

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields

(standards.iteh.ai)

Ultrasons – Sources d'impulsions de pression courtes non focalisées y compris les sources d'impulsions de pression balistiques – Caractéristiques des champs



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2020 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 Central Office
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 It also gives information on projects, replaced and withdrawn publications.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 online collection - oc.iec.ch

Discover our powerful search engine and read freely all the publications previews. 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 22 000 terminological entries in English and French, with equivalent terms in 18 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 online collection - oc.iec.ch

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. 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 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Ultrasonics – Non-focusing short pressure pulse sources including ballistic pressure pulse sources – Characteristics of fields

Ultrasons – Sources d'impulsions de pression courtes non focalisées y compris les sources d'impulsions de pression balistiques – Caractéristiques des champs

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 17.140.50

ISBN 978-2-8322-1007-2

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.....	5
INTRODUCTION.....	7
1 Scope.....	8
2 Normative references	8
3 Terms and definitions	9
4 List of symbols	20
5 Conditions of measurement	22
5.1 General.....	22
5.2 Measurements in the water test chamber	22
5.3 Measurements in the dry test bench.....	22
6 Test equipment.....	22
6.1 Water test chamber.....	22
6.1.1 Coordinate system.....	23
6.1.2 Hydrophone for water test chamber measurements	23
6.1.3 Hydrophone for pressure pulse measurements	23
6.2 Dry test bench	24
6.3 Voltage measurement	24
6.3.1 Oscilloscope or transient recorder	24
6.3.2 Pressure pulse waveform recording	25
7 Measurement procedure.....	25
7.1 Measurement procedure in the water test chamber	26
7.1.1 General.....	26
7.1.2 Spatial measurements.....	26
7.1.3 Non-focusing source.....	28
7.1.4 Weakly focusing source	29
7.1.5 Beam plots of peak-positive acoustic pressure	29
7.1.6 Beam plots of peak-negative acoustic pressure	29
7.1.7 Measurement centre point and beam axis.....	30
7.1.8 Beam width measurements.....	30
7.1.9 Beam pressure maximum extent measurements	31
7.1.10 Beam cross-sectional area and beam pressure maximum cross-sectional area.....	31
7.1.11 Beam pressure maximum volume measurements.....	31
7.1.12 Beam volume.....	31
7.2 Temporal measurements.....	31
7.3 Acoustic energy measurements	32
7.3.1 General	32
7.3.2 Pulse-pressure-squared integral	32
7.3.3 Derived pulse-intensity integral.....	32
7.3.4 Derived beam $-n$ dB pressure maximum acoustic pulse energy	32
7.3.5 Derived acoustic pulse energy	33
7.4 Dry test bench measurements.....	33
Annex A (informative) Acoustic pressure pulse therapy.....	34
A.1 Background.....	34
A.1.1 General	34
A.1.2 Development of relevant measurement standard	34

A.1.3	Current knowledge on biomedical effects	34
A.1.4	Availability of clinical and technical data	34
A.2	Other treatment devices and methods not subject to this document	35
A.2.1	Percutaneous continuous and modulated wave systems	35
A.2.2	Extracorporeal shock wave lithotripsy	35
A.2.3	Further exclusions	35
Annex B	(informative) Types of pressure pulse transducers	36
B.1	Overview	36
B.1.1	General	36
B.1.2	Principle of ballistic pressure pulse sources	36
B.1.3	Rail gun principle	36
B.1.4	Further generation principles	37
B.2	Non-focusing and focusing transducers	37
B.3	Examples of pressure pulse sources and their parameter sets	38
B.4	Positioning and targeting methods	43
Annex C	(informative) Field measurement	44
C.1	Measurement probes and hydrophones	44
C.2	Water test chamber	46
C.2.1	General	46
C.2.2	Degassing procedures	46
C.3	Dry test bench	46
C.3.1	General	46
C.3.2	Selection and attachment of the hydrophone	48
C.3.3	Attachment of the hand piece	49
C.3.4	Proof of the similarity of measurements in water and the dry test bench	49
C.3.5	Special measurements with the dry test bench	49
C.4	Acoustic pulse energy	50
C.4.1	General	50
C.4.2	Extrapolation of the applicator surface pressure value	51
Annex D	(informative) Lists of parameters	52
Bibliography	59
Figure 1	– Typical pressure pulse waveform at 2 mm distance from a ballistic pressure pulse source	25
Figure 2	– Typical pressure distribution along the beam axis of a non-focusing pressure pulse source	27
Figure 3	– Typical pressure distribution along the beam axis of a weakly focusing pressure pulse source	28
Figure 4	– Typical lateral pressure distributions of p_C at the beam pressure maximum of two ballistic pressure pulse sources	30
Figure B.1	– Applicator directly coupled to the patient	39
Figure B.2	– Pressure pulse source, non-symmetric (linear), directly coupled to the patient	39
Figure B.3	– Pressure pulse source, symmetric, distant from the patient	40
Figure B.4	– Applicator coupled to patient	40
Figure B.5	– Non-focused pressure pulse field	40
Figure B.6	– Non-focused pressure pulse field - n dB parameters (example: $n = 6$)	41
Figure B.7	– Non-focused pressure pulse field isobars	41

