point do not differ by more than 10 %, the sampling intervals can be extended, e.g. to 5 mm or 10 mm. The sampling intervals actually used shall be documented.

NOTE 1 It can be worthwhile to perform measurements in the vicinity of the **target location** to locate the **focus** and hence define the direction of the z axis, before making other measurements. (See Annex C.)

NOTE 2 The direction of the x axis will be provisional until the plot detailed in 7.2.2 has been completed.

NOTE 3 It is important to select hydrophones of sufficient linearity in negative and positive regions so that the 6 dB measurements can be made without distortion.

7.2.2 Beam plots of peak-compressional acoustic pressure

The values of **peak-compressional acoustic pressure** in the x-y plane which contains the focus shall be measured. The beam $-n$ dB and $-n$ MPa extents shall be determined from the $-n$ dB and $-n$ MPa contour plot. The values of n shall be determined by the manufacturer by an appropriate risk analysis process, for example from literature or expert input.

NOTE At each value of y that **peak-compressional acoustic pressure** is measured, **pulse intensity integral** can also be determined since the two curves are not identical and there can be significant differences between the areas under the curve as calculated from **peak-compressional acoustic pressure** versus **pulse intensity integral**. (See 7.4.1.)

The orientation of the x axis shall be chosen such that it corresponds to the direction of the maximum beam width.

The variation of **peak-compressional acoustic pressure** in x-z and y-z planes shall be measured and plotted at least as a $-n$ dB contour in each plane. The values of n shall be determined by the manufacturer by an appropriate risk analysis process, for example from literature or expert input.

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7.2.3 Beam plots of peak-rarefactional acoustic pressure

The values of **peak-rarefactional acoustic pressure** in x-z and y-z planes shall be measured. These measurements shall be used to estimate the site and magnitude of the maximum **peak-rarefactional acoustic pressure**. In practice, the oxygen content of the measurement water needs to be as low as possible, therefore degassing procedures as specified in IEC TR 62781, including frequent measurement of the oxygen content, shall be used. Cavitation occurrence can degrade the signals, in particular their rarefactional parts. If such behaviour is observed, multiple measurements with pulse-to-pulse pauses of more than five seconds shall be made. For the mapping of the peak-negative acoustic pressure distribution, the limits for spatial sampling intervals can be relaxed if the difference in p_r does not exceed 10 % from point to point, the sampling intervals can be chosen accordingly. The intervals used shall be declared.

7.2.4 Focus position

The separation of the **focus** and the **target location** shall be determined to a precision of ±2 mm in the x and y directions and ±3 mm in the z direction.

7.2.5 Focal −n dB width

The width of the −n dB and −n MPa contour in the x direction, **focal −n dB width, maximum**, $L_{fx,n\text{dB}}$, and in the y direction, **focal −n dB width, orthogonal**, $L_{fy,n\text{dB}}$ shall be measured from the results derived from 7.2.2.

NOTE The values of n are determined by the manufacturer by an appropriate risk analysis process, for example from literature or expert input.

7.2.6 Focal −n dB extent

The length of the −n dB and −n MPa contour along the z direction, $f_{z,n\text{dB}}$ shall be measured from the −n dB contour in the x-z plane derived from 7.2.2.

NOTE The values of n are determined by the manufacturer by an appropriate risk analysis process, for example from literature or expert input.

7.2.7 Focal −n dB cross sectional area

The **focal** −n dB and −n MPa **cross-sectional area** $A_{f,n\text{dB}}$ along the x and y axes shall be established from the spatial distribution values derived from 7.2.2.

NOTE It is reasonable to approximate the p_c to an ellipse with axes of lengths $L_{fx,n\text{dB}}$ and $L_{fy,n\text{dB}}$ or $L_{fx,n\text{MPa}}$ and $L_{fy,n\text{MPa}}$.

7.2.8 Focal −n dB volume

The **focal −n dB volume** and **focal** −n **MPa volume** along the x, y and z axes shall be established from the spatial distribution values derived from 7.2.2.

7.3 Temporal measurements

A **hydrophone** for **pressure pulse measurements** shall be positioned at the **focus** in such a way as to register the **peak-compressional acoustic pressure** to an accuracy of ±20 %.

The **pressure pulse waveform** shall be measured at the **focus**. The temporal limits for recording shall be equal to or greater than the values as specified in the **temporal integration limits** definitions. The following parameters shall be derived:

– **peak-compressional acoustic pressure**;
– **peak-rarefactional acoustic pressure**;
– **compressional pulse duration** and **rarefactional pulse duration**;
– **rise time**.

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7.4 Acoustic energy measurements

7.4.1 Pulse-pressure-squared integral

The **pulse-pressure-squared integral** at any point (r, θ) shall be given by Formula (2):

$$ppsi(r,\theta) = \int_T p^2(r,\theta,t)\,\mathrm{d}t \tag{2}$$

NOTE The temporal limits over which integration is performed, T, are either T_p or T_T. These temporal limits are specified in the **temporal integration limits** definitions.

