IEC 63045

Edition 1.0 2020-05

INTERNATIONAL STANDARD

colour inside

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

IEC 63045:2020-05(en)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.140.50

ISBN 978-2-8322-8340-0

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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- withdrawn,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.

INTRODUCTION

In this document, **pressure pulses** are single pulses of ultrasonic energy of up to 25 μs 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 μs. 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 µs.

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
$A_{z,n\mathrm{dB}}$
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
$z_{\mathrm{b},n\mathrm{dB}}$
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
$V_{b,n\mathrm{dB}}$
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
$w_{\mathrm{max},x,z,n\mathrm{dB}}$
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
$w_{\mathrm{max},y,z,n\mathrm{dB}}$
width of the −*n* dB contour of the **peak-positive acoustic pressure** p_c around the **beam pressure maximum**, in the *x*-*y* plane 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 $E_{n\text{MPa},z,\text{T}}$ parameter where n = 5 mm and z = 10 mm will be written as $E_{5\text{MPa},10,\text{T}}$.

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

$w_{\mathrm{max},y,z,n\mathrm{MPa}}$

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

$p_{\mathrm{c,bpm}}$

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

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

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

$L_{\mathrm{bpm},n\mathrm{dB}}$

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

$V_{\mathrm{bpm},n\mathrm{dB}}$

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

Note 1 to entry: A **beam pressure maximum isobar extent** only exists if the acoustic pressure on the **beam axis** drops by n MPa in $\pm z$ direction as compared to the **peak-positive acoustic pressure** at the **beam pressure maximum.** Otherwise, no **beam pressure maximum isobar extent** exists.

Note 2 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 3 to entry: The **beam pressure maximum isobar extent** is expressed in metres (m).

Note 4 to entry: The value of n is given as a subscript.

3.21
beam pressure maximum isobar volume
$V_{\mathrm{bpm},n\mathrm{MPa}}$
volume in space defined by the **peak-positive acoustic pressure** contours which are defined by an isobar of n MPa, measured around 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 volume** is expressed in units of metre cubed (m^3).

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

3.22
beam pressure maximum isobar width, maximum
$w_{\mathrm{bpm},x,n\mathrm{MPa}}$
maximum width of the n MPa 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: 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 width** is expressed in metres (m).

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

3.23
beam pressure maximum isobar width, orthogonal
$w_{\mathrm{bpm},y,n\mathrm{MPa}}$
width of the n MPa contour in the direction perpendicular to the direction of the **beam pressure maximum isobar width, maximum**, 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 is given as a subscript.

Note 2 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 3 to entry: The **beam pressure maximum isobar width, orthogonal** is expressed in metres (m).

3.24
beam pressure maximum distance
z_{bpm}
distance along the **beam axis** from the **source aperture** to the first point where the **peak-positive acoustic pressure** has a local maximum ≥ 3 dB larger than the **peak-positive acoustic pressure** at axial points in the neighbourhood of the local maximum

Note 1 to entry: 3 dB accounts for possible measurement uncertainties.

Note 2 to entry: The **beam pressure maximum distance** is expressed in metres (m).

Note 3 to entry: For a non-focusing source, the **beam pressure maximum distance** is located at the surface of the **source aperture**. See 7.1.3.

Note 4 to entry: For a weakly focusing source, the **beam pressure maximum distance** is located on the beam axis, but the peak-positive pressure at this point is not higher than the **peak-positive acoustic pressure** at the **source aperture**. See 7.1.4.

Note 5 to entry: If the **peak-positive acoustic pressure** p_c has a maximum along the **beam axis** which is higher than the **peak-positive acoustic pressure** p_c at the **source aperture**, this document does not apply, instead IEC 61846 applies.

3.25
compressional pulse duration

t_{FWHMpc}

time interval between the points where the **instantaneous acoustic pressure** at the **beam pressure maximum distance** first exceeds 50 % of the **peak-positive acoustic pressure** and the first time it falls below 50 % of the **peak-positive acoustic pressure**

Note 1 to entry: See Figure 1.

Note 2 to entry: The subscript "FWHM" stands for "full width at half maximum".

Note 3 to entry: The **compressional pulse duration** is expressed in seconds (s).

3.26
derived acoustic pulse energy

$E_{R,z}$

spatial integral of the **derived pulse-intensity integral** over a circular cross-sectional area of radius R in the x-y plane at any distance z from the **measurement centre point**

Note 1 to entry: The values of R and z shall be stated as subscripts.

Note 2 to entry: The **derived acoustic pulse energy** is expressed in joules (J).

3.27
derived beam −*n* dB pressure maximum acoustic pulse energy

$E_{bpm,n\mathrm{dB}}$

spatial integral of the **derived pulse-intensity integral** over the **beam pressure maximum −*n* dB cross-sectional area** measured around the **beam pressure maximum distance**

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

Note 2 to entry: This definition may overestimate E if the aperture of the **pressure pulse** generator is large.

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 **derived beam −*n* dB pressure maximum acoustic pulse energy** is expressed in joules (J).

3.28
derived beam isobar pressure maximum acoustic pulse energy

$E_{bpm,n\mathrm{MPa}}$

spatial integral of the **derived pulse-intensity integral** over the **beam pressure maximum isobar cross-sectional area**

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

Note 2 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 3 to entry: The **derived beam isobar pressure maximum acoustic pulse energy** is expressed in joules (J).

3.29
derived instantaneous intensity
I
quotient of squared **instantaneous acoustic pressure** and characteristic impedance of the medium at a particular instant in time at a particular point in an acoustic field

$$I(t) = \frac{p^2(t)}{Z} \tag{1}$$

where

$p(t)$ is the **instantaneous acoustic pressure**;

Z is the characteristic acoustic impedance of the medium

Note 1 to entry: In order to clarify that this parameter usually varies with time, (t) may be added in the formulae, for example $I(t)$.

Note 2 to entry: The **derived instantaneous intensity** is expressed in units of watt per metre squared (W/m^2).

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007+AMD1:2013, 3.78, modified – The formula and the notes have been rephrased.]

3.30
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).

3.31
end-of-cable loaded sensitivity of a hydrophone
M_L
ratio of the voltage at the end of any integral cable or connector of a **hydrophone**, when connected to a specified electrical input impedance, to the **instantaneous acoustic pressure** 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: See 3.26 of IEC 62127-1:2007.

Note 2 to entry: The **end-of-cable loaded sensitivity of a hydrophone** is expressed in units of volt per pascal (V Pa^{-1}).

3.32
focused pressure pulse field
field of a transducer having a **beam pressure maximum distance** that is larger than the **beam pressure maximum −6 dB extent, i.e.** $z_{bpm} > L_{bpm,6dB}$

Note 1 to entry: In a **focused pressure pulse field**, the **pressure pulse** amplitude adjacent to the **beam pressure maximum** is larger than the **pressure pulse** amplitude at any place at the **source aperture**. For the description of **focused pressure pulse fields**, IEC 61846 applies.

Note 2 to entry: Refer to Clause B.2 for more explanations.

3.33
hydrophone
transducer that produces electrical signals in response to waterborne acoustic signals

[SOURCE: IEC 60050-801:1994, 801-32-26]

3.34
instantaneous acoustic pressure
p
acoustic pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: In order to clarify that this parameter usually varies in time, (t) may be added in the formulae, for example $p(t)$.

Note 2 to entry: The **instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 60050-802:2011, 802-01-03, modified – The definition has been rephrased, and the notes to entry added.]

3.35
instantaneous intensity
I
acoustic energy transmitted per unit time in the direction of acoustic wave propagation per unit area normal to this direction at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: Instantaneous intensity is the product of **instantaneous acoustic pressure** and particle velocity. It is difficult to measure intensity in the ultrasound frequency range. For the measurement purposes referred to in this document and under conditions of sufficient distance from the external transducer aperture, the **instantaneous intensity** can be approximated by the **derived instantaneous intensity** (3.29).

Note 2 to entry: In order to clarify that this parameter usually varies in time, (t) may be added in the formulae, for example $I(t)$.

Note 3 to entry: **Instantaneous intensity** is expressed in units of watt per metre squared (W/m^2).

[SOURCE: IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, 3.34, modified – The parenthesis has been deleted in Note 1 to entry, and Note 2 to entry has been added.]

3.36
measurement centre point
centre of mass of the **source aperture** at the location in space (x, y, z) where the x, y and z coordinates are centred, i.e. (x = 0, y = 0, z = 0).

Note 1 to entry: See IEC 60050-113:2011, 113-03-12 (centre of mass).

Note 2 to entry: The **measurement centre point** may be abbreviated by the symbol O.

3.37
non-focused pressure pulse field
pulse field where the **pressure pulse** amplitude within it is nowhere larger than the **peak-positive pressure pulse** amplitude at any place at the **source aperture**, and the **pressure pulse** amplitude is decreasing with increasing distance from the **source aperture**

Note 1 to entry: See Clause B.2.

3.38
weakly focused pressure pulse field
pulse field where a local acoustic pressure maximum occurs, which has an amplitude less than the **peak-positive acoustic pressure** at the **source aperture**

Note 1 to entry: See Clause B.2.

3.39
peak-positive acoustic pressure
p_c
maximum compressional acoustic pressure at any spatial location in the **pressure pulse** field

Note 1 to entry: The **peak-positive acoustic pressure** is expressed in pascals (Pa).

Note 2 to entry: The **peak-positive acoustic pressure** is also called "peak-compressional pressure".

3.40
peak-negative acoustic pressure
p_r
maximum of the modulus of the rarefactional acoustic pressure at any spatial location in the **pressure pulse** field

Note 1 to entry: The **peak-negative acoustic pressure** is expressed in pascals (Pa).

Note 2 to entry: The **peak-negative acoustic pressure** is also called "peak-rarefactional pressure".

3.41
positive temporal integration limits
$t_{\mathrm{Pt,lim}}$
time between which the compressional acoustic **pressure pulse waveform** first exceeds 10 % of its **peak-positive acoustic pressure** value and the first time it falls below 10 % of its **peak-positive acoustic pressure** value

Note 1 to entry: The **positive temporal integration limits** are expressed in seconds (s).

3.42
positive temporal *n* MPa threshold integration limits
$t_{\mathrm{P}n\mathrm{MPa,lim}}$
time between which the **pressure pulse waveform** first exceeds a value of n MPa and the first time it falls below the n MPa value

Note 1 to entry: The value n is stated as subscript.

Note 2 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 3 to entry: The **positive temporal *n* MPa threshold integration limits** are expressed in seconds (s).

3.43
pressure pulse
acoustic wave emitted by the **pressure pulse equipment**, which consists of two significant wave components: one positive (or negative) half-cycle and one negative (or positive) trailing half cycle

Note 1 to entry: See Figure 1.

Note 2 to entry: Depending on the properties of the **pressure pulse** source, spurious additional signals of smaller amplitude may follow the significant wave components. Only signal parts adding more than 5 % to the energy content of the wave are considered as significant. Wave components, which are for example caused by inertial motions of a mechanical **applicator**, may appear several hundred microseconds to some milliseconds after the **pressure pulse**. These signals are outside the scope of this document. See [1] and [2].

3.44
pressure pulse equipment
device for treating a patient with extracorporeally induced **pressure pulses**

Note 1 to entry: Known applications are given in the Introduction.

3.45
pressure pulse waveform
temporal waveform of the **instantaneous acoustic pressure** at a particular point in a **pressure pulse** wave field and displayed over a period sufficiently long to include all significant acoustic information in the **pressure pulse**

3.46
pulse-pressure-squared integral
ppsi
time integral of the square of the **instantaneous acoustic pressure** over the **pressure pulse waveform**

Note 1 to entry: The **pulse-pressure-squared integral** is expressed in units of pascal squared times second (Pa^2s).

[SOURCE: IEC 62127-1:2007, 3.50, modified – The definition has been rephrased.]

3.47
rise time
t_r
time taken for the **instantaneous acoustic pressure** to increase from 10 % to 90 % of the **peak-positive acoustic pressure**

Note 1 to entry: See Figure 1.

Note 2 to entry: The **rise time** is expressed in seconds (s).

3.48
source aperture
active region of the **pressure pulse** source, assumed to lie on a planar surface, which transmits the **pressure pulses** to the patient

Note 1 to entry: For mechanical **applicators**, the **source aperture** usually is the patient side of the **applicator**, which is coupled to the patient.

Note 2 to entry: For other types of **applicators**, the **source aperture** is determined by the area which is coupled to the patient and transmits the **pressure pulses** to the patient. This area is determined by measurements of the **beam −*n* dB cross-sectional area** at a position as close as practical to the **source aperture**, where the value of n is determined such that the **derived acoustic pulse energy** in this area is reaching the same value as the **derived beam −*n* dB pressure maximum acoustic pulse energy** for the same value of n. The value of n shall be chosen such that the largest value of **derived beam −*n* dB pressure maximum acoustic pulse energy** is reached for a given setting of the **pressure pulse** source. 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: Depending on the construction, the **source aperture** may be circularly symmetric, but it may also have different **source aperture width** and **source aperture width, orthogonal** dimensions. If it is asymmetric, it is likely that the beam width parameters in the maximum direction and in the orthogonal direction have different values.

3.49
source aperture width
D_x
largest diameter or extent of the **source aperture**

Note 1 to entry: The normal vector of the **source aperture** determines the z-direction of the measurement coordinate system.

Note 2 to entry: For circular symmetric mechanical **applicators** which are excited by a force (e.g. an impinging projectile) at the symmetry axis, the **source aperture** is equal to the patient-side diameter of the **applicator**.

