

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**





THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2025 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC -

webstore.iec.ch/advsearchform

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications, symboles graphiques et le glossaire. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

Electropedia - www.electropedia.org

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.50

ISBN 978-2-8327-0132-4

**Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

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.....	30
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

- 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)"); the 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 cooperating 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 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", "cavitational 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	87/880/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_docs. 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 in 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 electrical technology*,

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*