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STN	**Ultrazvuk Terapeutické fokusované zdroje krátkych tlakových impulzov Charakteristika polí**	**STN EN IEC 61846 36 4887**

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/25

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EN IEC 61846

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Supersedes EN 61846:1998

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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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2028-03-31

This document supersedes EN 61846:1998 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61846:2025 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 61828:2020 NOTE Approved as EN IEC 61828:2021 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60050-113	2011	International Electrotechnical Vocabulary - Part 113: Physics for electrotechnology	-	-
IEC/TR 62781	-	Ultrasonics - Conditioning of water for ultrasonic measurements	-	-
IEC 60565-1	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 1: Procedures for free-field calibration of hydrophones	EN IEC 60565-1	-
IEC 60565-2	-	Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 2: Procedures for low frequency pressure calibration	EN IEC 60565-2	-
IEC 62127-1	2022	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields	EN IEC 62127-1	2022
IEC 62127-2	2025	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields	EN IEC 62127-2	2025
IEC 62127-3	-	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields	EN IEC 62127-3	-
IEC 63045	2020	Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields	EN IEC 63045	2020

IEC 61846

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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

IEC 61846:2025-01(en-fr)

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

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*