IEC 63045

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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

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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.

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

Note 1 to entry: The value of n and the axial distance z from the measurement centre point shall be stated as subscript.

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

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

3.3
beam −*n* dB extent
$z_{\text{b},n\text{dB}}$
distance along the **beam axis** from the **source aperture** to the point where the **peak-positive acoustic pressure** has dropped farthest by $-n$ dB relative to the acoustic pressure at the **source aperture**

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

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 3 to entry: The **beam −*n* dB extent** is expressed in metres (m).

3.4
beam −*n* dB volume
$V_{b,n\text{dB}}$
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
$w_{\text{max},x,z,n\text{dB}}$
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
$w_{\text{max},y,z,n\text{dB}}$
width of the −*n* dB contour of the **peak-positive acoustic pressure** p_c around the **beam pressure maximum**, in the *x*-*y* plane 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

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

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

Note 1 to entry: Typical values of n MPa are: 5 MPa, 3 MPa, 1 MPa. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

Note 2 to entry: **Beam isobar width, orthogonal** is expressed in metres (m).

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

3.13
beam pressure maximum

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

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

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

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

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

Note 2 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

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

3.15
beam pressure maximum −*n* dB extent

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

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

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

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

Note 3 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

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

3.16
beam pressure maximum −*n* dB volume

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

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

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

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

Note 3 to entry: Typical values of $-n$ dB are: −3 dB, −6 dB, −10 dB, −12 dB, −20 dB. Reasonable values of n for clinical approval and communication to the users can be identified by a risk analysis process, by applicable safety standards, by consulting notified bodies, expert communities (e.g. ISMST – International Society for Medical Shockwave Treatment) or through literature.

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

3.17
beam pressure maximum −*n* dB width, maximum

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

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

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

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

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

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

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

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