Note 3 to entry: The **source aperture width** is expressed in metres (m).

3.50
source aperture width, orthogonal
D_y
diameter or extent of the **source aperture** orthogonal to the **source aperture width**

Note 1 to entry: For circular symmetric mechanical **applicator**s and for other circular symmetric source types, the **source aperture width, orthogonal** is identical to the **source aperture width.** If they are asymmetric, it is likely that the beam width parameters in the maximum direction and in the orthogonal direction have different values.

Note 2 to entry: The **source aperture width, orthogonal** is expressed in metres (m).

3.51
target location
V_t
location in space where the manufacturer intends the user to locate the biological tissue to be treated, given as a three-dimensional position vector (x_t, y_t, z_t) relative to the **measurement centre point**

Note 1 to entry: For different applications, the **target locations** may differ and shall be given by the manufacturer.

Note 2 to entry: The **target location** is expressed in metres (m).

3.52
total temporal integration limits
$t_{Tot,lim}$
times between which the absolute value (modulus) of the acoustic **pressure pulse waveform** first exceeds 10 % of its maximum value and the last time it reduces below 10 % of its maximum value

Note 1 to entry: The **total temporal integration limits** are expressed in seconds (s).

3.53
total temporal MPa threshold integration limits
$t_{Tot,n\text{MPa},lim}$
times between which the **pressure pulse waveform** first exceeds a value of n MPa and the last time it falls below the n MPa value

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

Note 2 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 3 to entry: The **total temporal MPa threshold integration limits** are expressed in seconds (s).

4 List of symbols

$A_{bpm,n\text{dB}}$	beam pressure maximum $-n$ dB cross-sectional area
$A_{bpm,n\text{MPa}}$	beam pressure maximum isobar cross-sectional area
$A_{z,n\text{dB}}$	beam $-n$ dB cross-sectional area
$A_{n\text{MPa},z}$	beam isobar cross-sectional area
D_x	source aperture width
D_y	source aperture, orthogonal
$E_{bpm,n\text{dB}}$	derived beam $-n$ dB pressure maximum acoustic pulse energy
$E_{R,z}$	derived acoustic pulse energy
I, $I(t)$	(derived) instantaneous intensity

$L_{\text{bpm},n\text{dB}}$	beam pressure maximum $-n$ dB extent
$L_{\text{bpm},n\text{MPa}}$	beam pressure maximum isobar extent
L_{p}	thickness of dry test bench pad
M_{L}	end-of-cable loaded sensitivity of the hydrophone
p, $p(t)$	instantaneous acoustic pressure
p_{c}	peak-positive acoustic pressure
$p_{\text{c,bpm}}$	beam pressure maximum
$PII(x,y,z)$	derived pulse-intensity integral
$ppsi$	pulse-pressure-squared integral
p_{r}	peak-negative acoustic pressure
t_{FWHMpc}	compressional pulse duration
$t_{\text{P}n\text{MPa,lim}}$	positive temporal n MPa threshold integration limits
$t_{\text{Pt,lim}}$	positive temporal integration limits
t_{r}	rise time
$t_{\text{Tot},n\text{MPa,lim}}$	total temporal MPa threshold integration limits
$t_{\text{Tot,lim}}$	total temporal integration limits
$V_{\text{b},n\text{dB}}$	beam $-n$ dB volume
$V_{\text{bpm},n\text{dB}}$	beam pressure maximum $-n$ dB volume
$V_{\text{b},n\text{MPa}}$	beam isobar volume
V_{t}	target location
$w_{\text{bpm},x,n\text{dB}}$	beam pressure maximum $-n$ dB width, maximum
$w_{\text{bpm},x,n\text{MPa}}$	beam pressure maximum isobar width, maximum
$w_{\text{bpm},y,n\text{dB}}$	beam pressure maximum $-n$ dB width, orthogonal
$w_{\text{bpm},y,n\text{MPa}}$	beam pressure maximum isobar width, orthogonal
$w_{\text{max},x,z,n\text{dB}}$	beam $-n$ dB width, maximum
$w_{\text{max},x,z,n\text{MPa}}$	beam isobar width, maximum
$w_{\text{max},y,z,n\text{dB}}$	beam $-n$ dB width, orthogonal
$w_{\text{max},y,z,n\text{MPa}}$	beam isobar width, orthogonal
x, y, z,	spatial coordinates
$z_{\text{b},n\text{dB}}$	beam $-n$ dB extent
z_{bpm}	beam pressure maximum distance
$z_{\text{be},n\text{MPa}}$	beam isobar extent
Z	characteristic acoustic impedance of the medium

5 Conditions of measurement

5.1 General

Measurements shall be performed in a situation approximating conditions of actual operation. Parameters which shall be considered and documented include:

– **pressure pulse** generator drive level range and level(s) for the measurements;
– rate of **pressure pulse** release;
– ambient temperature.

5.2 Measurements in the water test chamber

In the water test chamber, the following conditions shall be considered and documented:

– electrical conductivity of water in a measuring tank;
– temperature of water in a measuring tank;
– dissolved oxygen content of water in a measuring tank.

Degassed water (see IEC TR 62781 for recommendations) at a specified nominal room temperature should be used in the measuring tank (test chamber) which shall be large enough to allow the measurement environment to approximate free-field conditions. Great care shall be taken to ensure that bubbles do not collect on the **hydrophone** nor anywhere in the beam path.

The conductivity of the water shall be suitable for the **hydrophone** being used. The calibration data of the **hydrophone** shall be known at the temperature of the water in the measuring tank and at appropriate frequencies.

NOTE Depending on the rarefactional amplitude p_r of the **pressure pulses**, ultrapure water can be advisable to reduce the occurrence of cavitation nuclei.

5.3 Measurements in the dry test bench

In the dry test bench, the following parameters shall be considered and documented:

– material and thickness of a tissue mimicking pad;
– coupling conditions between **source aperture** and tissue mimicking pad (e.g. dry, wet, silicone oil, ultrasound coupling gel, grease);
– coupling force of the pressure probe or **hydrophone** to a tissue mimicking pad;
– coupling force of the **source aperture** to a tissue mimicking pad.

6 Test equipment

6.1 Water test chamber

The test chamber shall be a water tank constructed in a form that can be securely fixed to the **pressure pulse** generator so that the acoustic output from the **pressure pulse** generator is coupled into a volume of water. The chamber shall be sufficiently large to allow the expected position of any measurement point to be several centimetres away from any reflective boundary, in particular the water surface. The distance between all measurement points and reflective boundaries shall be chosen such that no spurious or multiple reflections of the **pressure pulse** interfere with the measurements. Thus, the distance between the measurement point and the closest surface shall be at least

$$c(T)\cdot t_{\text{Tot,lim}}/2$$

where

$c(T)$ is the speed of sound in water given in m/s as a function of temperature T;

$t_{\text{Tot,lim}}$ is the total temporal integration limit and given in seconds.

There shall be a suitable mechanical holder for the **hydrophone** which is mounted on a coordinate positioning system to allow adjustment and measurement of the position of the **hydrophone** in three orthogonal directions relative to the **measurement centre point**. One axis (usually the z axis) of the coordinate positioning system shall be collinear with the **beam axis**. The relative position of the **hydrophone** shall be measurable with a precision of 0,5 mm or better.

Care shall be taken to ensure that coupling membrane(s) between the **source aperture** and the water do not influence the measurements. Coupling media, for example ultrasound coupling gel, shall be applied as specified by the manufacturer if the **source aperture** is not directly submerged in the water.

6.1.1 Coordinate system

All measurement coordinates and distances shall be given relative to the centre of mass of the **source aperture**, which defines the **measurement centre point**. All coordinates (x,y,z) shall be documented relative to the **measurement centre point**.

The coordinates of the **target location(s)** shall be given relative to the **measurement centre point**.

6.1.2 Hydrophone for water test chamber measurements

The **hydrophone** shall have characteristics complying with IEC 62127-1, IEC 62127-2 and IEC 62127-3.

The **hydrophone** shall have a frequency range from < 10 kHz to at least f_{max}, where f_{max} is calculated according to Formula (2) – see Annex C:

$$f_{\text{max}} = 5 \,/\, t_{\text{r}} \tag{2}$$

Calibration shall be performed in the frequency range of $1/(2\, t_{\text{FWHMpc}})$ to 5 MHz in accordance with the requirements of IEC 62127-2, IEC 60565-1 and IEC 60565-2. The frequency response shall not vary by more than ±3 dB over the calibrated frequency range. The effective diameter of the **hydrophone** should be as small as possible and its value shall be stated.

NOTE 1 The lower frequency limit of current **hydrophone** calibration according to IEC 62127-3 is 0,5 MHz. For the calibration at lower frequencies, refer to IEC 60565-1 and IEC 60565-2.

NOTE 2 The upper frequency limit of the **hydrophone** as defined here is sufficient as long as no significant non-linear steepening of the signals occur in the **pressure pulse** field.

6.1.3 Hydrophone for pressure pulse measurements

Examples for appropriate **hydrophone**s for **pressure pulse** measurements are listed in Table C.1.

For quality assurance, consistency checks may be required for periodic measurements of the **pressure pulse** source in order to assure that the device remains inside the specifications. These consistency checks can be required at regular intervals, for example each year, and additionally after servicing and repair. The **hydrophone** for quality assurance purposes shall have a robust construction and shall have a frequency response which does not vary by more than ±3 dB per octave over the frequency range from 0,5 MHz to 5 MHz. The effective diameter of the **hydrophone** should be as small as possible, it shall not exceed the **source aperture** and its value shall be stated.

Measurements undertaken using the **hydrophone** should not vary by more than ±10 % over the duration of the measurements. If they do, additional investigative studies should be carried to establish whether the variation is due to the variations in source output or a change in sensitivity of the **hydrophone** employed. This might involve using an alternative **hydrophone** or changing the experimental conditions. Regular re-calibration of the sensitivity is advisable (see IEC 62127-2:2007, 5.4).

Data measured with the **hydrophone for quality assurance purposes** shall not be published as absolute values for the characterization of a **pressure pulse** source.

Examples for appropriate **hydrophones** for quality assurance measurements are listed in Table C.2.

Two different **hydrophones** are permitted because many of those suitable for measurements at close distances to the **source aperture**, in particular on the z-axis, are very fragile. A more robust, less highly specified device is therefore permitted for general field measurements and for use in the dry test bench.

Care shall be taken when selecting a more robust **hydrophone** to select a type which will provide the needed linearity and **peak-negative acoustic pressure** values of the high acoustic pressures encountered.

If only measurements at the **beam axis** are done, for example in the dry test bench, then the effective diameter of the **hydrophone** may be larger but shall not exceed the **source aperture**.

6.2 Dry test bench

The dry test bench provides a convenient tool for rapid measurements of some of the key parameters of the **pressure pulse** source. It avoids the use of a water bath, which is difficult when measurements have to be done in the production line, on the premises of a hospital etc. Additionally, the test bench setup and adjustments of the **pressure pulse** source require no lab environment and can be done in a short time, even by trained personnel in the medical practice.

The dry test bench (for a design example, see Figure C.1 and Figure C.2), consists of a platform, a pad holder, and a holder for the hand piece. A **hydrophone** as described in 6.1 is located inside the pad holder containing a silicone pad which mimics human tissue (1). The **hydrophone** is attached to the silicone pad and needs to be coupled bubble-free to the rear surface of the pad in order to pick up the **pressure pulses** released from the **source aperture** through the pad. A mechanical fixture holds the hand piece in a stable position (2) and a rear holder exerts an adjustable retention force to the rear side of the hand piece (3), which shall fulfil the requirements of the application force which is defined by the manufacturer for the intended use of the **pressure pulse equipment**. The **source aperture** is in contact with the silicone pad on the adjacent side of the **hydrophone.**

Coupling media, for example ultrasound coupling gel, shall be applied between **source aperture** and pad as specified by the manufacturer as coupling conditions to the human skin. In the case of a concave **source aperture** surface, particular care shall be taken not to trap air bubbles between **source aperture** and pad.

NOTE For different medical applications, the specified application force can differ.

6.3 Voltage measurement

6.3.1 Oscilloscope or transient recorder

The device used to observe and measure the **hydrophone** output signal shall be appropriate for the purpose, its frequency response and input capacitance and resistive impedance shall be reported. A digital oscilloscope with a sampling frequency greater than 100 MHz is the preferred option, although a transient recorder and digital storage for subsequent computer display may be satisfactory.

The **end-of-cable loaded sensitivity of the hydrophone** shall be determined as specified in 5.1.2 of IEC 62127-1:2007; this value shall then be used to calculate the incident acoustic pressures from the observed **hydrophone** output voltages.

6.3.2 Pressure pulse waveform recording

The output voltage waveform from the **hydrophone** shall be recorded in such a way as to allow the measurement or calculation of:

- **instantaneous acoustic pressure**, $p(t)$;
- **peak-negative acoustic pressure**, p_r;
- **peak-positive acoustic pressure**, p_c;
- **rise time**, t_r;
- **compressional pulse duration**, t_{FWHMpc};
- **instantaneous intensity**, $I(t)$.

This requires using an oscilloscope or transient recorder set at sampling frequency, which is at least two times higher than the maximum frequency contained in the **pressure pulse** signal. For practical purposes, the maximum frequency should be at least $5/t_r$.

A typical **pressure pulse waveform** is shown in Figure 1.

