SIST

SLOVENSKI STANDARD
oSIST prEN IEC 61846:2023

01-september-2023

Ultrazvok - Terapevtsko usmerjeni viri kratkih tlačnih impulzov - Karakteristike polj

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

Ultraschall - Druckpuls-Lithotripter - Feldcharakterisierung

Ultrasons - Lithotripteurs à ondes de pression - Caractérisation des champs

Ta slovenski standard je istoveten z: prEN IEC 61846:2023

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.140.50	Elektroakustika	Electroacoustics

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87/836/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61846 ED2**	
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IEC TC 87 : ULTRASONICS	
SECRETARIAT: United Kingdom	SECRETARY: Mr Petar Luzajic
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY	
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TITLE:

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

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – THERAPEUTIC FOCUSED SHORT PRESSUREPULSE SOURCES – CHARACTERISTICS OF FIELDS

FOREWORD

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

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: Old standard: PRESSURE PULSE LITHOTRIPTERS 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 e.g. stone diseases, orthopaedic pain, tissue, cardiac and brain diseases.
The term “focused” was added to differentiate this standard from IEC 63045 “Non-focusing short pressure pulse sources including ballistic pressure pulse sources” [26].

The term “short” was added to align the nomenclature to IEC 63045 and differentiate this standard from standards in the HIFU / HITU fields.

b) Scope 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) 3. Definitions: 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 was aligned to those in recently published standards, e.g. IEC 62127-1.
New definitions were added which describe parameters appearing in newer relevant literature, e.g. “momentum”, “average positive acoustic pressure”, “cavitation induction index”, “pulse to pulse variability”, “total pressure pulse energy dose”.

d) 6. Test equipment: 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:

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

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

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The National Committees are requested to note that for this document the stability date is 20XX..

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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 is up today 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 another standard (IEC 63045:2020).

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

This International Standard 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 International Standard is applicable to

– **therapy equipment** using extracorporeally induced focused pressure pulse waves;

– **therapy equipment** producing focused mechanical energy excluding thermal energy.

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

This international standard 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 International Standard 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 International Standard 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 particular standard 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 standard may 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 60050-13:2011 International Electrotechnical Vocabulary – Part. 113: Physics for electrotechnology,

IEC/TR 62781:2012 Ultrasonics – Conditioning water for ultrasonic measurement,

IEC 60565-1:2020 Underwater acoustics – Hydrophones – Calibration of hydrophones – Part 1: Procedures for free field calibration of hydrophones,

IEC 60565-2:2019 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

3 Terms and definitions

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

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://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 choses the appropriate quantity and threshold value based on their clinical significance, based on literature and/or risk analysis.”

Note 2 to entry: The **derived acoustic pulse energy** is expressed in Units of 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 Units of 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_{FWHMpC}
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 to entry: The **compressional pulse duration** is expressed in Units of seconds (s)

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

3.5

derived pulse-intensity integral

$PII(x,y,z)$ 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 of a hydrophone

$\underline{M}_L$

quotient of the Fourier transformed hydrophone voltage-time signal 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 **instantaneous acoustic pressure** waveform in the undisturbed free field of a plane wave in the position of the acoustic centre of the **hydrophone** if the **hydrophone** were removed

Note 1 to entry: The **end-of-cable loaded sensitivity of a hydrophone** 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.

Note 2 to entry: Reformulated from 3.25 of IEC 62127-1:2022.

3.7

focal −*n* dB cross-sectional area

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

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 and the axial distance z from the measurement centre point 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

$f_{z,n\mathrm{dB}}$

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 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 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 may 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