Figure B.8 – Weakly-focused pressure pulse field –6 dB contour and parameters	42
Figure B.9 – Weakly-focused pressure pulse field volume and isobar parameters	42
Figure B.10 – Weakly-focused pressure pulse field parameters	43
Figure C.1 – Design example of a dry test bench in two views	47
Figure C.2 – Detail of the measurement chamber item of the dry test bench	48
Table C.1 – Hydrophone types for pressure pulse measurements	45
Table C.2 – Measurement techniques and probes for quality assurance purposes	46
Table D.1 – List of device parameters	52
Table D.2 – Pressure pulse parameters	53
Table D.3 – Additional parameters useful for the correlation with biological effects	55
Table D.4 – Graphical representations of pressure pulse data	56
Table D.5 – Data of hydrophones and measurement conditions	57

iTeh STANDARD PREVIEW (standards.iteh.ai)

IEC 63045:2020

<https://standards.iteh.ai/catalog/standards/sist/6b7392c6-94d7-47af-bfa6-7181f2a54311/iec-63045-2020>

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – NON-FOCUSING SHORT PRESSURE
PULSE SOURCES INCLUDING BALLISTIC
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.
- 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) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 63045 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
87/741/FDIS	87/743/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.

Words in **bold** in the text are defined in Clause 3.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[IEC 63045:2020](#)

<https://standards.iteh.ai/catalog/standards/sist/6b7392c6-94d7-47af-bfa6-7181f2a54311/iec-63045-2020>

INTRODUCTION

In this document, **pressure pulses** are single pulses of ultrasonic energy of up to 25 μ s duration which have only one significant positive and one negative peak carrying more than 95 % of the energy (see definitions). Focused **pressure pulses** (sometimes called "strongly focused") are characterized by a peak acoustic pressure in a point in the sound field distant from the **source aperture**. Parameters and measurement methods for focusing **pressure pulse** sources are described in IEC 61846. The parameters and measurement methods of any other types of **pressure pulses**, i.e. weakly focused and non-focused **pressure pulses**, are described in this document.

Devices with non-focusing/weakly focusing **pressure pulse** sources are used for the extracorporeal treatment of soft tissue pain situations in, for example, the shoulder, the heel spur or the tennis elbow and for trigger point therapy. Further, still under research are applications in orthopaedics, pain therapy, treatment of angina pectoris, stem cell therapy of infarcted cardiac areas, treatment of erectile dysfunction, of cellulitis, and wound repair.

The patients receive between 3 to 5 treatments of 10 min to 20 min duration with approximately or on average 1 000 pulses. Each **pressure pulse** consists of one significant compressional part and a trailing negative part and has an overall duration of less than 25 μ s. In present devices, 1 to 35 pulses per second are released to the target tissue. The pulses are usually applied to the patient by a manually guided hand piece. Targeting is commonly done by asking the patient to direct the pulses to the point of maximum pain.