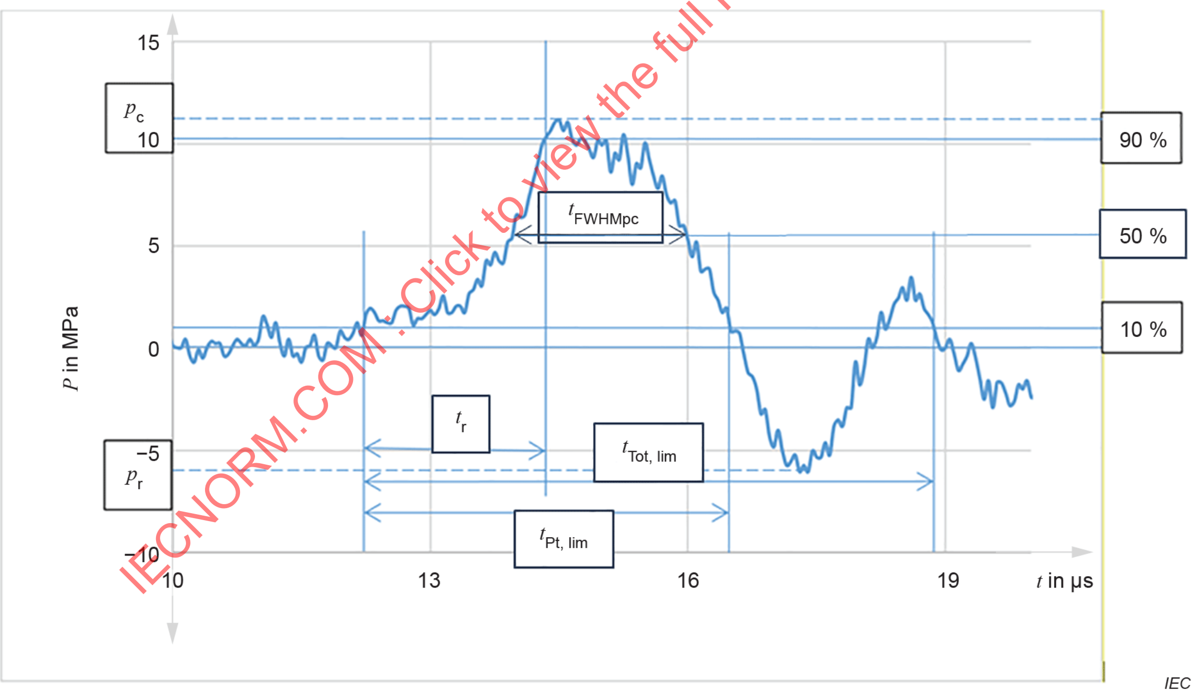


Figure 1 – Typical pressure pulse waveform at 2 mm distance from a ballistic pressure pulse source

7 Measurement procedure

The measurements shall be made at a minimum of three energy settings of the **pressure pulse equipment**: minimal, clinically typical and maximum setting. If only one setting is used, this setting shall be the maximum available for clinical application. The settings used shall be documented. If the device has exchangeable **applicators** (e.g. different size, shape or weight), the parameters shall be measured and documented for each **applicator**.

Measurements of the **instantaneous acoustic pressure** $p(t)$ shall be performed at single shots. Measurement of the **pressure pulse** field parameters at the slowest possible repetition rate (advisable: single pulse mode with pauses of at least one second) shall be made in the water test chamber.

Measurements of the **pressure pulse** parameters p_c, p_r, t_r, t_{FWHMpc}, $PII(x,y,z)$ at fixed distances from the **source aperture** along the **beam axis** shall be made at the lowest energy setting, a typical clinical setting, and the highest setting. These measurements shall each be made at three typical clinical repetition rates (lowest, typical, and highest) at 5 mm distance in the dry test bench (see 6.2 and 7.4).

Depending on the used technology to produce the **pressure pulses**, some of the parameters can vary from pulse to pulse. Thus, the pulse-to-pulse variance of measurement parameters should be added by stating the standard deviation of at least $N = 10$ measurements.

An informative list of parameters of **pressure pulse equipment** is given in Table D.1 to Table D.5, along with references to Clause 3 and practical comments.

NOTE The decision on which parameters shall be delivered for clinical approval and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature.

7.1 Measurement procedure in the water test chamber

7.1.1 General

Using the x-y-z coordinate positioning system, with the z direction being the **beam axis**, the following measurements shall be made to define the spatial characteristics of the beam.

The x axis shall be taken as the direction of the maximum beam width in the x-y plane perpendicular to the **beam axis**.

For every measurement, the coordinates of the **hydrophone** relative to the **measurement centre point** shall be documented.

NOTE If the **peak-positive acoustic pressure** p_c has a maximum along the **beam axis** which is higher than the **peak-positive acoustic pressure** p_c at the **source aperture**, this document does not apply, instead IEC 61846 applies.

7.1.2 Spatial measurements

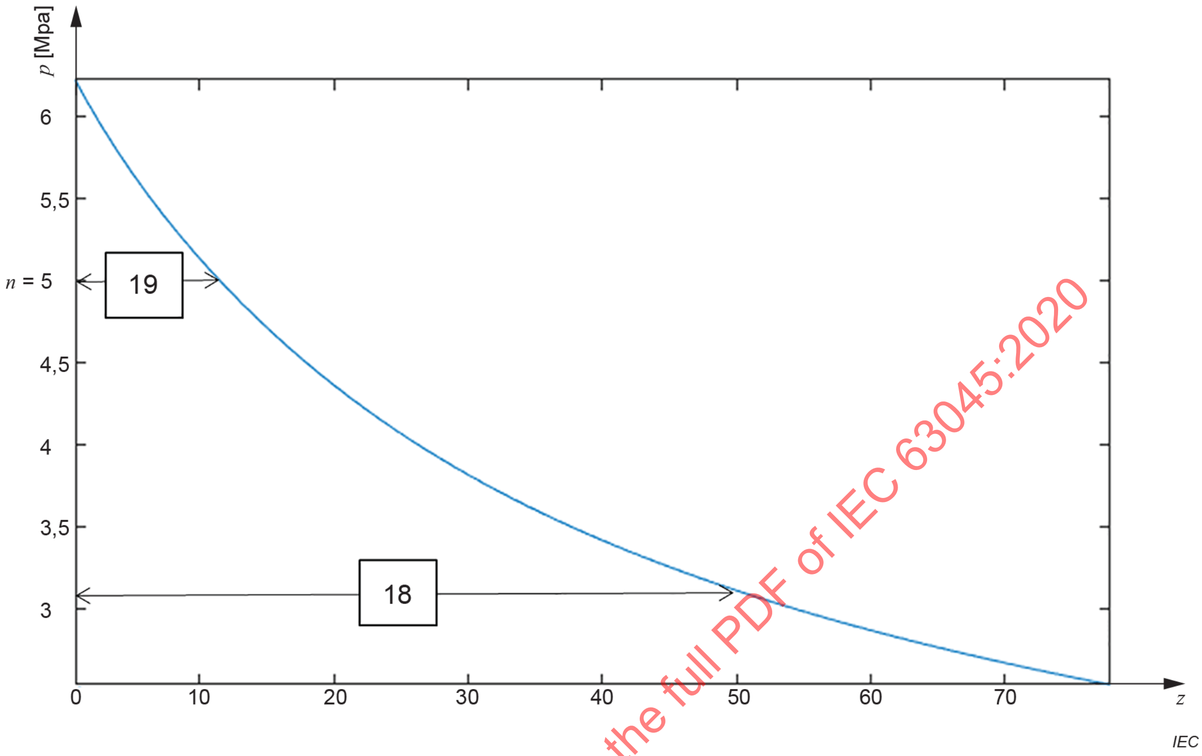
The spatial distribution of the acoustic pressure shall be measured in the water test chamber. The maximum sampling interval shall be the lesser of 1 mm or 1/5th of the minimum width of the **beam −6 dB width** in the x-y plane. It shall be the lesser of 2 mm or 1/5 th of the maximum dimension of the **beam −6 dB extent** in the x-z plane. If the values of p_c from sampling point to sampling point do not differ by more than 10 %, the sampling intervals can be extended, for example to 5 mm or 10 mm. The sampling intervals actually used shall be documented.

NOTE 1 In the case of a weakly focusing system, it can be worthwhile to perform measurements in the plane of the **target location** parallel to the **source aperture** to locate the **beam pressure maximum** of that plane and hence define the direction of the z axis, before making other measurements (see Annex C).

NOTE 2 The direction of the x axis will be provisional until the plot detailed in 7.1.2 or 7.1.3 has been completed.

Care shall be used in selecting **hydrophones** of sufficient linearity in negative and positive acoustic pressure regions so that the $-n$ dB measurements can be made without distortion of the **pressure pulse** signals.

The first set of spatial measurements shall be determined to find the **beam axis**, starting at the smallest possible z-distance (e.g. 1 mm) from the **measurement centre point**. Examples for typical axial pressure distributions and their parameters are given in Figure 2 (non-focusing) and Figure 3 (weakly focusing).

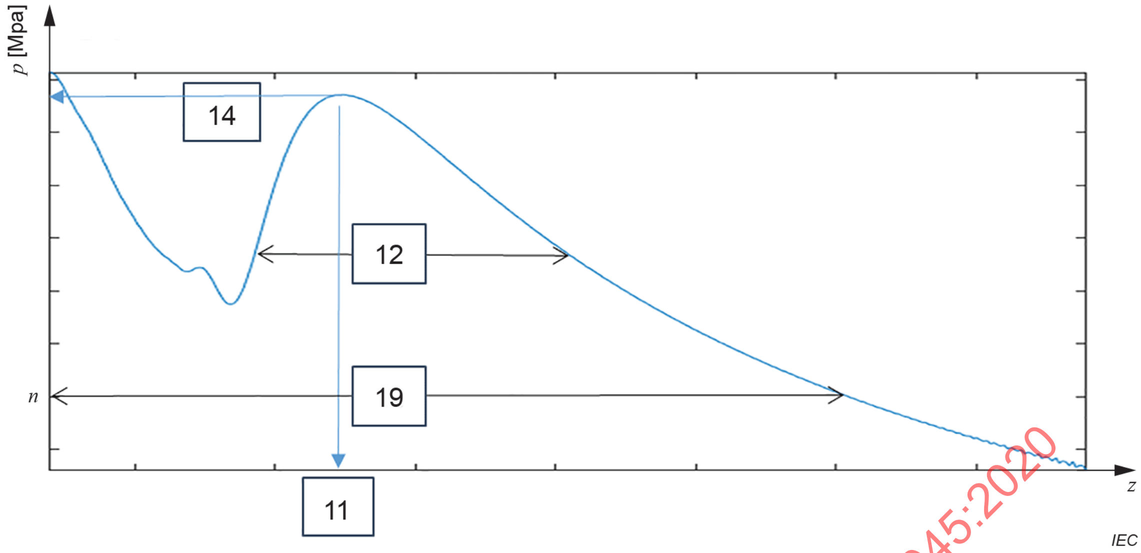


Key

18 beam −6 dB extent $z_{b,6dB}$

19 5 MPa beam isobar extent $z_{be,5MPa}$

Figure 2 – Typical pressure distribution along the beam axis of a non-focusing pressure pulse source



Key

11 beam pressure maximum distance, z_{bpm}

12 beam pressure maximum -6 dB extent $L_{bpm,6dB}$

14 beam pressure maximum $p_{c,bpm}$

19 n MPa beam isobar extent $z_{be,n\text{MPa}}$

Figure 3 – Typical pressure distribution along the beam axis of a weakly focusing pressure pulse source

The next measurement shall be along the **beam axis** (z-axis), which is perpendicular to the **source aperture** in order to identify the existence and position of local maxima. If they exist but are not higher than the **peak-positive acoustic pressure** p_c at the **source aperture**, the weakly focusing character of the source is confirmed. If the **peak-positive acoustic pressure** p_c has a maximum along the **beam axis** which is higher than the **peak-positive acoustic pressure** p_c at the **source aperture**, this document does not apply, instead IEC 61846 applies.

In order to allow comparison of several **pressure pulse** sources, the spatial acoustic pressure distributions in the x- and y-directions shall be measured at z = 5 mm ± 3 mm from the **source aperture**; the z position shall be documented.

Depending on the character of the source (non-focusing or weakly focusing), further measurement planes shall be selected as indicated in 7.1.3 to 7.1.12.

7.1.3 Non-focusing source

In the non-focusing case, the **peak-positive acoustic pressure** p_c has its maximum at the **source aperture**. In this case, the first measurement distance from the **source aperture** surface for measurements in x- and y- direction shall be z = 5 mm ± 3 mm. Further measurement distances from the **source aperture** may be chosen. The **closest** z position shall be as close to the **source aperture** surface as feasible, for example z = 1 mm or 5 mm.

NOTE In the case of mechanical applicators, the **applicator** can make an inertial oscillatory motion about its resting position, caused by the impact of the projectile. The maximum excursion amplitude of the **applicator** from its resting position needs to be taken into account.

The maximum excursion amplitude can be determined either by the technical description from the manufacturer or by approaching the **applicator** with the tip of a thin rod (e.g. a copper wire or a needle) on the **applicator** axis while **pressure pulses** are released, until the rod is hit by the **applicator**. An appropriate minimal measurement distance then is 1 mm from the hit position. The maximum excursion amplitude shall be documented.

The z distances should be chosen such that the **beam axis** can be found with good accuracy, and sufficiently low uncertainty for the determination of beam width parameters can be established. Starting from each z position, lateral (x- and y-) measurements shall be made in both + and − direction at least at three z distances from the source. The farthest measurement plane should be chosen far enough to easily identify the **beam −*n* dB extent**, and other **beam isobar extent**(s).

