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2026-02-02

Ultralyd – Terapeutisk fokuserede chokbølger – Karakterisering af felter

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

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March 2025

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English Version

Ultrasonics - Therapeutic focused short pressure pulse sources - Characteristics of fields (IEC 61846:2025)

Ultrasons - Sources d'impulsions de pression courtes focalisées thérapeutiques - Caractéristiques des champs (IEC 61846:2025)

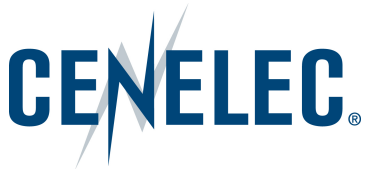
Ultraschall - Therapeutisch fokussierte Kurzdruckimpulsquellen - Feldeigenschaften (IEC 61846:2025)

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Comité Européen de Normalisation Electrotechnique
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European foreword

The text of document 87/879/FDIS, future edition 2 of IEC 61846, prepared by TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61846:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-03-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-03-31

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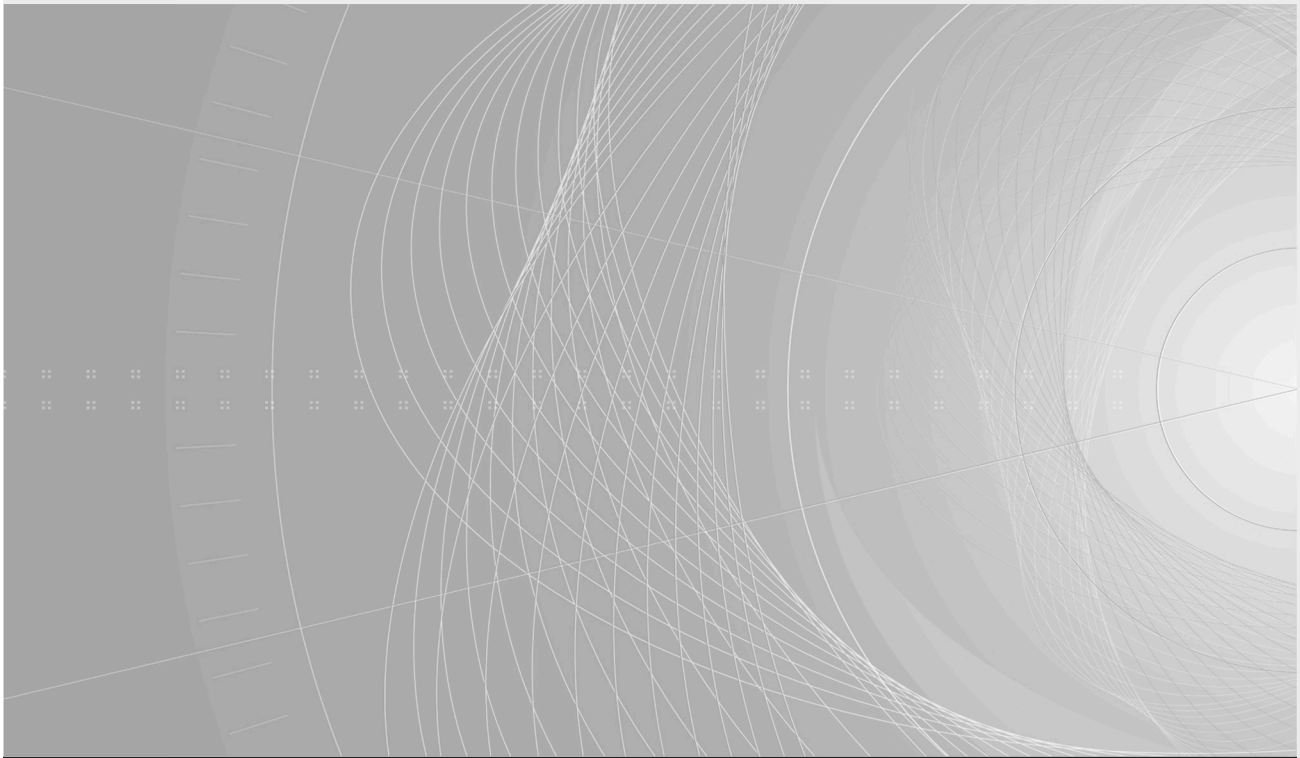
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INTERNATIONAL STANDARD

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



IEC 61846:2025 ED2

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Therapeutic focused short pressure pulse sources – Characteristics of fields

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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.

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.

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- reconfirmed,
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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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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 62127-3, *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
$t_{FWHM,pc}$
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 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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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 SEE: Figure C.1.

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

3.5
derived pulse-intensity integral
PΠ(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
$A_{f,ndB}$
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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$L_{fz,ndB}$
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
$V_{f,ndB}$
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
$L_{fx,ndB}$
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
$L_{fy,ndB}$
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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$A_{f,nMPa}$
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

$L_{fz,nMPa}$
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

$V_{f,nMPa}$
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

$L_{fx,nMPa}$
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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$L_{fy,nMPa}$
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).

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.]

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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 $\int_D \rho v \mathrm{d}V = \int_D v \mathrm{d}m$, where ρ is the mass density in a domain having quasi-infinitesimal volume d*V* and mass d*m*, 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 · m · s^{-1}.

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

[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.]

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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 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 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.

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

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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
$t_{Tot,n\text{MPa},lim}$
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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C_{II}
indicator of the likelihood of cavitation occurrence caused by pressure pulses, which can cause bioeffects

$$C_{II}(x,y,z) = C_M \times |p_r(x,y,z)| \times \sqrt{2t_{pr}(x,y,z)} \quad (2)$$

where $C_M = (1MPa \times \sqrt{1\ \mu s})^{-1}$ 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
$S_{FI}(x,y,z)$
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 (W/m^2).

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