The first use of non-focused/weakly focused **pressure pulses** to treat soft tissue pain situations was described in 1999. The first devices used the ballistic principle for the generation of the **pressure pulses**, which is based on an "air-gun" like acceleration of a projectile by pressurized air. The projectile impinges on the rear side of a larger metal **applicator**, the front side of which instantly releases one fast **pressure pulse** to the patient. Today, most of the devices on the market use this design and often are called "radial shock wave devices" or "ballistic sources" although a true shock wave is not created. Also, other pulse generating principles are being applied including variations of common lithotripter sources (electromagnetic, piezoelectric, electrohydraulic).

Before this first occurrence, focused **pressure pulses** were used clinically beginning in 1993 for the treatment of shoulder calcifications, tennis elbow pain and heel spur pain, initially using lithotripter-like electrohydraulic, electromagnetic or piezoelectric sources. These focused **pressure pulses** can be characterized by IEC 61846, but the parameters described therein are not sufficiently applicable to characterize the parameters and fields of weakly focused and non-focused **pressure pulses** and their propagation characteristics.

This document specifies methods of measuring and characterizing the acoustic **pressure pulses** generated by non-focusing/weakly focusing **pressure pulse equipment** and their propagation characteristics.

ULTRASONICS – NON-FOCUSING SHORT PRESSURE PULSE SOURCES INCLUDING BALLISTIC PRESSURE PULSE SOURCES – CHARACTERISTICS OF FIELDS

1 Scope

This document is applicable to

- therapy equipment using extracorporeally induced non-focused or weakly focused **pressure pulses**;
- therapy equipment producing extracorporeally induced non-focused or weakly focused mechanical energy,

where the **pressure pulses** are released as single events of duration up to 25 μ s.

This document does not apply to

- therapy equipment using focusing **pressure pulse** sources such as extracorporeal lithotripsy equipment;
- therapy equipment using other acoustic waveforms like physiotherapy equipment, low intensity ultrasound equipment and HIFU/HITU equipment.

This document specifies

- measurable parameters which are used in the declaration of the acoustic output of extracorporeal equipment producing a **non-focused or weakly focused pressure pulse field**,
- methods of measurement and characterization of **non-focused or weakly focused pressure pulse fields**.

NOTE 1 The parameters defined in this document do not – at the time of publication – allow quantitative statements to be made about clinical efficacy and possible hazard. In particular, it is not possible to make a statement about the limits for these effects.

NOTE 2 Figure B.1 to Figure B.10 and Figure 2 to Figure 4 are useful to understand the geometry of the field applied in this document.

This document has been developed for equipment intended for use in **pressure pulse** therapy, for example therapy of orthopaedic pain like shoulder pain, tennis elbow pain, heel spur pain, muscular trigger point therapy, lower back pain, etc. It is not intended to be used for extracorporeal lithotripsy equipment (as described in IEC 61846), physiotherapy equipment using other waveforms (as described in IEC 61689) and HIFU/HITU equipment (see IEC 60601-2-62 and IEC TR 62649).

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 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 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

IEC 62127-1:2007/AMD1:2013

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62127-3, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

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

applicator

part of the ballistic **pressure pulse** source which emits the **pressure pulses** to the patient

Note 1 to entry: In the case of a ballistic **pressure pulse** source, the front side of the **applicator** is often coupled to the skin of the patient using an ultrasound coupling gel or other agent and releasing the **pressure pulses** to the patient. In this case, the front of the **applicator** is equal to the **source aperture**.

Note 2 to entry: Depending on the design of the source, there may be a space between the source emitting the **pressure pulses** (e.g. membrane, surface of piezoelectric crystals, spark gap etc.) and the **source aperture**. Usually, this space is composed of an acoustically conducting pad coupling material or a fluid, which transmits the **pressure pulses** from the source to the **source aperture** (see 3.48).

3.2

beam $-n$ dB cross-sectional area

$A_{z,n\text{dB}}$

area enclosed by the **peak-positive acoustic pressure** contour in any plane perpendicular to the **beam axis**, where all points on the contour have a pressure of $-n$ dB relative to the value at the **beam axis** in this plane

Note 1 to entry: The value of n and the axial distance z from the measurement centre point shall be 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 **beam $-n$ dB cross-sectional area** is expressed in units of metre squared (m^2).