The measurement distances should be chosen at typical **target location**s for the medical applications the device is intended for. If the device is intended to be used for different medical applications, then at least the closest and the farthest locations should be considered, for example for skin treatment < 5 mm, for rotator cuff tendons 20 mm etc. Other typical distances are 1 mm, 10 mm, 20 mm etc. The parameters shall be documented in a way that the measurement distance is clearly stated.

7.1.4 Weakly focusing source

In the weakly focusing case, one of the z positions and the respective x-y measurement plane shall be at the z-position of **beam pressure maximum distance.** At least two other measurement planes shall be before and after this position at a distance which establishes the intended treatment focal volume.

Depending on the construction of the **pressure pulse** source, the **pressure pulse** wave field can be focused or weakly focused in one direction, and non-focused in the orthogonal direction. In order to document the focusing parameters, it may be necessary to make measurements according to both this document and IEC 61846.

NOTE The note and the second paragraph of 7.1.3 also apply for weakly focusing sources.

7.1.5 Beam plots of peak-positive acoustic pressure

The values of **peak-positive acoustic pressure** in the selected x-y planes shall be measured. The values of n shall be determined by the manufacturer by an appropriate risk analysis process, for example from literature or expert input. The **beam −*n* dB extents** shall be determined from the $-n$ dB contour plot.

At each value of y where the **peak-positive acoustic pressure** is measured, the pulse intensity integral should also be determined since the two curves are not identical and there can be significant differences between the areas under the curve as calculated from **peak-positive acoustic pressure** versus pulse intensity integral (see 7.4).

The orientation of the x- axis shall be chosen such that it corresponds to the direction of the maximum beam width. The variation of **peak-positive acoustic pressure** in x-z and y-z planes shall be measured and plotted at least as a $-n$ dB acoustic pressure contour in each plane. Appropriate values of n shall be determined by the manufacturer by an appropriate risk analysis process, from literature or by consulting experts.

7.1.6 Beam plots of peak-negative acoustic pressure

The values of **peak-negative acoustic pressure** in the selected x-y planes shall be measured at the same z positions as above. These measurements shall be used to estimate the site and magnitude of the maximum **peak-negative acoustic pressure**. These measurements are very difficult to make in practice and the limits for spatial sampling intervals may be relaxed. If the difference in p_r does not exceed 10 % from point to point, the sampling intervals may be chosen accordingly. The intervals used shall be documented. Particular care needs to be taken in the event of cavitation, which usually results in large signal variations from pulse to pulse, particularly in the negative pulse portions. Such events shall be reported.

NOTE The occurrence of cavitation becomes more likely at repeat rates higher than 1 per second, if the water is contaminated with small particles such as dust or contains dissolved gas (e.g. more than 2 mg/l dissolved oxygen). Cavitation bubbles at the **hydrophone** surface can also damage the **hydrophones**. In order to reduce cavitation, long pauses between single pulses and the use of ultrapure water are advisable.

7.1.7 Measurement centre point and beam axis

The **measurement centre point** shall be located at the **source aperture** centre of mass. The position of the centre of mass can be taken from drawings or approximated from the **source aperture width** and the **source aperture width, orthogonal.**

The **beam axis** location of the **beam pressure maximum** and the **target location**(s) shall be determined to a precision of ±2 mm in the x and y directions and ±3 mm in the z direction.

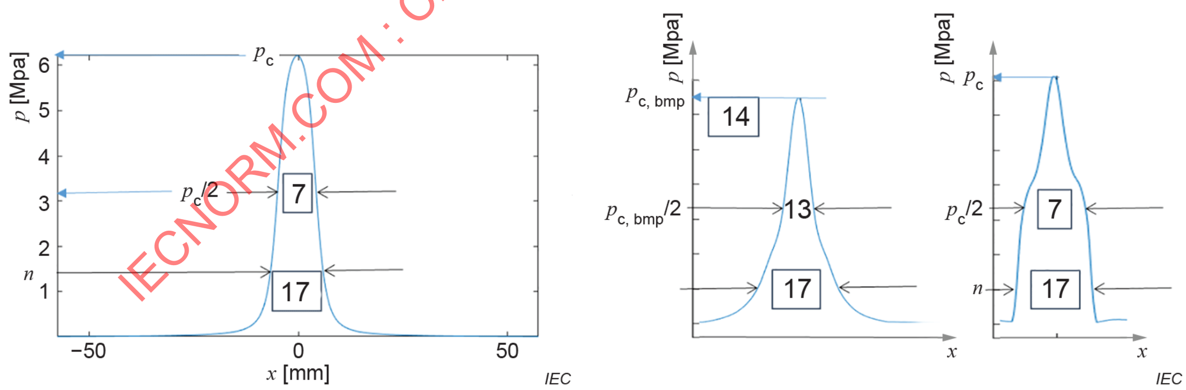
7.1.8 Beam width measurements

Regarding the width of the $-n$ dB contour in the x and in the y direction, the **beam $-n$ dB width, maximum**, and the **beam $-n$ dB width, orthogonal** shall at least be measured in a plane perpendicular to the **beam axis** at the z-position of the **target location** or at z = 5 mm ± 3 mm from the **source aperture**. The chosen z-position shall be documented. The values of n shall be determined by the manufacturer by an appropriate risk analysis process, from literature or expert consultation.

Regarding the width of any n MPa contour in the x and in the y direction, the **beam isobar width, maximum** and the **beam isobar width, orthogonal** shall be measured in a plane perpendicular to the **beam axis** at the z-position of the **target location** or at z = 5 mm ± 3 mm from the **source aperture** or at the z-position of the **measurement centre point**. The chosen value(s) of n and the z-position shall be documented.

NOTE Reasonable values of n which are to be delivered for clinical approval and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature.

The following Figure 4 shows typical lateral distribution plots and parameters of non-focusing (left image) and weakly focusing (right image) **pressure pulse** sources.



a) Non-focusing b) Weakly focusing

Key

7 beam -6 dB width, maximum $w_{\text{max},x,z,\text{6dB}}$,

13 beam pressure maximum -6 dB width, maximum $w_{\text{bpm},x,\text{6dB}}$,

14 beam pressure maximum $p_{\text{c,bpm}}$,

16 n MPa beam pressure maximum isobar width, $w_{\text{bpm},x,n\text{MPa}}$,

17 n MPa beam isobar width, maximum at axial position z $w_{\text{bpm},x,z,n\text{MPa}}$

Figure 4 – Typical lateral pressure distributions of p_c at the beam pressure maximum of two ballistic pressure pulse sources

7.1.9 Beam pressure maximum extent measurements

The **beam pressure maximum isobar extent**, which is length of the n MPa contour along the z direction, shall also be determined from measurements along the **beam axis**.

In the case of a weakly focusing **pressure pulse** source, the **beam pressure maximum −*n* dB extent** which is the length of the $-n$ dB contour along the z direction, shall be determined from measurements along the **beam axis**.

In the case of a non-focusing **pressure pulse** source, the first axial position of the $-n$ dB contour is at the **source aperture.**

Reasonable values of n which shall be delivered for clinical approval and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature.

7.1.10 Beam cross-sectional area and beam pressure maximum cross-sectional area

The **beam cross-sectional area** at any z-position and the **beam pressure maximum cross-sectional area** shall be established from lateral measurements along the x- and y-axes at the respective z-positions measured in the water bath. The z-positions shall be given as subscript.

NOTE It is reasonable to approximate the **beam pressure maximum cross-sectional area** to an ellipse with axes of lengths f_x and f_y (weakly focusing) or b_x and b_y (non-focusing).

7.1.11 Beam pressure maximum volume measurements

Applies for weakly focusing sources only. In the case of a weakly focusing source, the **beam pressure maximum −*n* dB volume** and **the beam pressure maximum isobar volume**(s) shall be established from the spatial distributions measured in the water bath.

NOTE It is reasonable to approximate the **beam pressure maximum volume** to an ellipsoid with axes of lengths $w_{\text{max},x,z,n}$, $w_{\text{max},y,z,n}$ and $z_{\text{b},n}$ and $w_{\text{max},x,z,n\text{MPa}}$, $w_{\text{max},y,z,n\text{MPa}}$ and $z_{\text{be},n\text{MPa}}$

7.1.12 Beam volume

The **beam −*n* dB volume** and **the beam isobar volume**(s) shall be established from the beam width and beam extent at the respective z positions; the z position shall be given as subscript.

NOTE 1 It is reasonable to approximate the **beam volume** to an ellipsoid with axes of lengths $w_{\text{max},x,z}$, $w_{\text{max},y,z}$ and $z_{\text{be},n\text{dB}}$ and $w_{\text{max},x,z,n\text{MPa}}$, $w_{\text{max},y,z,n\text{MPa}}$ and $z_{\text{be},n\text{MPa}}$.

NOTE 2 Reasonable values of n which shall be delivered for clinical approval, and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature.

7.2 Temporal measurements

A **hydrophone** should be positioned at the **beam axis** in such a way as to register the **peak-positive acoustic pressure** to the best achievable precision, i.e. the measurement should be repeated at any z-position by varying the x- and y-position of the probe until the point of maximum pressure is identified. Temporal measurements of the **pressure pulse waveform** $p(t)$ shall be repeated at least 10 times. Standard deviations and coefficients of variation shall be reported.

In the case of weakly focusing sources, the **pressure pulse waveform** $p(t)$ shall be measured at the acoustic **beam pressure maximum distance**. As the position of the acoustic **beam pressure maximum distance** varies depending on the transducer design, these measurements shall be done in water.

In the case of non-focusing sources, the measurements shall be made at 5 mm ± 3 mm in front of the **source aperture**.

The following parameters shall be derived:

– **peak-positive acoustic pressure**;
– **peak-negative acoustic pressure**;
– **compressional pulse duration**;
– **rise time**.

7.3 Acoustic energy measurements

7.3.1 General

The following quantities shall be calculated using the **hydrophone** measurements of the **instantaneous acoustic pressure**-time curves $p(r,\varphi,t)$ from 7.3 in an area S around the **beam axis** at distance z from the **measurement centre point**, at the points (r,φ) given in polar coordinates, where r denotes the distance of the point from the **beam axis**, and φ is the angle.

7.3.2 Pulse-pressure-squared integral

The **pulse-pressure-squared integral** at any point (r,φ) shall be given by:

$$ppsi(r,\varphi) = \int_T p^2(r,\varphi,t)\,dt \quad (3)$$

where

$p(r,\varphi,t)$ is the **instantaneous acoustic pressure** at position (r,φ) and time t.

The temporal limits over which integration is performed, T, shall be stated and can be either $t_{\text{Pt,lim}}$ or $t_{\text{Tot,lim}}$ or $t_{\text{Pt}n\text{MPa,lim}}$ or $t_{\text{Tot,}n\text{MPa,lim}}$; they shall be documented as a subscript.

7.3.3 Derived pulse-intensity integral

The **derived pulse-intensity integral** at any point (r,φ) shall be given by:

$$PII(r,\varphi) = \frac{1}{Z}\,ppsi(r,\varphi) = \frac{1}{Z}\int_T p^2(r,\varphi,t)\,dt \quad (4)$$

where

Z is the characteristic acoustic impedance of water (see Annex C).

The temporal limits over which integration is performed, T, shall be stated and can be either $t_{\text{Pt,lim}}$ or $t_{\text{Tot,lim}}$ or $t_{\text{Pt,}n\text{MPa,lim}}$ or $t_{\text{Tot,}n\text{MPa,lim}}$; they shall be documented as a subscript.

7.3.4 Derived beam −*n* dB pressure maximum acoustic pulse energy

The **derived beam −*n* dB pressure maximum** acoustic pulse energy shall be calculated from the **pulse-pressure-squared integral** taken within the region of the **beam pressure maximum −*n* dB cross-sectional area**. The **derived** beam **−*n* dB pressure maximum acoustic pulse energy** may be calculated from:

$$E_{\text{bpm,}-n\text{dB}} = \frac{1}{Z}\iint_{T,S} p^2(r,\varphi,t)\,dS\,dt = \int_S PII(r,\varphi)\,dS \quad (5)$$

where

S is the surface lying in the plane passing through the **beam pressure maximum distance** and perpendicular to the **beam axis**, with spatial polar coordinates r and φ; bounded by the $-n$ dB contour.

Reasonable values of n which shall be delivered for clinical approval and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature.

7.3.5 Derived acoustic pulse energy

The **acoustic pulse energy** shall be calculated from measurements of the **derived pulse intensity integral** taken within an area S defined as a circular cross-sectional area of radius R around a z position on the **beam axis**.

$$E_{\mathrm{R}} = \frac{1}{Z}\iint_{T,S} p^2(r,\varphi,t)\,dS\,dt = \int_S PII(r,\varphi)\,dS \qquad (6)$$

The value of R shall be specified and should be chosen to mimic a typical treatment area, for example 10 mm. The values of R and z and the integration time T shall be stated as subscripts of E, for example $E_{10\mathrm{mm},T,z}$.

