INTERNATIONAL STANDARD

IEC 61846

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1998-04

Ultrasonics –

Pressure pulse lithotripters – Characteristics of fields

Ultrasons –

Lithotripteurs à ondes de pression – Caractérisation des champs

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For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – PRESSURE PULSE LITHOTRIPTERS – CHARACTERISTICS OF FIELDS

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 61846 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this standard is based on the following documents:

FDIS	Report on voting
87/115/FDIS	87/118/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Annexes A, B, C and D are for information only.

In this standard, the following print types are used:

– requirements and definitions: in roman type;
– NOTES: in smaller roman type;
– *compliance: in italic type;*
– terms used throughout this standard which have been defined in clause 3: **small case roman bold type**.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

Extracorporeal lithotripsy is used for the clinical treatment of renal, ureteric and biliary stones. Lithotripsy employs high-intensity acoustic waves to produce disintegration of the stones through a process of sequential application of pressure waves. Several different forms of lithotripsy equipment are now commercially available from a number of manufacturers.

This International Standard specifies methods of measuring and characterizing the acoustic pressure field generated by lithotripsy equipment.

ULTRASONICS – PRESSURE PULSE LITHOTRIPTERS – CHARACTERISTICS OF FIELDS

1 Scope

This International Standard is applicable to

– **lithotripsy equipment** using extracorporeally induced pressure waves;

– **lithotripsy equipment** producing focused mechanical energy.

This International Standard does not apply to percutaneous and laser **lithotripsy equipment**.

This International Standard specifies

– measurable parameters which could be used in the declaration of the acoustic output of extracorporeal **lithotripsy equipment**,

– methods of measurement and characterization of the pressure field generated by **lithotripsy equipment**.

NOTE – The parameters defined in this International Standard do not – at the present time – allow quantitative statements to be made about effectiveness and possible hazard. In particular, it is not possible to make a statement about the limits for these effects.

While this particular standard has been developed for equipment intended for use in **lithotripsy**, it has been developed such that, as long as no other specific standards are available to be used for other medical applications of therapeutic extracorporeal **pressure pulse** equipment, this standard may be used as a guideline.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 60050(801):1994, *International Electrotechnical Vocabulary (IEV) – Chapter 801: Acoustics and electroacoustics*

IEC 60866:1987, *Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

3 Definitions

For the purpose of this International Standard, the following definitions apply.

3.1 acoustic pulse energy

3.1.1
derived acoustic pulse energy
spatial integral of the **derived pulse-intensity integral** over a circular cross-sectional area of radius R in the x-y plane which contains the **focus**

Symbol: E_R
Unit: joule, J

3.1.2
derived focal acoustic pulse energy
spatial integral of the **derived pulse-intensity integral** over the **focal cross-sectional area**

Symbol: E_f
Unit: joule, J

NOTE – This definition may overestimate E if the aperture of the **pressure pulse** generator is large.

3.2
beam axis
line passing through the geometric centre of the aperture of the **pressure pulse** generator and the **focus**

NOTE – This line is taken as the z axis. See 6.1 and clause 7.

3.3
compressional pulse duration
time interval beginning at the first time the **instantaneous acoustic pressure** exceeds 50 % of the **peak-positive acoustic pressure** and ending at the next time the **instantaneous acoustic pressure** has that value (see figure C.1)

Symbol: t_{FWHMp+}
Unit: second, s

NOTE – The subscript "FWHM" stands for "full width, half maximum".

3.4
derived pulse-intensity integral
time integral of the **instantaneous intensity** at a particular point in a **pressure pulse** field over the **pressure pulse waveform** (see 3.31 of IEC 61102)

Symbol: PII
Unit: joule per metre squared, J/m^2

3.5
end-of-cable loaded sensitivity of a hydrophone
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 (see 3.14 of IEC 61102)

Symbol: M_L
Unit: volt per pascal, V Pa^{-1}

3.6
focal cross-sectional area
area of the **peak-compressional acoustic pressure** contour which is –6 dB relative to the value at the **focus** and is in the plane, perpendicular to the **beam axis,** which contains the **focus**

Symbol: A_f
Unit: metre squared, m^2

3.7
focal extent
shortest distance along the *z* axis that connects points on the –6 dB contour of **peak-positive acoustic pressure** in the *x-z* plane on either side of the **focus**

Symbol: f_z
Unit: metre, m

3.8
focal volume
volume in space contained within the surface defined by the –6 dB (relative to the value at the **focus**) **peak-compressional acoustic pressure** contours measured around the **focus**

Symbol: V_f
Unit: metre cubed, m^3

NOTE – It is difficult to measure –6 dB points throughout the volume around the **focus**. It is reasonable in practice to approximate the **focal volume** from measurements taken in three orthogonal directions: the **beam axis** (*z* axis); the direction of maximum beam diameter (*x* axis); the axis perpendicular to the *x* axis (*y* axis).