3.3

beam $-n$ dB extent

$z_{b,n\text{dB}}$

distance along the **beam axis** from the **source aperture** to the point where the **peak-positive acoustic pressure** has dropped farthest by $-n$ dB relative to the acoustic pressure at the **source aperture**

Note 1 to entry: The value of n shall be 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 **beam $-n$ dB extent** is expressed in metres (m).

3.4

beam $-n$ dB volume

$V_{b,ndB}$

volume in space defined by the $-n$ dB (relative to the **beam pressure maximum value**) **peak-positive acoustic pressure** contours measured around the **beam axis**

Note 1 to entry: It may be difficult to measure $-n$ dB points throughout the volume around the **beam**. It is reasonable in practice to approximate the **beam $-n$ dB volume** from measurements taken in three orthogonal directions: the **beam axis** (z axis); and the two orthogonal axes (x, y) 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 **beam $-n$ dB volume** is expressed in units of metre cubed (m^3).

Note 4 to entry: The value of n shall be stated as a subscript.

Note 5 to entry: See IEC 61828.

3.5

beam $-n$ dB width, maximum

$w_{\max,x,z,ndB}$

maximum width of the $-n$ dB contour of the **peak-positive acoustic pressure** p_c around the z axis in the x - y plane at any distance z

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 **beam $-n$ dB width, maximum** is expressed in metres (m).

Note 3 to entry: The values of z and n shall be stated as subscripts.

3.6

beam $-n$ dB width, orthogonal

$w_{\max,y,z,ndB}$

width of the $-n$ dB contour of the **peak-positive acoustic pressure** p_c around the **beam pressure maximum**, in the x - y plane at any distance z , in the direction perpendicular to the direction of the beam width maximum

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 **beam $-n$ dB width, orthogonal** is expressed in metres (m).

Note 3 to entry: The values of z and n are stated as subscripts.

3.7

beam axis

line passing through the centre of mass of the **source aperture** of the **pressure pulse** generator and perpendicular to the **source aperture** surface

Note 1 to entry: This line is taken as the z axis. See 6.1.1 and Clause 7.

Note 2 to entry: For a definition of centre of mass, see IEC 60050-113:2011, 113-03-12.

3.8

beam isobar cross-sectional area

$A_{n\text{MPa},z}$

area enclosed by the **peak-positive acoustic pressure** contour which is delimited by a peak-positive pressure value n , at any point on the **beam axis**, and is in the plane, perpendicular to the **beam axis** at that point on the **beam axis**

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 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: This definition helps manufacturers and researchers to define the size of an area, where a certain peak pressure value is exceeded. This definition is based on the assumption that an observed or estimated therapeutic effect or side effect can be found inside a region where a certain threshold pressure value (or energy flux density value) is exceeded. See for example, in Table D.3, the $E_{n\text{MPa},z,T}$ parameter where $n = 5$ mm and $z = 10$ mm will be written as $E_{5\text{MPa},10,T}$.

Note 3 to entry: The **beam isobar cross-sectional area** is expressed in units of metre squared (m^2).

Note 4 to entry: The values of z and n are stated as subscripts.

3.9

beam isobar extent

$z_{\text{be},n\text{MPa}}$

distance along the **beam axis** from the **source aperture** to the point where the **peak-positive acoustic pressure** has dropped farthest to a value of n MPa

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 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 **beam isobar extent** is expressed in metres (m).

Note 3 to entry: The value of n is stated as a subscript.

3.10

beam isobar volume

$V_{b,n\text{MPa}}$

volume in space defined by the **peak-positive acoustic pressure** n MPa isobar contours measured around the **beam axis**

Note 1 to entry: The **beam isobar volume** is expressed in units of metre cubed (m^3).

Note 2 to entry: It may be difficult to measure n MPa points throughout the volume around the **beam**. It is reasonable in practice to approximate the **beam isobar volume** from measurements taken in three orthogonal directions: the **beam axis** (z axis); and the two orthogonal axes (x,y) which are also orthogonal to the **beam axis**.

Note 3 to entry: Reasonable values of n MPa 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.

3.11

beam isobar width, maximum

$w_{\text{max},x,z,n\text{MPa}}$

maximum width of the contour of the **peak-positive acoustic pressure** p_c around the z axis in the x - y plane at any distance z with an acoustic pressure value of n MPa

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 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 **beam isobar width, maximum** is expressed in metres (m).