7.4 Dry test bench measurements

With the dry test bench, measurements on the beam axis at a fixed distance from the **source aperture** can be made at higher pulse-repetition rates. At single pulses and at higher pulse repeat rates, parameters which can be measured in the dry test bench are:

– **derived instantaneous intensity** $I(x = 0, y = 0, z = L_{\mathrm{p}}, t)$
– **instantaneous acoustic pressure** $p(x = 0, y = 0, z = L_{\mathrm{p}}, t)$
– **peak-negative acoustic pressure** $p_{\mathrm{r}}(x = 0, y = 0, z = L_{\mathrm{p}})$
– **peak-positive acoustic pressure** $p_{\mathrm{c}}(x = 0, y = 0, z = L_{\mathrm{p}})$
– **pulse-pressure-squared integral** $ppsi\ (x = 0, y = 0, z = L_{\mathrm{p}})$
– **rise time** $t_{\mathrm{r}}(x = 0, y = 0, z = L_{\mathrm{p}})$
– **compressional pulse duration** $t_{\mathrm{FWHMpc}}(x = 0, y = 0, z = L_{\mathrm{p}})$
– **derived pulse-intensity integral** $PII(x = 0, y = 0, z = L_{\mathrm{p}})$

L_{p} is the thickness of the tissue mimicking pad of the dry test bench, which also determines the distance of the **hydrophone** from the **source aperture**. The use of the dry test bench and procedures are described in Clause C.4. It is advisable to demonstrate the similarity of the pressure-time-signals measured in water with the signals in the dry test bench in single-pulse mode as described in C.3.4 (proof measurement).

NOTE 1 The dry test bench can also be used for the evaluation of signal stability at higher pulse repetition rates. These measurements are of particular interest in quality assurance and device servicing.

If no absolute pressure values, in particular only **peak-positive acoustic pressure** values, are needed, **hydrophones** as defined in Table C.2 may be used. In this case, other parameters can be subjected to large measurement errors and should not be used.

NOTE 2 The dry test bench can be used for ballistic **pressure pulse** sources with mechanical **applicators**. Due to different mechanical construction, it is possible they are not applicable for other **pressure pulse** sources, for example piezoelectric, electromagnetic or electrohydraulic.

NOTE 3 Due to possible reflections of the **pressure pulse** at the **hydrophone,** the **time signals** $p(x = 0, y = 0, z = L_{\mathrm{p}}, t)$ and parameters derived thereof are only valid for a maximum time which can be estimated by $2 \times L_{\mathrm{p}}/c_{\mathrm{p}}$, where c_{p} is the longitudinal speed of sound of the tissue mimicking pad material, which for silicone typically lies in the range 900 ms^{-1} to 1050 ms^{-1}(data taken from [35]).

Annex A
(informative)

Acoustic pressure pulse therapy

A.1 Background

A.1.1 General

Non-focusing and weakly focusing (in most cases ballistic) **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. The patients receive in average 3 treatments (range from 1 to 5 sessions) of 10 min to 20 min duration with approximately or on average 1000 pulses. The pulses have a typical duration of 0,1 µs to 25 µs and consist of one compressional pulse and a trailing rarefactional pulse. Depending on source construction characteristics, a number of spurious signals may occur, which usually have significantly less amplitudes.

The pulses are usually applied by a manually guided hand piece; targeting is done by asking the patient to direct the pulses to the point of maximum pain. In case of treatment of calcifying tendonitis, the calcium deposit should be targeted, for example by localizing it with X-ray and/or sonography technology.

The first use of non-focused or weakly focused **pressure pulses** was described in 1999.

More strongly focused **pressure pulses** for soft tissue pain applications have been employed clinically since 1993, initially using lithotripter-like electrohydraulic, electromagnetic or piezoelectric sources [25] [33].

A.1.2 Development of relevant measurement standard

In the past, the acoustic parameters of the non-focusing **pressure pulse** sources, like ballistic sources, were often stated in terms of IEC 61846, which describes strongly **focused pressure pulse field**s. While the acoustic pressure-time curves of these "lithotripter" pulses may have some characteristics comparable to those of **pressure pulse** therapy, the acoustic fields differ significantly in their extensions and propagation characteristics. In particular, the use of parameters like focal dimensions and energies is not appropriate for the description of divergent and non-focused fields and leads to confusion and misinterpretation of possible biological effects.

A.1.3 Current knowledge on biomedical effects

Although the theory behind the biomedical effects of the **pressure pulses** inside the body is not completely established, some facts can be mentioned:

– a decreasing level of pain in the target area during 30 pulses to 100 pulses by influencing the threshold of nerve reaction;

– aggregation of biochemical substances associated with pain and inflammatory processes like substance P, which is known as a pain mediating amino-acid built in afferent neurons of spinal nerves, etc.;

– generation of capillary blood vessels in the treated regions in the time after treatment.

A.1.4 Availability of clinical and technical data

Despite the fact that non-focusing **pressure pulse** sources have been in clinical use for 20 years, there is still a lack of studies, which satisfy all the conditions of evidence-based medicine. In particular, the amount and quality of measurement data mostly is not yet sufficient.

This lack has hampered gaining better knowledge on the bio-effects and potential side effects, as well as linking these effects to the acoustic output data of the devices.

A comparative study of certified devices and a post-marketing surveillance study of the clinical usage could strongly help this situation.

It is also strongly encouraged to publish the technical data either in peer reviewed journals or at least make the data publicly accessible for everybody, for example on websites of the manufacturers or scientific communities.

A.2 Other treatment devices and methods not subject to this document

A.2.1 Percutaneous continuous and modulated wave systems

Ultrasonic energy has been used since the 1950's to treat neuromuscular and orthopaedic pain. Most of the treatments use the ultrasonic energy to generate thermal effects in tissue, not exceeding temperatures of about 43 °C in order to avoid damage to the tissue by denaturation of proteins. The methods to characterize such kinds of devices are described in physiotherapy standards (IEC 61689).

A.2.2 Extracorporeal shock wave lithotripsy

This method is a first-line therapy for renal stones smaller than 20 mm and for upper ureteric stones smaller than 10 mm. The process has become popular with patients due to the non-invasive nature of the procedure and the short treatment and recovery time. Several different forms of the equipment are now available from a number of manufacturers.

An important factor in the procedure is the accurate targeting to the stone location and the orientation of the transducer to position the ultrasonic energy at the stone. This is carried out by using strongly focused **pressure pulses** and using X-ray or diagnostic acoustic scanning in three dimensions.

Even if some **pressure pulse** sources are designed to be used for both **pressure pulse** therapy and for lithotripsy, the characterization and safety of these devices is outside the scope of this document. They are described in IEC 61846 and IEC 60601-2-36.

A.2.3 Further exclusions

It is not proposed to discuss percutaneous or semi-invasive systems, including laser generated **pressure pulses**, although the latter may be a combination of localized plasma and **pressure pulse** action. Only extracorporeally induced non-focusing **pressure pulse** methods and instruments are considered.

Annex B
(informative)

Types of pressure pulse transducers

B.1 Overview

B.1.1 General

Several techniques are at present employed for the generation of the required **pressure pulse**, the operating principles being: mechanical excitation (ballistic); rail gun type excitation; spark discharge; piezoelectric excitation; electromagnetic induction. Future equipment may use other sources, for example based on multichannel discharge shock wave sources and microelectromechanic (MEMS) technologies. In the electrical systems, the short duration high peak energy is supplied by the electrical discharge of a bank of capacitors into an electromechanical transducer. The ballistic system employs a projectile, which is propelled by pressurized air pulsed towards the rear side of the **applicator**.

Typical pulse repetition rates range from one per second to 21 per second. Both driving energy and pulse repetition frequency can be adjusted, sometimes supported by a graphical user interface and a data base of predefined treatment applications.

B.1.2 Principle of ballistic pressure pulse sources

The **pressure pulse** sources use pressurized air to drive a cylindrical metal projectile (typical mass 3 g) guided in a tube of about 20 cm length onto the rear surface of a circular cylindrical rod or cone waveguide (**applicator**, mass about 30 g). The patient side surface of the waveguide can be a flat, concave or convex shaped piston with a diameter of 6 mm to 36 mm (typical value 15 mm); it is the **source aperture** in most known devices.

When the **applicator** is hit by the projectile, a pulsed compression wave travels through the material and is transferred at the adjacent side, which is the **source aperture**, into the patient via a coupling gel. This pulse has a duration of about 4 µs and can be adjusted to an amplitude of about 3 MPa to > 10 MPa. Depending on the shape of the **applicator**, some smaller pulses may occur, which are generated by reflections of the stress waves inside the **applicator**.

After the rapid compression pulse (and its reflections), a slower inertial motion of the **applicator** due to the impulse impact of the projectile occurs. It has some 100 µs to several milliseconds duration and is damped by elastic rings, which reduce the excursion of the **applicator** to minimal distances (< 1 mm). The measurement and description of this inertial motion of the **applicator** is outside the scope of this document. A measurement method is described in [1] and discussed in [2].

The components of the **pressure pulse** source are composed in a "hand piece", which is manually guided by the clinician during treatment.

B.1.3 Rail gun principle

A rail gun type generator consists of an electrically conducting coil, which accelerates a projectile when the coil is energized by electrical current. The projectile is guided in a tubular barrel towards the rear side of the **applicator**. The **pressure pulse** is then generated the same way as described in B.1.2 (ballistic principle).

B.1.4 Further generation principles

B.1.4.1 Spark gap

A spark gap, often mounted in a focus of a reflector, is used to generate the **pressure pulses**. Further information on spark gap sources is available in IEC 61846. The reflector may be shaped to generate a divergent, strongly focused, planar or weakly focused wave. It is closed by a flexible diaphragm and filled with degassed water or other acoustically efficient transmissive liquid. Application to the patient may be done by enclosing the source into a hand piece and many different versions are available.

Close control of the duration and intensity of the discharge is necessary and the electrical charge characteristics are accurately monitored.

B.1.4.2 Piezoelectric

The transducer consists of a single piezoelectric ceramic plate or – more frequently – is composed of piezoelectric ceramic elements mounted in a mosaic pattern on backing plate. Each element is synchronized to ensure simultaneous operation. In order to allow for higher energies, two or more layers can be stacked.

For weak focusing, plane wave sources can also be used and focusing is produced using acoustic lenses manufactured from plastics or metals. Self-focusing designs are achieved by spherical shaping of the backing plate.

B.1.4.3 Electromagnetic

One type of electromagnetic transducer employs a spirally wound "pancake" coil to move a metal diaphragm in a liquid-filled cylinder. The plane wave front may be focused with an acoustic lens. The front of the cylinder in contact with the patient is closed by a flexible diaphragm.

Another type uses a cylindrical electromagnetic transducer mounted on the axis of an appropriately shaped reflector, which converts the radial acoustic wave into a planar or focused wavefront towards the patient.

B.2 Non-focusing and focusing transducers

The term "focusing" transducer is commonly used for a device which has a smaller beam width in some regions of the **pressure pulse** field than a device which is "non-focusing". A "non-focusing" transducer can still have a minimum beam −6 dB width at a position far from the aperture. More information on different types of transducers is given in IEC 61828:2001, Clause 3.

For **pressure pulse** transducers described in this document, the differentiation between focusing, non-focusing and weakly focusing is not useful from practical aspects.

1) The measurement of the −20 dB **source aperture width** is difficult, since it requires measurement of acoustic pressures that are −20 dB below the maximum compressional acoustic pressure in a plane as close as possible to the transducer. It may be especially difficult in focusing sources, since particularly with these sources the absolute levels in that plane are low.
2) The distinction between non-focusing and weakly focusing sources depends on the measurement of the beam pressure maximum compared to the **peak-positive acoustic pressure** at the **source aperture**. If the signal is noisy, the same source could be either classified as non-focusing or weakly focusing with some consequences in further parameters to be reported.

In order to overcome the limitations and problems, an alternative for focus type differentiation is used in this document: a focused **pressure pulse** field. It is the field of a transducer having a **beam pressure maximum distance** that is larger than the **beam pressure maximum -6 db extent**, i.e. $z_{\text{bpm}} > L_{\text{bpm,6dB}}$.

NOTE 1 If the beam pressure maximum −6 dB volume can be described as an ellipsoid, the ellipsoid is fully outside the **source aperture**.

Strongly focusing sources, as used in **pressure pulse** lithotripters as well as in other **pressure pulse equipment**, are described in IEC 61846.

The scope of this document is to deal with non- or weakly focusing sources. If the **beam pressure maximum distance** is less than or equal to the **beam pressure maximum −6 dB extent**, then the **pressure pulse** field is non- or weakly focused.

There is an equivalent parameter for each focal parameter, which shall be stated for weakly focusing sources only:

– focal cross-sectional area = **beam pressure maximum … cross-sectional area** at z, where z is the **beam pressure maximum distance** on the **beam axis**.
– focal extent = **beam pressure maximum … extent**
– focal volume = **beam pressure maximum … volume**
– focal width, maximum = **beam pressure maximum … width, maximum**
– focal width, orthogonal = **beam pressure maximum … width, orthogonal**
– focus = **beam pressure maximum distance**

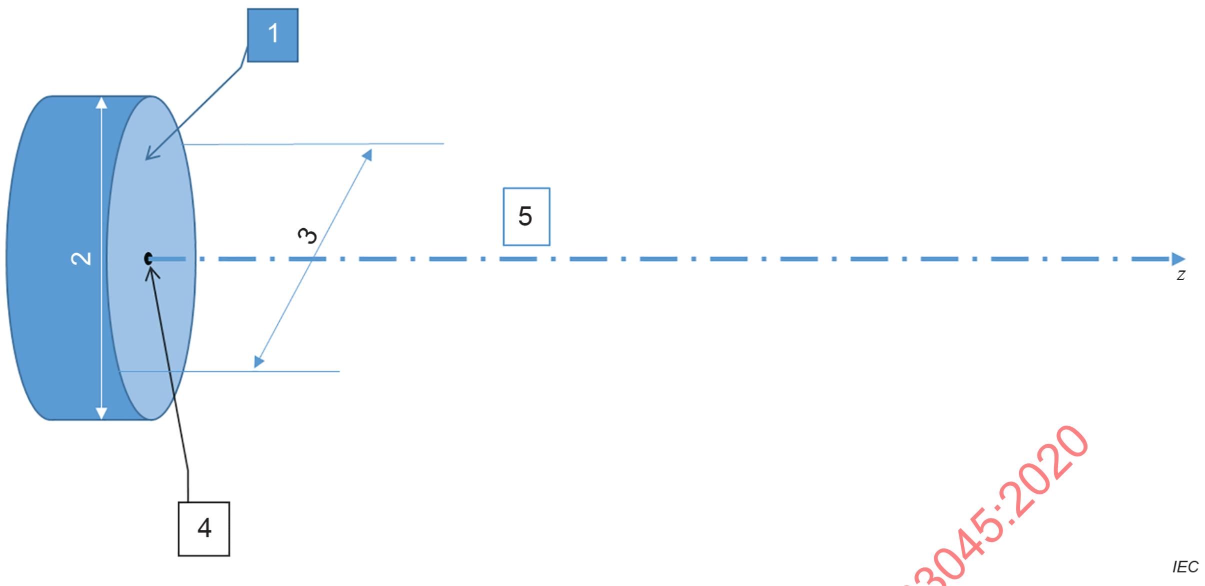
NOTE 2 the "…" stands for **isobar** or −n **dB**.

