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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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INTERNATIONAL
ELECTROTECHNICAL
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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.

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.

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

- reconfirmed,
- withdrawn, or
- revised.

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.

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*

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
$t_{\text{FWHM,pc}}$
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".

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

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

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
$A_{\mathrm{f},n\mathrm{dB}}$
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).

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).

3.12
focal *n* MPa cross-sectional area

$A_{\mathrm{f},n\mathrm{MPa}}$

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

$L_{\mathrm{f}z,n\mathrm{MPa}}$

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

$V_{\mathrm{f},n\mathrm{MPa}}$

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

$L_{\mathrm{f}x,n\mathrm{MPa}}$

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)

3.16
focal *n* MPa width, orthogonal
$L_{\mathrm{fy},n\mathrm{MPa}}$
width of the n MPa contour of $p_{\mathrm{c+}}$ 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

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

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 ($\mathrm{W/m^2}$).