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|------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>STN</b> | <b>Ultrazvuk<br/>Terapeutické fokusované zdroje<br/>krátkých tlakových impulzov<br/>Charakteristika polí</b> | <b>STN<br/>EN IEC 61846</b><br><br>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

Obsahuje: EN IEC 61846:2025, IEC 61846:2025

Oznámením tejto normy sa od 31.03.2028 ruší  
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Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 61846**

March 2025

ICS 11.040.50

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**

**EN IEC 61846:2025 (E)****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 (dop) 2026-03-31 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-03-31 document have to be withdrawn

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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.cenelec.eu](http://www.cenelec.eu).

| <u>Publication</u> | <u>Year</u> | <u>Title</u>                                                                                                                   | <u>EN/HD</u>   | <u>Year</u> |
|--------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------|----------------|-------------|
| 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

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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IEC 61846

Edition 2.0 2025-01

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

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

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

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

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## CONTENTS

|                                                                                        |    |
|----------------------------------------------------------------------------------------|----|
| FOREWORD.....                                                                          | 4  |
| INTRODUCTION.....                                                                      | 6  |
| 1 Scope.....                                                                           | 7  |
| 2 Normative references .....                                                           | 7  |
| 3 Terms and definitions .....                                                          | 8  |
| 3.1 Acoustic pulse energy.....                                                         | 8  |
| 4 List of symbols .....                                                                | 17 |
| 5 Conditions of measurement .....                                                      | 18 |
| 6 Test equipment.....                                                                  | 18 |
| 6.1 Test chamber.....                                                                  | 18 |
| 6.2 Hydrophone .....                                                                   | 18 |
| 6.2.1 General .....                                                                    | 18 |
| 6.2.2 Hydrophone for pressure pulse measurements .....                                 | 19 |
| 6.2.3 Hydrophones for quality assurance .....                                          | 19 |
| 6.3 Voltage measurement .....                                                          | 20 |
| 6.3.1 Oscilloscope or transient recorder .....                                         | 20 |
| 6.3.2 Pressure-pulse-waveform recording.....                                           | 20 |
| 7 Measurement procedure .....                                                          | 21 |
| 7.1 General.....                                                                       | 21 |
| 7.2 Spatial measurements .....                                                         | 21 |
| 7.2.1 General .....                                                                    | 21 |
| 7.2.2 Beam plots of peak-compressional acoustic pressure .....                         | 21 |
| 7.2.3 Beam plots of peak-rarefactional acoustic pressure .....                         | 22 |
| 7.2.4 Focus position .....                                                             | 22 |
| 7.2.5 Focal $-n$ dB width .....                                                        | 22 |
| 7.2.6 Focal $-n$ dB extent.....                                                        | 22 |
| 7.2.7 Focal $-n$ dB cross sectional area .....                                         | 22 |
| 7.2.8 Focal $-n$ dB volume .....                                                       | 22 |
| 7.3 Temporal measurements.....                                                         | 22 |
| 7.4 Acoustic energy measurements .....                                                 | 23 |
| 7.4.1 Pulse-pressure-squared integral .....                                            | 23 |
| 7.4.2 Derived pulse-intensity integral.....                                            | 23 |
| 7.4.3 Derived focal acoustic pulse energy.....                                         | 23 |
| 7.4.4 Derived acoustic pulse energy .....                                              | 23 |
| 7.4.5 Average positive pressure .....                                                  | 24 |
| 7.4.6 Momentum.....                                                                    | 24 |
| Annex A (informative) Short pressure pulse therapy.....                                | 25 |
| A.1 Background.....                                                                    | 25 |
| A.2 Percutaneous continuous wave systems and alternative burst wave applications ..... | 25 |
| A.3 Exclusions .....                                                                   | 25 |
| A.4 Extracorporeally induced lithotripsy.....                                          | 26 |
| Annex B (informative) Types of pressure wave transducers .....                         | 27 |
| B.1 Overview.....                                                                      | 27 |
| B.1.1 General .....                                                                    | 27 |
| B.1.2 Spark discharge.....                                                             | 27 |

|                       |                                                                                                                                                                                             |    |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| B.1.3                 | Piezoelectric.....                                                                                                                                                                          | 27 |
| B.1.4                 | Electromagnetic.....                                                                                                                                                                        | 27 |
| B.2                   | Positioning systems .....                                                                                                                                                                   | 28 |
| Annex C (informative) | Field measurement .....                                                                                                                                                                     | 29 |
| C.1                   | Measurement probes and hydrophones.....                                                                                                                                                     | 29 |
| C.2                   | Test chamber.....                                                                                                                                                                           | 31 |
| C.3                   | Degassing procedures .....                                                                                                                                                                  | 31 |
| C.4                   | Acoustic pulse energy.....                                                                                                                                                                  | 32 |
| Bibliography          | .....                                                                                                                                                                                       | 36 |
| Figure C.1            | – Typical measured pressure pulse waveform and parameters at the focus .....                                                                                                                | 33 |
| Figure C.2            | – Typical spatial pressure distribution measurements in three orthogonal coordinates of a focused pressure pulse source.....                                                                | 34 |
| Figure C.3            | – Schematic of focusing and focal geometry of a high amplitude pulsed focused acoustic pressure field produced by an electrohydraulic type shock wave generator commonly used in ESWT ..... | 35 |
| Figure C.4            | – Examples of the different focal regions according to –6 dB and 5 MPa contour in the focal peak-compressional pressure axial and lateral distribution .....                                | 35 |
| Table C.1             | – Hydrophones for focus and field measurements .....                                                                                                                                        | 30 |
| Table C.2             | – Measurement techniques and probes for quality assurance purposes .....                                                                                                                    | 31 |

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://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](http://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*

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