In order to distinguish between non-focusing and weakly focusing sources, the decay of the **peak-positive acoustic pressure** p_{c} relative to the **beam pressure maximum** in the direction away from the **source aperture** should be used.

– The ideal decay of the acoustic pressure p_{c} of a ballistic or radial **pressure pulse** source is $1/(z-z_{\text{bmax}})^2$ where z_{bmax} is the position of the **beam pressure maximum distance**. Weakly focusing sources decay at a slower slope due to focusing. Quantitative criteria: measure p_{c} along the **beam axis**. With a planar **pressure pulse** source, the ratio between the **peak compressional pressure** p_{c} at a distance of 20 mm along the **beam axis** and the **peak compressional pressure** p_{c} at the focus should be ¼. If the ratio is smaller than $1/\left(2\sqrt{2}\right)$ the source is non-focusing. The factor $\sqrt{2}$ accounts for measurement inaccuracies, possible effects of an extended source as compared to an ideal point source etc.
– Equivalent alternative: plot $\log_{10} p_{\text{c}}(z)$ versus $\log_{10} z$. If the slope is smaller than −1,5, the source is non-focusing.

B.3 Examples of pressure pulse sources and their parameter sets

Figures B.1 to B.3 show sketches of the geometry of several **pressure pulse** sources.



Key

1 source aperture

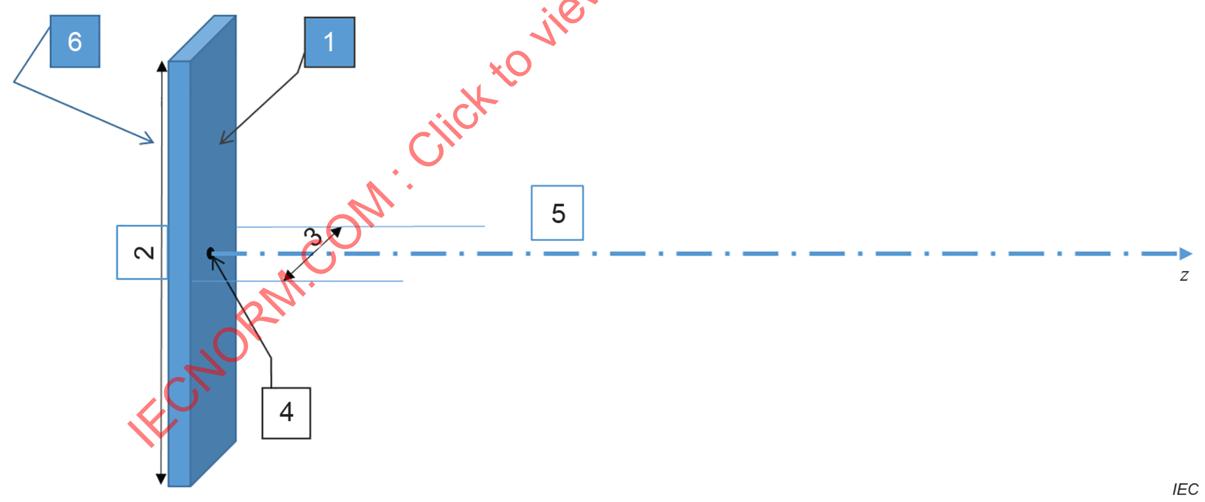
2 source aperture width, D_x

3 source aperture width, orthogonal, D_y

4 measurement centre point O where $(x, y, z) = (0, 0, 0)$

5 beam axis (z)

Figure B.1 – Applicator directly coupled to the patient



Key

1 source aperture

2 source aperture width, D_x

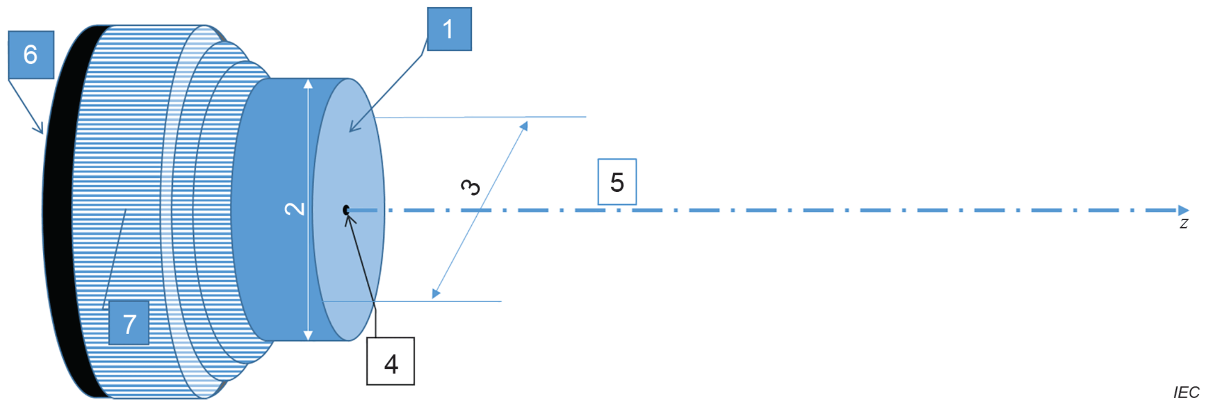
3 source aperture width, orthogonal, D_y

4 measurement centre point O where $(x, y, z) = (0, 0, 0)$

5 beam axis (z)

6 pressure pulse source

Figure B.2 – Pressure pulse source, non-symmetric (linear), directly coupled to the patient



Key

1 source aperture

2 source aperture width D_x

3 source aperture width, orthogonal D_y

4 measurement centre point O where $(x, y, z) = (0, 0, 0)$

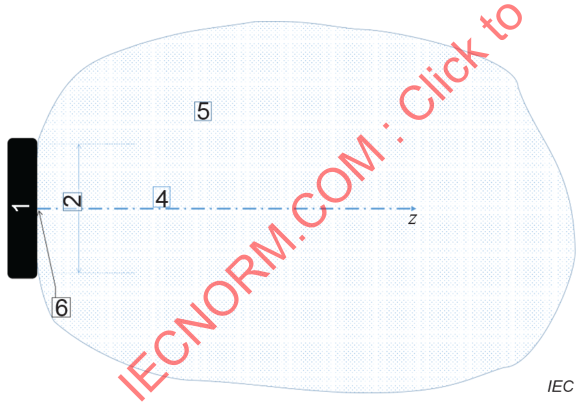
5 beam axis (z)

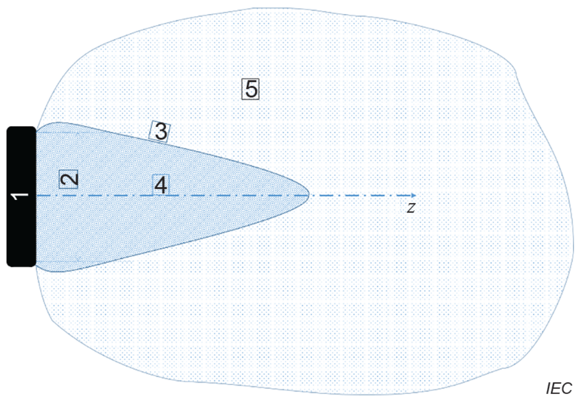
6 pressure pulse source

7 acoustic stand-off, for example coupling pad or water

Figure B.3 – Pressure pulse source, symmetric, distant from the patient

Figure B.24 and Figure B.35 show sketches of typical **pressure pulse** field distributions and parameters and demonstrate how to describe their geometrical parameters, related to the geometrical axes and the coupling situation to the patient.





Key

1 applicator

2 source aperture width D_x

3 -6 dB contour of beam $-n$ dB volume in the x,z plane

4 beam axis (z)

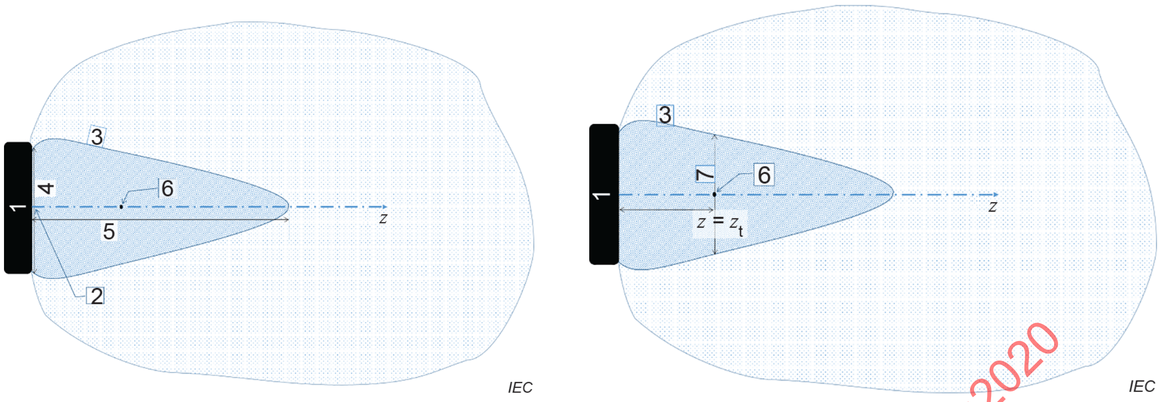
5 patient

6 measurement centre point O where $(x, y, z) = (0, 0, 0)$

Figure B.4 – Applicator coupled to patient

Figure B.5 – Non-focused pressure pulse field

Figure B.6 and Figure B.7 show sketches of typical **non-focused pressure pulse field** distributions and parameters.



Key

1 applicator

2 beam pressure maximum distance z_{bpm}

3 −6 dB contour of beam −n dB volume in the x,y plane

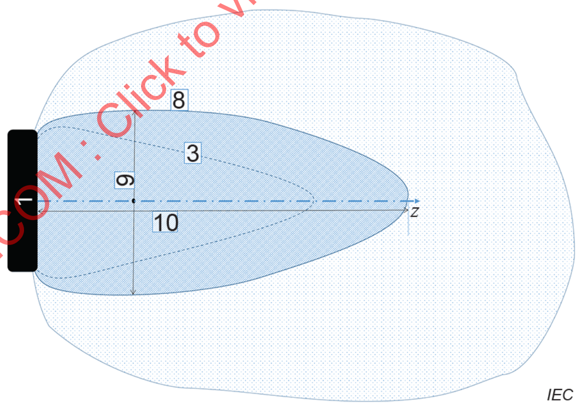
4 beam pressure maximum −6 dB width, maximum $w_{\text{bpm},x,\text{6dB}}$

5 beam −6 dB extent $z_{\text{b,6dB}}$

6 target location V_t at (0, 0, z_t)

7 beam −6 dB width, maximum in the target location plane (x, y, z_t), $w_{\max,0,z_t,\text{6dB}}$

Figure B.6 – Non-focused pressure pulse field -*n* dB parameters (example: *n* = 6)



Key

1 applicator

3 −6 dB contour of beam −n dB volume in the x,z plane

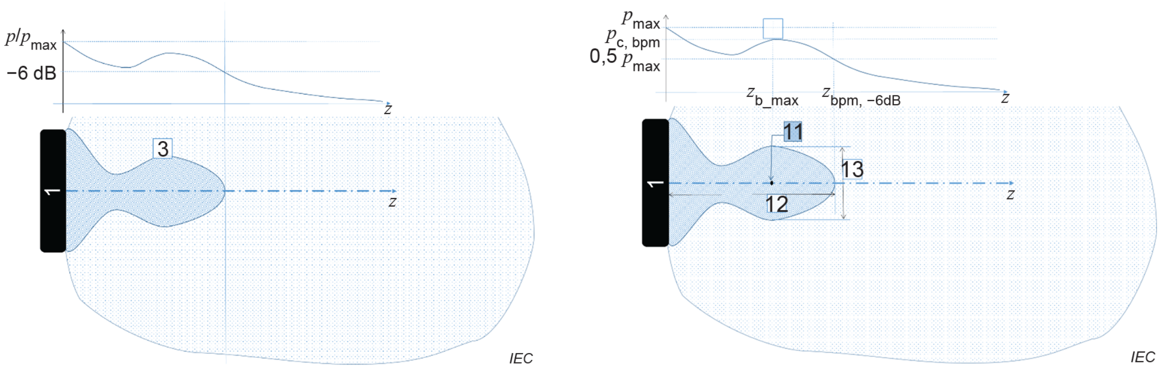
8 n MPa contour of beam isobar volume in the x,z plane

9 n MPa beam isobar width, maximum $w_{\max,x,z,n\text{MPa}}$ at an axial position z

10 n MPa beam isobar extent $z_{\text{be},n\text{MPa}}$

Figure B.7 – Non-focused pressure pulse field isobars

Figure B.8, Figure B.9, and Figure B.10 show sketches of typical **weakly focused pressure pulse field** distributions and parameters.