7.4.2 Derived pulse-intensity integral

The derived pulse-intensity integral at any point (r, θ) shall be given by Formula (3):

$$PII(r,\theta) = \frac{1}{Z}\int_T p^2(r,\theta,t)\mathrm{d}t \tag{3}$$

NOTE The temporal limits over which integration is performed, T, are either T_p or T_T. These temporal limits are specified in the **temporal integration limits** definitions.

This measurement shall be made with a **focus** type **hydrophone**.

7.4.3 Derived focal acoustic pulse energy

The **derived focal acoustic pulse energy** shall be calculated from measurements of the **derived pulse-intensity integral** taken within the region of the **focal −n dB cross-sectional area** $A_{f,n\mathrm{dB}}$.

The **derived focal acoustic pulse energy** can be calculated from Formula (4):

$$E_{f,n\mathrm{dB}} = \frac{\pi}{Z}\int_R\int_T p^2(r,\theta,t)\,r\,\mathrm{d}r\,\mathrm{d}t = \pi\int_R PII(r,\theta)\,r\,\mathrm{d}r \tag{4}$$

where

$p(r,\theta,t)$ is the **instantaneous acoustic pressure** at position (r, θ) and time t;

Z is the characteristic acoustic impedance of water (see Annex C).

The surface area $A_{f,n\mathrm{dB}}$ lying in the plane passing through the **focus** and perpendicular to the **beam axis**, with spatial polar coordinates r and θ; bounded by the −n dB contour shall be approximated by a circular area with radius $R = \sqrt{A_{f,n\mathrm{dB}} / \pi}$.

NOTE The temporal limits over which integration is performed, T, can be either $t_{Pt,lim}$ or $t_{Tot,lim}$ or $t_{Pt,n\mathrm{MPa},lim}$ or $t_{Tot,n\mathrm{MPa},lim}$; they should be documented as a subscript. These temporal limits are specified in the **temporal integration limits** definitions.

7.4.4 Derived acoustic pulse energy

The acoustic pulse energy in any plane perpendicular to the **beam axis** which cuts this axis at a coordinate z shall be calculated from measurements of the derived pulse intensity integral taken within a circular cross-sectional area S_z of radius R.

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$$E_R(z) = \frac{\pi}{Z}\int_R\int_T p^2(r,\theta,z,t)\,r\,\mathrm{d}r\,\mathrm{d}t = \pi\int_R PII(r,\theta,z)\,r\,\mathrm{d}r \tag{5}$$

The axial position z and the value of R shall be specified by the manufacturer by an appropriate risk analysis process, for example from literature or expert input. For example, the R value can be based on approximating the $-n$ dB amplitude or intensity decrease versus the on-axis value at the same axial position z by a circular contour; or it can represent a circular contour of a certain pressure of n MPa or intensity value of n mJ/mm^2, which correlates to a clinical effect.

7.4.5 Average positive pressure

The average positive pressure is calculated from the **peak-compressional-pressure** values $p_c(r)$ along the radius r inside a circular area which is delimited by a radius R_h. The radius R_h is derived from the typical size of the area to be treated. This can be the typical size of a target like a kidney stone or a targeted tissue area, or the largest size of a threshold value of pressure, derived pulse intensity integral, or any other quantity. This quantity is stated as a second index. The manufacturer chooses the appropriate quantity and threshold value based on their clinical significance, based on literature and/or risk analysis.

$$p_{c,AVG} = \frac{1}{\pi R_h^{\,2}}\int_0^{2\pi}\int_0^{R_h} p_C(r,\theta)\,r\,\mathrm{d}r\,\mathrm{d}\theta \tag{6}$$

NOTE See [24].

7.4.6 Momentum

The **momentum** of a shock wave is a vector quantity in the direction of propagation. In order to simplify the calculation, it is limited to the absolute value of a vector by considering only waves propagating normal to a circular, planar target surface and perpendicular to the axis of the **pressure pulse** source, which is hitting the target surface at the centre. The **momentum** of a **pressure pulse** wave within a cross section area A is calculated from Formula (7):

$$M = \int_{AT}\int p(A,t)\,\mathrm{d}t\,\mathrm{d}A \tag{7}$$

The area A is derived from the typical size of the area to be treated, and p is the **instantaneous acoustic pressure** measured at this area. This can be the typical size of a target like a kidney stone or a targeted tissue area, or the largest size of a threshold value of pressure, derived pulse intensity integral, or any other quantity. This quantity is stated as index. The manufacturer chooses the appropriate quantity and threshold value based on their clinical significance, based on one or more of clinical significance, literature and risk analysis. The integration time T is determined by the pulse duration of the positive portion of the pressure pulse $t_{Pt,lim}$. These temporal limits are specified in the **temporal integration limits** definitions.

NOTE See [23].

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