3.9
focal width, maximum
maximum width of the –6 dB contour of p_+ around the **focus** in the *x-y* plane which contains the **focus**

Symbol: f_x
Unit: metre, m

3.10
focal width, orthogonal
width of the –6 dB contour of p_+ around the **focus,** in the *x-y* plane which contains the **focus**, in the direction perpendicular to f_x

Symbol: f_y
Unit: metre, m

3.11
focus
location in the **pressure pulse** field of the maximum **peak-positive acoustic pressure**

3.12
hydrophone
transducer that produces electrical signals in response to waterborne acoustic signals [IEV 801-32-26] (see also IEC 60866)

3.13
instantaneous acoustic pressure
pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field (see also 801-21-19 of IEC 60050(801))

Symbol: p
Unit: pascal, Pa

3.14
instantaneous intensity
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

For measurement purposes referred to in this standard, where far-field conditions may be assumed, the **instantaneous intensity**, I, is expressed as:

$$I = \frac{p^2}{Z}$$

where

p is the **instantaneous acoustic pressure**;

Z is the characteristic acoustic impedance of the medium.

(See also 3.21 of IEC 61102.)

Symbol: I
Unit: watt per metre squared, W/m^2

3.15
lithotripsy equipment
device for disintegrating calculi and other concretions within the body

NOTE – Known applications include renal stones, gallstones, pancreatic duct stones, salivary stones, orthopaedic pain and calcification in tendons.

3.16
peak-negative acoustic pressure, peak-rarefactional acoustic pressure
maximum of the modulus of the rarefactional acoustic pressure at any spatial location in the **pressure pulse** field (see 3.26 of IEC 61102)

Symbol: p_-
Unit: pascal, Pa

3.17
peak-positive acoustic pressure, peak-compressional acoustic pressure
maximum compressional acoustic pressure at any spatial location in the **pressure pulse** field (see 3.27 of IEC 61102)

Symbol: p_+
Unit: pascal, Pa

3.18
pressure pulse
acoustic wave emitted by the **lithotripsy equipment**

3.19
pressure pulse waveform
temporal waveform of the **instantaneous acoustic pressure** at a specified position in a **pressure pulse** field and displayed over a period sufficiently long to include all significant acoustic information in the **pressure pulse**

3.20
pulse-pressure-squared integral
time integral of the square of the instantaneous acoustic pressure over the pressure pulse waveform

Symbol: p_i
Unit: pascal squared seconds

3.21
rise time
at the **focus**, time taken for the **instantaneous acoustic pressure** to increase from 10 % to 90 % of the **peak-positive acoustic pressure** (see figure C.1)

Symbol: t_r
Unit: second, s

3.22
target location
location in space where the manufacturer intends the user to locate the calculi

3.23
temporal integration limits

3.23.1
positive temporal integration limits
times between which the **positive acoustic pressure** first exceeds 10 % of its maximum value and the first time it reduces below 10 % of its maximum value

Symbol: T_P
Unit: seconds

3.23.2
total temporal integration limits
times between which the absolute value (modulus) of **pressure pulse waveform** first exceeds 10 % of its maximum value and the last time it reduces below 10 % of its maximum value

Symbol: T_T
Unit: seconds

4 List of symbols

A_f: **focal cross-sectional area**

E_f: **derived focal acoustic pulse energy**

E_R: **derived acoustic pulse energy**

f_x: **focal width, maximum**

f_y: **focal width, orthogonal**

f_z: **focal extent**

I: **instantaneous intensity**

M_L: **end-of-cable loaded sensitivity of the hydrophone**

p: **instantaneous acoustic pressure**

p_-: **peak-negative acoustic pressure**

p_+: **peak-positive acoustic pressure**

p_i: **pulse-pressure-squared integral**

PII: **derived pulse-intensity integral**

t_r: **rise time**

t_{FWHMp+}: **compressional pulse duration**

T_P: **positive temporal integration limits**

T_T: **total temporal integration limits**

V_f: **focal volume**

Z: characteristic acoustic impedance of the medium

5 Conditions of measurement

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

– **pressure pulse** generator drive level;
– rate of **pressure pulse** release;
– ambient temperature;
– electrical conductivity of water in the measuring tank;
– temperature and oxygen content of water in the measuring tank.

The values of these parameters at which the measurements are made shall be noted.

Degassed water (see annex C) at 20 °C to 40 °C should be used in the measuring tank (test chamber) which shall be large enough to allow the measurement environment to approximate free-field conditions. If degassed water is not used, great care shall be taken to ensure that bubbles do not collect on the hydrophone nor anywhere in the beam path.