Key

1 applicator

3 −6 dB contour of beam $-n$ dB volume in the x,z plane, $V_{\text{b,6dB}}$

11 beam pressure maximum distance, z_{bpm}

12 beam −6 dB extent $z_{\text{b,−6dB}}$, here also: beam pressure maximum −6 dB extent $L_{\text{bpm,6dB}}$, which exists only if the on-axis pressure drops by at least -6 dB on both sides of z_{bpm}

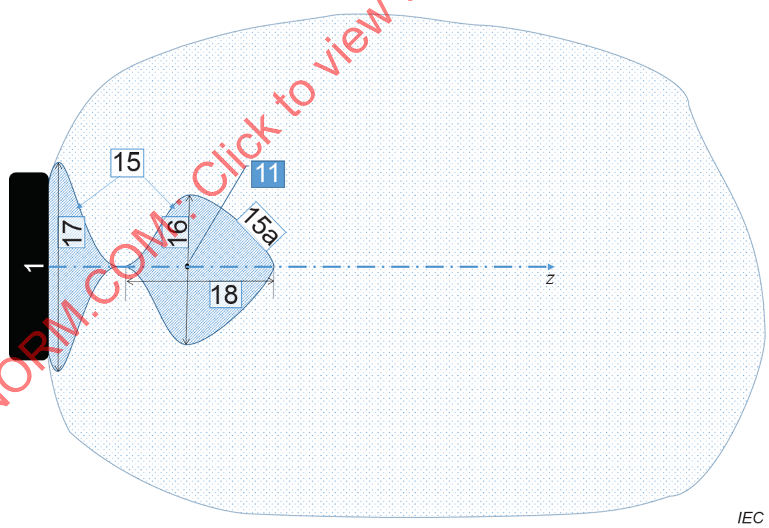
13 beam pressure maximum −6 dB width, maximum $w_{\text{bpm},\ x\text{,6dB}}$

14 beam pressure maximum $p_{\text{c,bpm}}$

Upper curves = axial pressure distribution at x = 0

Lower curves = contours

Figure B.8 – Weakly-focused pressure pulse field −6 dB contour and parameters



Key

1 applicator

11 beam pressure maximum distance, z_{bpm}

15 n MPa contour of beam isobar volume $V_{\text{b},n\text{MPa}}$ in the x,z plane

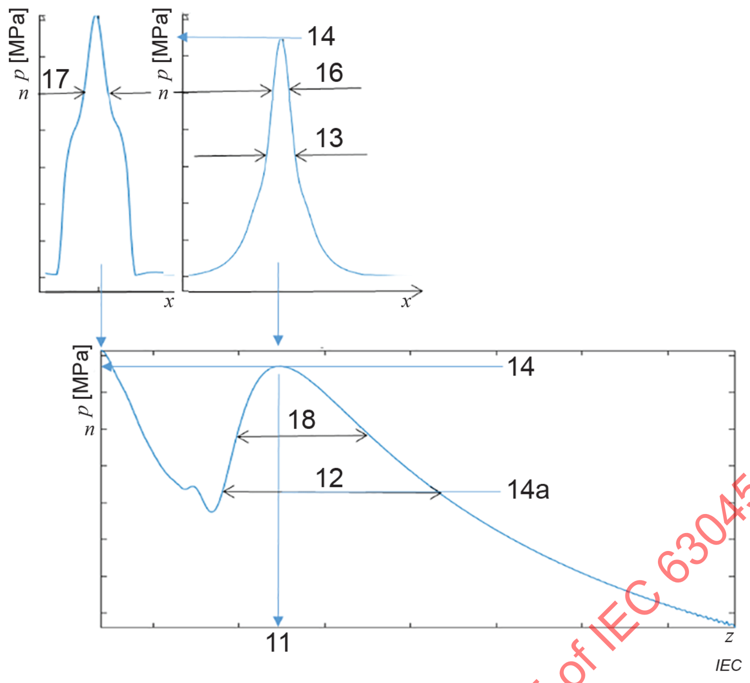
15a n MPa contour of beam pressure maximum isobar volume $V_{\text{bpm},n\text{MPa}}$ in the x,z plane

16 beam pressure maximum isobar width, maximum $w_{\text{bpm},x,n\text{MPa}}$

17 beam isobar width, maximum $w_{\text{max},x,z,n\text{MPa}}$

18 beam pressure maximum isobar extent $L_{\text{bpm},n\text{MPa}}$

Figure B.9 – Weakly-focused pressure pulse field volume and isobar parameters



Key

11 beam pressure maximum distance, z_{bpm}

12 beam pressure maximum −6dB extent $z_{\mathrm{bpm,6dB}}$

13 beam pressure maximum −6 dB width, maximum $w_{\mathrm{bpm},x,\mathrm{6dB}}$

14 beam pressure maximum $p_{\mathrm{c,bpm}}$

14a −6dB of $p_{\mathrm{c,bpm}}$

16 beam pressure maximum isobar width, maximum $w_{\mathrm{bpm},x,n\mathrm{MPa}}$

17 beam isobar width, maximum $w_{\mathrm{max},x,z,n\mathrm{MPa}}$

18 beam pressure maximum n MPa isobar extent $L_{\mathrm{bpm},n\mathrm{MPa}}$

Upper curves = lateral pressure distributions

Lower curve = axial pressure distribution

Figure B.10 – Weakly-focused pressure pulse field parameters

B.4 Positioning and targeting methods

The accurate external positioning of the **pressure pulse source** is of great importance to ensure therapeutic success and avoid side effects. Lithotripsy devices using focused **pressure pulses** always need an imaging device to target the stones.

In contrast, **pressure pulse** devices for pain therapy are often applied by targeting at the point or the area of maximum pain, which is indicated by the patient and may be adjusted during treatment by asking for patient feedback. In order to achieve the intended therapeutic results, the physician needs to know the position of the **target location** for the intended treatment, which should be stated by the manufacturer of the device, for every intended medical application. In some devices, the **target location** may be adjusted by pads, or by variable coupling bellows or other means supplied by the manufacturer.

Annex C
(informative)

Field measurement

C.1 Measurement probes and hydrophones

A number of pressure wave measuring devices have been used for determining the characteristics of lithotripter fields (see [1]). Conventional **hydrophones** and pressure transducers are generally inadequate for these measurements due to the transient nature of the pulse, the short rise-time and the very short time of the occurrence. The high pressures found in the field and the beam maximum of typical non-focusing and weakly focusing **pressure pulse** sources enforce limitations on the type of detector not normally found in other applications. The high-frequency response required, up to 100 MHz, for the short-duration pulses also imposes limits on the design of robust elements (see [20] [21]).

The measuring **hydrophone** should ideally have a flat frequency response extending over the range from well below the acoustic working frequency of the equipment, usually approximately 0,1 MHz, to a frequency as high as possible (see [21] and [22]). Thus ideally, the **hydrophone** should have an overall frequency response flat to within ±3 dB over the range of 0,01 MHz to 10 MHz. Furthermore, the **hydrophone** should also have an active element of effective diameter which is no greater than 1 mm over the whole frequency range. It is realised that currently used **hydrophones** do not comply with this demanding specification. Therefore, the **hydrophone** performance specifications given in 6.1.2 and 6.1.3 are strictly insufficient, but are considered practical and realizable at the present time.

Below is a general discussion about **hydrophones** and detection methods which have been used to monitor and characterize **pressure pulses**.

Detectors are required to perform two functions: measurement of the amplitude of the **pressure pulse** at the measurement point; trace of the shape of the pressure envelope. Piezoelectric polymer membrane **hydrophones** are widely employed (see Table C.1 and Table C.2). Some **hydrophones** with a rigid backing to the polymer element do not reproduce the rarefaction portion of **pressure pulses** demonstrated with membrane type **hydrophones**. Cavitation may also have an effect on single shots as the building of the bubbles takes some energy from the pulse. If cavitation occurs, the rarefactional part of the pulse will be shortened.

Whichever type is used, care has to be taken to ensure that the output of the **hydrophone** is properly terminated and handled before being fed into the measuring device. Capacitance **hydrophones** and optical techniques involving interferometry are available but require relatively complicated and difficult handling procedures.

Fresnel type acousto-optic **hydrophones** have been developed (see [11] to [14]). Quartz-glass seems to be capable of reproducing the rarefaction acoustic pressure more faithfully than membrane **hydrophones**. Due to the optical laser noise level, signals of acoustic pressure smaller than 1 MPa may be subjected to noise. Fibre-optic types are reported to be more sensitive to the presence of cavitation bubbles and the fibre tip has a more limited lifetime than the glass-block type. However, their repair and recalibration are described as being uncomplicated.

Piezo-optic **hydrophones** have the same high quality of **pressure pulse** reproduction as fibre **hydrophones**, and they are more robust as fibre **hydrophones**, because they use a solid glass block instead of the fragile fibre. The noise level is better than the noise level of fibre **hydrophones**, but they require a comparably large space in the measurement tank.

An electromagnetic probe has been developed [16] which is based on the pressure wave stimulated movement of a metal ball coupled to a coil held within a magnetic field. This extremely robust device is more useful for the indication of the total energy of the **pressure pulse** rather than its shape.

Pressure sensitive paper is also available for use at the pressures found in the sound fields of a **pressure pulse** device although its value for quantitative measurements is not clear (see [4]).

The spatial and temporal measurements are carried out only for the pattern evaluation and basic evaluation in specialized laboratories with precision **hydrophones** and precision instruments. The continuous day-to-day monitoring of **pressure pulse** source performance may be carried out by scanning in a few non-focal planes perpendicular to the **beam axis** at specified axial distances from the **measurement centre point**. In this case, the user may not need a precision **hydrophone** with extended frequency range, but the **hydrophone** may be chosen for maximum service life.

Table C.1 gives guidance on the choice of different **hydrophone**s for **pressure pulse** measurements. Table C.2 gives guidance on other techniques and probes, which may be used for quality assurance purposes.

Table C.1 – Hydrophone types for pressure pulse measurements

Description	Use	Remarks	Literature (examples)
PVDF spot-poled membrane of appropriate thickness	Precision **hydrophone**	Life may be restricted to few **pressure pulses**	See [5] to [7], [18] and [19]
PVDF needle type	Precision and quality assurance **hydrophone**	Widely used for **pressure pulse** device measurements	See [9], [10] and [24]
PVDF capsule type	Precision and quality assurance **hydrophone**		See [26], [30] and [32]
Laser optic fibre	Precision **hydrophone**	Easy repair and recalibration following stress failure, may suffer with high noise level due to quantum processes in the laser	See [11] to [14]
Piezooptic pressure point type	Precision **hydrophone**	Easy repair and recalibration following stress failure, also as multispot **hydrophone**, requires more space in the water bath than other **hydrophone** types	See [28], [31] to [33]

Table C.2 – Measurement techniques and probes for quality assurance purposes

Probe	Features	Parameter measured	Literature (examples)
Capacitive coupling	Large sensitive area	Pressure waveform	See [15]
Capacitively coupled PVDF spot poled membrane	Large sensitive area, very robust	Pressure waveform	See [8]
Steel ball Electromechanical	Very robust	Energy per pulse Pressure waveform	See [16]
Pressure sensitive paper	Robust, qualitative field parameters	Spatial pressure distribution, semi quantitative peak pressure measurement	See [4]
Piezoelectric **hydrophone**s with metal-coated elements	Robust	Pressure waveform	Used for quality control of stability of **pressure pulse** generation

C.2 Water test chamber

C.2.1 General

The measurement of the pressure wave and the mapping of the **pressure pulse** field can be carried out in a chamber filled with degassed water.

In one type of test chamber, a transducer positioning system is mounted at the top of the chamber with remotely controlled stepping motors for driving the **hydrophone** carrier in three separate axes. The pressure-pulse generator is placed beneath the acoustic diaphragm and pressed firmly against it after coating with a coupling gel to assist in energy transfer. In some **pressure pulse** devices, the pressure-pulse generator may be inclined, and it will be necessary to construct the chamber base at a matching angle.

For measurements of **pressure pulse waveform** and **peak-positive acoustic pressure**, it is essential that the **hydrophone** is accurately positioned on the beam axis.