Note 3 to entry: The value of n is stated as a subscript.

3.12**beam isobar width, orthogonal** $w_{\max,y,z,n\text{MPa}}$

width of the contour of the **peak-positive acoustic pressure** p_c around the z axis in the x - y plane at any distance z , in the direction perpendicular to the direction of the **beam isobar width, maximum** with an acoustic pressure value of n MPa

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 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: **Beam isobar width, orthogonal** is expressed in metres (m).

Note 3 to entry: The values of z and n are stated as subscripts.

3.13**beam pressure maximum** $p_{c,bpm}$

peak-positive acoustic pressure amplitude at the **beam pressure maximum distance**

Note 1 to entry: The **beam pressure maximum** is expressed in pascals (Pa).

3.14**beam pressure maximum $-n$ dB cross-sectional area** $A_{bpm,n\text{dB}}$

area enclosed by the **peak-positive acoustic pressure** contour which is $-n$ dB relative to the value at the **beam pressure maximum distance** and is in the plane perpendicular to the **beam axis**, which contains the **beam pressure maximum**

Note 1 to entry: The value of n shall be stated as a 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 beam pressure maximum $-n$ dB cross-sectional area** is expressed in units of metre squared (m^2).

3.15**beam pressure maximum $-n$ dB extent** $L_{bpm,n\text{dB}}$

distance along the z axis between the $-n$ dB points of the **peak-positive acoustic pressure** on either side of the **beam pressure maximum**

Note 1 to entry: The value of n shall be stated as a subscript.

Note 2 to entry: A **beam pressure maximum** only exists if the acoustic pressure on the **beam axis** drops by at least $-n$ dB in $\pm z$ direction as compared to the **beam pressure maximum**. Otherwise, no **beam pressure maximum $-n$ dB extent** exists.

Note 3 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 4 to entry: The **beam pressure maximum $-n$ dB extent** is expressed in metres (m).

3.16**beam pressure maximum $-n$ dB volume** $V_{bpm,n\text{dB}}$

volume in space defined by the n dB (relative to the value at the **beam pressure maximum**) **peak-positive acoustic pressure** contours measured around the **beam pressure maximum**

Note 1 to entry: The value of n shall be stated as a subscript.

Note 2 to entry: It may be difficult to measure $-n$ dB points throughout the volume around the **beam pressure maximum** (IEC 61828).

Note 3 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 4 to entry: The **beam pressure maximum $-n$ dB volume** is expressed in units of metre cubed (m^3).

3.17

beam pressure maximum $-n$ dB width, maximum

$w_{\text{bpm},x,n\text{dB}}$

maximum width of the $-n$ dB contour of the **peak-positive acoustic pressure** p_c around the **beam pressure maximum** in the x - y plane which contains the **beam pressure maximum**

Note 1 to entry: The value of n shall be 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 **beam pressure maximum $-n$ dB width, maximum** is expressed in metres (m).

3.18

beam pressure maximum $-n$ dB width, orthogonal

$w_{\text{bpm},y,n\text{dB}}$

width of the $-n$ dB contour of the **peak-positive acoustic pressure** p_c around the **beam pressure maximum**, in the x - y plane which contains the **beam pressure maximum**, in the direction perpendicular to the direction of the **beam pressure maximum width**

Note 1 to entry: The value of $-n$ shall be stated as a 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 **beam pressure maximum $-n$ dB width, orthogonal** is expressed in metres (m).

3.19

beam pressure maximum isobar cross-sectional area

$A_{\text{bpm},n\text{MPa}}$

area enclosed by the **peak-positive acoustic pressure** contour which is delimited by an isobar of n MPa, where this isobar is in that plane perpendicular to the **beam axis**, which contains the **beam pressure maximum**

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 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 **beam pressure maximum isobar cross-sectional area** is expressed in units of metre squared (m^2).

Note 3 to entry: The value of n is given as a subscript.

3.20

beam pressure maximum isobar extent

$L_{\text{bpm},n\text{MPa}}$

distance along the z axis between the points on either side of the **beam pressure maximum** of n MPa