C.2.2 Degassing procedures

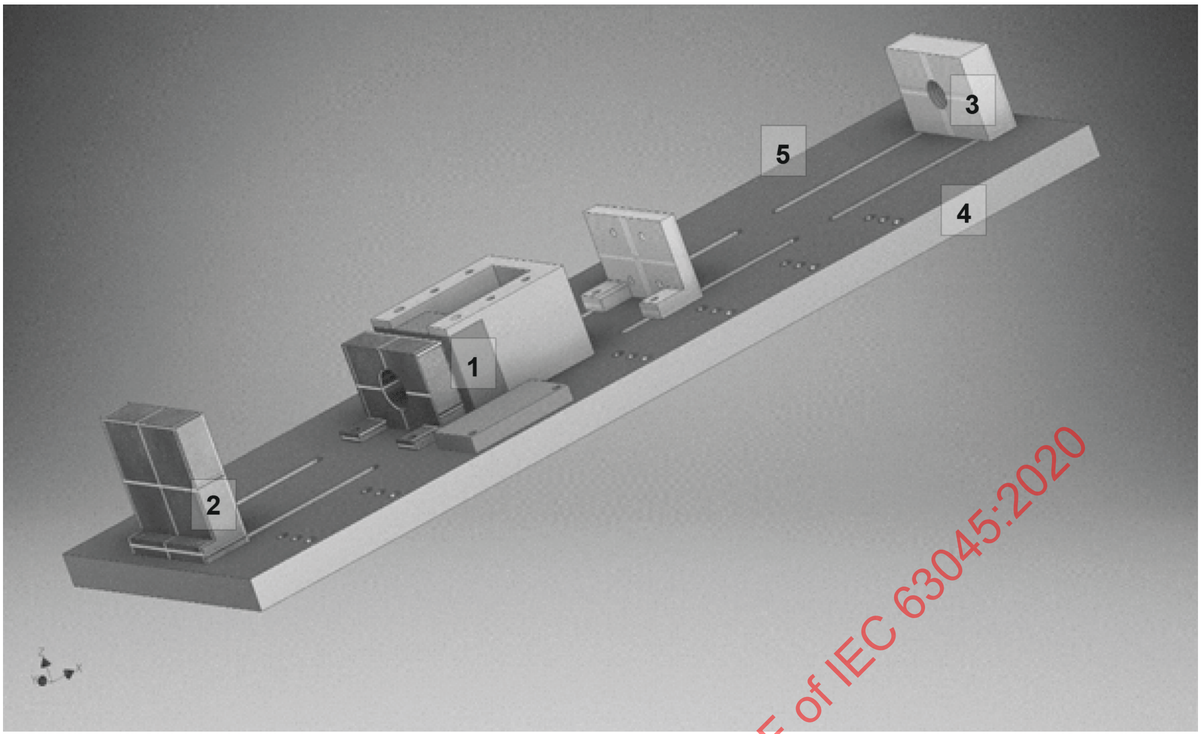
It is important that bubbles do not collect at the surface of the **hydrophone**, the surface of the **applicator** or any other surface in the **pressure pulse** wave path between **hydrophone** and **applicator**. Measurements involving water baths should use degassed and – depending on the type and requirement of the **hydrophone** – distilled water. The requirement for degassing may be relaxed if the interval between pulses is sufficiently long so that bubbles created have time to be reabsorbed. Nevertheless, cavitation may also have an effect on single shots as the building of the bubbles takes some energy from the pulse. If cavitation occurs, the rarefactional part of the pulse will be shortened. In order to reduce cavitation seeds, it may be useful to use ultra-pure water, if accessible.

A description of appropriate degassing methods is given in IEC TR 62781. The efficacy of the procedure may be checked by determination of the dissolved oxygen content in samples of degassed water using dissolved oxygen test kits or sensors.

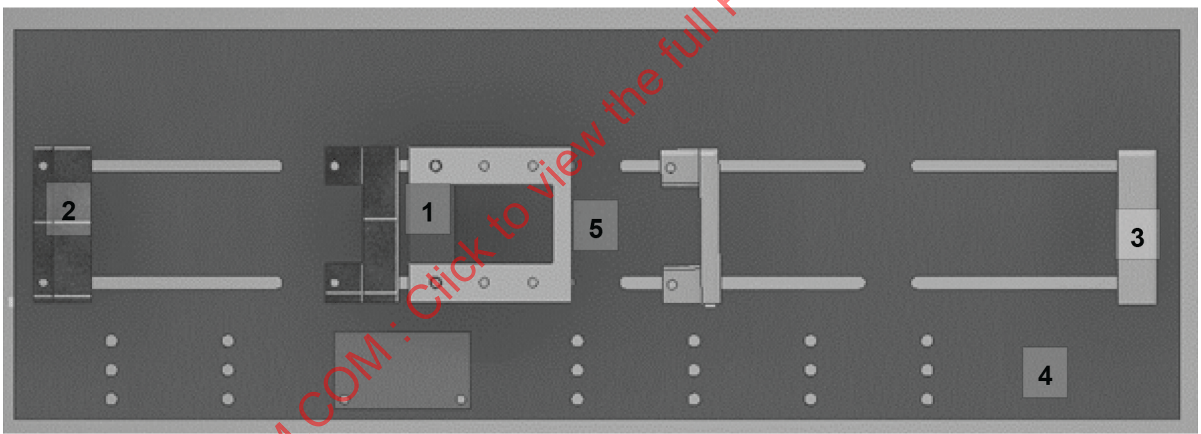
C.3 Dry test bench

C.3.1 General

The dry test bench (for a design example, see Figure C.1) provides a simple means for measuring on-axis **pressure pulse** data.



IEC



IEC

Key

1 hydrophone and tissue mimicking pad chamber

2 hand piece holder

3 rear holder

4 base plate

5 adjustable retention-force spring

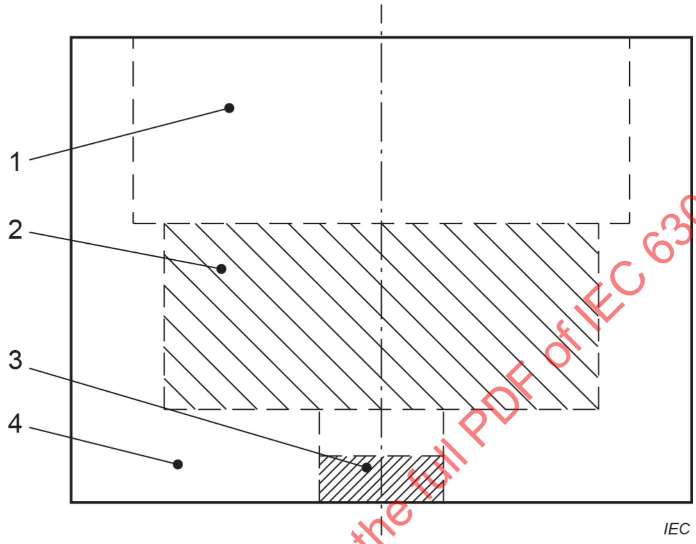
NOTE Items 1 to 3 are fixed to the base plate item 4.

Figure C.1 – Design example of a dry test bench in two views

A typical dry test bench consists of the following components.

- Test chamber with pressure sensor (Figure C.2). The pressure sensor is attached to the back of the tissue mimicking pad, for example by holding it in place with a spring, rubber bands etc. Acoustical coupling to the tissue mimicking pad needs to be assured, for example by using a layer of coupling fluid like water, oil, grease, ultrasound coupling agent etc.

- Tissue mimicking pad, made of silicone, 5 mm thick diameter, which shall be at least the diameter of the **source aperture**. Typical material data: hardness 60 Shore ± 5 Shore, density 1,15 g/cm^2 ± 0,2 g/cm^2, tensile strength 5 N/mm^2, elongation at break 350 %, tear strength 14,7 N/mm, translucent, corresponding to FDA § 177.2600.
- Holding bracket for the hand piece, which is able to hold the hand piece in a stable position during measurements.
- Counter-force spring, which allows to press the hand piece with a static force to the tissue mimicking pad.
- Pressure sensor, which has the same specifications as the **hydrophone**.



Key

1 opening for the applicator

2 tissue-mimicking pad

3 opening and fixture for the hydrophone

4 housing

Figure C.2 – Detail of the measurement chamber item of the dry test bench

Some types of **hydrophones** may be used both in water and in the dry test bench.

NOTE 1 The dry test bench can also be used for the evaluation of signal stability at higher pulse repetition rates. These measurements are of particular interest in quality assurance and device servicing.

If no absolute pressure values, in particular only **peak-positive acoustic pressure** values, are needed, **hydrophones** as defined in Table C.2 may be used. In this case, other parameters may be subjected to large measurement errors and should not be used.

NOTE 2 The dry test bench can be used for ballistic **pressure pulse** sources with mechanical **applicators**, where the front side usually is the **source aperture**. Due to different mechanical construction, it is possible they are not applicable for other **pressure pulse** sources, for example piezoelectric, electromagnetic or electrohydraulic.

NOTE 3 Due to possible reflections of the **pressure pulse** at the **hydrophone,** the **time signals** $p(x = 0, y = 0, z = L_p, t)$ and parameters derived thereof are only valid for a maximum time which can be estimated by $2 \times L_p/c_p$, where c_p is the longitudinal speed of sound of the silicone pad material.

C.3.2 Selection and attachment of the hydrophone

It is necessary to use a **hydrophone** which is to reproduce the pressure-time signal of the **pressure pulse source** similar to the signal measured in water at the same distance from the **source aperture** and lateral position at the same driver setting in single-pulse mode.

Care shall be taken to attach the **hydrophone** in a stable position to the rear side of the tissue-mimicking pad. In order to assure a good coupling between **hydrophone** and pad, a drop of water, oil or ultrasound coupling gel can be used. Care should be taken that the **hydrophone** does not bounce or is relocated from its original position during the measurement.

C.3.3 Attachment of the hand piece

The hand piece is placed in the hand piece holder and fixed (e.g. by levers, rubber bands etc.) in a position which avoids lateral displacements during the measurements. The **source aperture** is centred and pressed to the front side of the tissue-mimicking pad, for a good acoustic transmission ultrasound gel can be used. The force exerted by the **source aperture** on the pad should be similar to that described by the manufacturer for patient treatments. The actual force is then exerted by changing/adjusting the spring at the rear holder and is monitored during measurements by a force sensor.

Compression of the tissue mimicking pad by the force should be avoided. This compression would decrease the pad thickness and lead to measurement errors. The **source aperture** should be prevented from compressing the pad, otherwise the proof measurement as described in C.3.4 will also show higher pressure values with the test bench in comparison to the water measurements.

C.3.4 Proof of the similarity of measurements in water and the dry test bench

Similarity of the signals can be demonstrated by recording the signal in water $p_{\mathrm{w}}(t)$ and the signal in the dry test bench $p_{\mathrm{d}}(t)$ and then integrating the squared difference of the signals over the time range T, which also is used for the calculation of the **derived pulse-intensity integral**s, such as $t_{\mathrm{Pt,lim}}$ or $t_{\mathrm{Tot,lim}}$ or $t_{\mathrm{P},n\mathrm{MPa,lim}}$ or $t_{\mathrm{Tot},n\mathrm{MPa,lim}}$.

$$E = \int_T \left(\frac{p_{\mathrm{w}}(t) - p_{\mathrm{d}}(t)}{p_{\mathrm{w}}(t)} \right)^2 dt \qquad \text{(C.1)}$$

Proof is established when the error E is less than 0,05. If this figure cannot be achieved, the measurements shall be entirely made in water.

C.3.5 Special measurements with the dry test bench

With the dry test bench, measurements of the pulse-to-pulse variation of the **pressure pulses** at different pulse repetition rates can be done by recording the **peak-positive acoustic pressure** p_{c} amplitudes of at least 20 consecutive **pressure pulses** at a given pulse repetition rate, for example 1 per second, 5 per second, 10 per second etc. Stable **pressure pulse equipment** will only show minor deviations of p_{c} from pulse to pulse. The deviations can be documented by giving the maximum differences in p_{c} of the 20 consecutive pulses, or by stating a statistical variation, for example the standard deviation.

Another measurement parameter is the constancy over time of the output of the **pressure pulse equipment**. By recording the p_{c} of at least 20 to 100 consecutive **pressure pulses** both from the start of the pulse series as well as during continuous release of **pressure pulses** at a given energy setting, the change of p_{c} values over time can be documented.

C.4 Acoustic pulse energy

C.4.1 General

The energy per pulse can be calculated by integrating the field over the $-n$ dB surface around the axis, in the case of weakly focused fields in the focus plane. Reasonable values of n which shall be delivered for clinical approval and communication to the users can be identified by a risk analysis process, by appropriate safety standards if applicable, or by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or the literature. Refer to Figure 1 and Figure 4 for explanation of some of the parameters used to describe a typical **pressure pulse waveform** and spatial distribution in an area S around the z-axis.

The energy in a **pressure pulse** in the area S can be approximated by:

$$E_Z = \frac{1}{Z}\iint_{S,T} p^2(x,y,t)\,dt\,dS \qquad \text{(C.2)}$$

where

p is the acoustic pressure function;

S is the measurement surface, in the x-y plane (in weakly focused fields containing the **beam pressure maximum**);

t is time;

Z is the characteristic acoustic impedance of water (Z = 1,5 × 10^6 kg m^{-2} s^{-1})

For a beam with circular symmetry:

$$E_{R,Z} = 2\pi\int_0^R PII(r)\,r\,dr \qquad \text{(C.3)}$$

where

R is the $-n$ dB beam radius based on the plot of **peak-positive acoustic pressure**;

$PII(r)$ is the **derived pulse-intensity integral** at the radial distance r, given by:

$$PII(r) = \frac{1}{Z}\int_0^T p^2(r,t)\,dt \qquad \text{(C.4)}$$

In evaluating E, the results from measurements along four radii along two orthogonal diameters should be averaged. One numerical solution of Formula (C.3) is:

$$E = \frac{\pi}{2}\sum_{i=1}^{N}\left(PII_i + PII_{i-1}\right)\cdot\left(r_i^2 - r_{i-1}^2\right) \qquad \text{(C.5)}$$

Here, it is assumed that a measurement of the beam has been made radially at $N + 1$ points from r = 0 to r = R and that the **derived pulse-intensity integral** at point $r = r_i$ is PII_i. Also r_0 = 0 and r_N = R.